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ANNEX 11 TO THE DECISION

WORK PROGRAMME 2014 – 2015

8. Health, demographic change and wellbeing

(European Commission C(2013)XXX of XX December 2013)

26 09 2013

Introduction to health, demographic change and wellbeing

The Horizon 2020 societal challenge of 'health, demographic change and wellbeing' (SC1) for the years 2014 and 2015 includes 36 topics in the 'personalising health and care' focus area call, and 15 topics in the 'co-ordination activities' call. A small number of additional topics (other actions) designed to support the implementation of the challenge are also included and are not subject to calls for proposals. The total budget available is approximately EUR 1.20bn.

The choice to focus on personalising health and care is informed by the ageing of the European population, an increasing communicable and non-communicable disease burden and the fall-out from the economic crisis. In combination, these factors are jeopardising the sustainability and equity of European health and care systems, on which Europe already spends nearly 10% GDP.

The personalising health and care call aims to create opportunities for real breakthrough research and radical innovation in response to these challenges, by supporting the translation of findings into the clinic and other health and care settings to improve health outcomes, reduce health inequalities and to promote active and healthy ageing.

Topics in the call are divided into 7 areas which reflect the need for a translational and integrated approach to the challenge, providing support both to longer and mid-term research as well as to shorter term innovation activities. Topics in the areas of 'understanding health…' and 'improved health information and data exploitation' provide underpinning, longer term support to topics in the areas of 'prevention…', 'diagnosis…', 'treatment..', 'advancing active and healthy ageing' and 'delivering integrated, sustainable and citizen centred care'.

Taken together, work to be supported by these topics will improve our understanding of the causes and mechanisms underlying health, healthy ageing and disease; improve our ability to monitor health and to prevent, detect, treat and manage disease; support older persons to remain active and healthy; and test and demonstrate new models and tools for health and care delivery. In doing so, support will be provided to research and innovation performers, including significant, tailored support to small and medium sized enterprises.

Societal challenge 1 is also implemented by the innovative medicines initiative[1] (IMI), the European and developing countries clinical trials partnership[2] (EDCTP). The active and assisted living programme[3] (AAL) will complement the longer term research and innovation

[1] http://www.imi.europa.eu/content/documents#horizon_2020

[2] http://www.edctp.org/Towards_EDCTP2.799.0.html

[3] http://www.aal-europe.eu/why-another-aal-programme/

activities under this societal challenge by focusing on market oriented research and SMEs. Finally, topics in this work programme also respond to the priorities of the European Innovation Partnership on Active and Healthy Ageing[4] (EIP-AHA).

SC1 2014-2015 builds on the later calls of corresponding programmes in the 7th Framework Programme[5] by providing less detailed topic descriptions, allowing greater freedom to the applicant community to respond to these topics in the way they consider most appropriate, and should allow more innovative approaches and the broadening of participation. As a consequence, many topics will be evaluated in two stages, where the first requests only a short summary of the proposed project and only those which proceed to the second stage will provide a full proposal and receive a detailed report of the evaluation. Exceptions to the two stage approach include a number of 'closer to market' type topics, including those which make use of the SME instrument.

[4] http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing

[5] In a similar manner to work programmes published under FP7, this version may be amended shortly to include further guidance on provisions on open access, data sharing management plans and specific ethical aspects.

Call for personalising health and care

H2020-PHC-2014/2015

Understanding health, ageing and disease

PHC 1 – 2014: Understanding health, ageing and disease: determinants, risk factors and pathways

Specific challenge: The development and preservation of good health, and the occurrence of common diseases and disabilities result from varying degrees of interaction between the genetic make-up of individuals, and behavioural, environmental, occupational, nutritional and other modifiable lifestyle factors over the life course. Better knowledge of these factors will improve risk identification and validation, and allow better diagnosis, risk-based prevention strategies and policies, as well as stratified treatment and a healthy and productive working life. This is particularly important given Europe's ageing population, and the need for improved preventive and therapeutic measures providing good health and prolonged independence.

In this context, the two following requirements have been identified: the need for further exploration of the role of genetic, epigenetic and non-genetic factors (e.g. environmental, occupational and behavioural) in health and human disease development; and the need for a better understanding of the mechanisms underlying the process of healthy human ageing

Scope: Proposals are invited which address this challenge by specifically focusing on:

EITHER:

i. The identification and validation of trends and determinants of health, and risk factors for disease, through the generation, integration and validation of data derived from different sources (e.g. molecular, behavioural, clinical and/or environmental epidemiology, exposure sciences, genetics etc.). This should involve the exploitation of existing cohorts and longitudinal studies and the assessment of the necessity to establish new ones, as well as where relevant, the valorisation of knowledge gained from population-based bio-banks.

OR:

ii. The identification of determinants and pathways characteristic of healthy ageing (from early stages of development onwards) and of health deterioration caused by time, exposure to environmental factors and disease accumulation.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 to 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

In both cases, this will provide a better understanding of the combined effects of factors causing health and disease, with the knowledge generated underpinning the future development of evidence based prevention, diagnostic, therapeutic and other strategies.

i. In particular, this will provide:
   - Clinically relevant re-classification of diseases under study
   - Evidence for effective patient stratification
   - New perspectives for clinical research for better disease prevention, better and earlier diagnostics, health promotion and therapy development

ii. In particular this will provide:
   - A better understanding of pathways of healthy ageing in order to establish new strategies for promotion of healthy ageing, targeted disease prevention and clinical interventions

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 2 – 2015: Understanding diseases: systems medicine

Specific challenge: The development of new, evidence-based treatments relies on an improved understanding of the often very complex pathophysiology of diseases. Systems (bio) medicine approaches have the potential to tackle this complexity through the integration of a variety of biological and medical research data and computational modelling. A European collaborative approach is required to assemble the necessary multidisciplinary expertise (e.g. modern biology, medicine, mathematics, computational technologies) for implementing systems (bio) medicine approaches.

Scope: Applicants will propose new avenues for understanding the complexity of clinical phenotypes in multifactorial diseases and/or their co-morbidities. This will entail the development/optimisation and/or application of systems medicine approaches, and integration of biomedical and clinical data to produce or refine disease models using advanced statistical, computational and mathematical approaches. The predictive value of such models should be validated in well-phenotyped patient cohorts and their clinical potential proven.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 to 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: This will provide:
- Leverage of existing investments in Europe in the field of systems biomedicine
- New directions for better disease prevention, prognosis and therapy development

- Systems medicine tools and approaches tailored for medical research and/or the clinic, which represent an improvement over established practice.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 3 - 2015: Understanding common mechanisms of diseases and their relevance in co-morbidities

Specific challenge: The development of new treatments will rely heavily on an improved understanding of the pathophysiology of diseases. There is therefore a need to address the current knowledge gaps in disease aetiology in order to support innovation in the development of evidence-based treatments. In this context, a better understanding of the mechanisms that are common to several diseases, in particular of those leading to co-morbidities, constitutes an important challenge.

Scope: Proposals should focus on the integration of pre-clinical and clinical studies for the identification of mechanisms common to several diseases. Proposals will assess and validate the relevance of these common mechanisms and of their biomarkers (where relevant) on the development of disease-specific pathophysiology, as well as their role in the development of co-morbidities.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 to 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: This will provide:

- A better understanding of disease pathways and / or mechanisms common to a number of diseases
- New directions for clinical research for better disease prevention, health promotion, therapy development, and the management of co-morbidities

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

Effective health promotion, disease prevention, preparedness and screening

PHC 4 – 2015: Health promotion and disease prevention: improved inter-sector co-operation for environment and health based interventions

Specific challenge: Better health promotion and disease prevention interventions can make a significant contribution to equitable health improvements and thus the sustainability of health

and care systems. A "health in all policies" approach has been identified as a promising means to stimulate and foster environments that support health, wellbeing and behaviour change. This requires a multi-sector approach that aims to improve health by addressing such factors as housing; water and sanitation systems; transportation; communication, education and information; occupational health and safety; food production and distribution, and the physical and social environments.

Scope: Given the breadth of sectors, the specific focus of this topic for 2015 is the integration of environment and health sectors (including but not limited to climate change, air quality, water and sanitation, workplace, etc.).

Using a multidisciplinary approach and involving relevant stakeholders such as policy makers, the private sector, civil society organisations etc. proposals will:

- Develop inter-sector interventions (and/or policy initiatives) to promote health or prevent disease based on existing evidence. These interventions will address key environmental stressors for which changes in relevant EU and international policies related to environment and health would have the greatest impact;
- Document success characteristics of these interventions, including those which overcome barriers to inter-sector co-operation; contextual factors such as the interplay between politics and economics should be addressed;
- Assess these inter-sector interventions for their health, economic and social benefits.

In line with the Union's strategy for international cooperation in research and innovation[6], research activities will be developed as a European contribution to existing international activities and those under development.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- On the basis of quantitative and qualitative indicators, evidence on effective interventions taking a 'health in all' approach, linking environment and health, allowing informed decisions on multi-sector interventions and related policies
- Impact on health and care systems and other public services in terms of their sustainability,

[6] COM(2012)497

- Contribution to the EU commitment to the Rio+20 agenda and the new UN Sustainable Development Goals (SDGs), as well as the Parma declaration 2010.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [Link]

PHC 5 – 2014: Health promotion and disease prevention: translating 'omics' into stratified approaches

Specific challenge: 'Omics' research (including but not limited to genomics, epi-genomics, meta-genomics and proteomics) is moving at a breath-taking pace. A major challenge for the next decade is to determine when and how this wealth of 'omics' information can be usefully applied by both the public and private sectors for the development of personalised /stratified approaches in health promotion and disease prevention, i.e. taking into account the variability between individuals.

Scope: Proposals will:

Develop and assess a personalised / stratified health promotion or disease prevention programme, taking into account the 'omics' characteristics of individuals, complemented by environmental and/or lifestyle factors;

Include the development of tools and methods for the use of 'omics' data in such programmes;

Include a multi-disciplinary approach to assess the validity and utility of 'omics' data in preventive medicine or in prevention programmes targeting specific population groups. This will include:

- The assessment of the predictive value of such programmes in identifying at-risk groups throughout their lives, as compared with conventional methods;
- The assessment of the usefulness of 'omics' data for improving the health of individuals or populations;
- The assessment of the behavioural, ethical, legal and social implications, as well as of the cost-effectiveness of the programme;

It will also:

Include risk-benefit communication to various groups involved in such a programme, including individuals, policy makers and regulators.

Preference will be given to proposals focusing on diseases with either high prevalence or which present a high risk to the individual, or a high cost to society.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Evidence on the validity, utility and cost-effectiveness of 'omics' based health promotion and disease prevention programmes, allowing informed decisions on the organisation of health and care systems

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 6 – 2014: Evaluating existing screening and prevention programmes

Specific challenge: Some existing population based screening and disease prevention programmes have not been assessed for their effectiveness, or vary in terms of their application within and across countries throughout Europe. This may result in inappropriate interventions, delayed provision of the correct treatment, increased disease burden, health inequities and increased costs for health and care systems.

Such programmes therefore need systematic evaluation for their impact on health outcomes, cost effectiveness and health equity.

Scope:

Proposals will assess existing screening and disease prevention strategies and programmes, on the basis of health outcomes, quality-of-life, equity and cost-effectiveness and ethical considerations, at the level of the individual or stratified population groups, across Europe.

Comparison between different countries/regions, demographic groups and cultures will be made in order to identify specific contextual link elements as well as to identify opportunities for exchange of knowledge and experience between countries and regions.

Research will include the development of new methods or the adaptation of existing ones for this type of assessment. These methods and tools (including self-assessment tools) should be applied in different health systems and organisational infrastructures to test their applicability in different political, economic and societal contexts.

Due attention will be paid to the further development and dissemination of methodological expertise, including capacity building across Europe, from the outset in order that the expertise generated is not lost.

The Commission considers that proposals requesting a contribution from the EU between the range of 2 to 3 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Evidence for the increased use, or discontinuation of, existing screening and prevention programmes allowing informed decisions by policymakers
- Capacity building in the assessment of such screening and prevention programmes.
- Improved health outcomes, greater health equity and cost effectiveness based on the implementation of effective screening and prevention programmes

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 7 – 2014: Improving the control of infectious epidemics and foodborne outbreaks through rapid identification of pathogens (see also SC2)

Specific challenge: Human and animal health worldwide is increasingly threatened by potential epidemics caused by existing, new and emerging infectious diseases (including from antimicrobial resistant pathogens), placing a burden on health and veterinary systems, reducing consumer confidence in food, and negatively affecting trade, food chain sustainability and food security.

The increasing incidence and more rapid spread of such diseases are facilitated by modern demographic, environmental, technological and societal conditions. Many of these infections are zoonoses, necessitating an integrated, cross-border, "one health" approach to research and public health measures in the human and veterinary field, including the food chain.

Scope: Sequence based data for pathogens will be generated, stored and analysed in combination with clinical, microbiological, epidemiological and other data needed for risk assessment (RA) in an appropriate information system for all sectors (public health, food, animal).

The system will improve pathogen monitoring by rapid identification, comparison, and geographical mapping. It will include predictive models on RA, to identify 'high-risk' areas and disease-emergence patterns. It will ensure links and consistency with existing networks and databases (TESSY, RASFF, EWRS, EFSA/ECDC[7], molecular testing database) and data

[7] TESSY = The European surveillance system
RASFF = Rapid Alert System for Food and Feed
EWRS = Early Warning and Response System
EFSA = European Food Safety Authority
ECDC = European Centre for Disease Prevention and Control

protection requirements. Access to the system will be granted to relevant animal, food safety and human health service stakeholders (including EFSA and ECDC).

Harmonised standards for sampling, sequencing, (meta-) data collection, management and sharing should be developed. Likewise, better management tools for authorities, businesses and citizens and risk communication tools for authorities should be developed. The cost effectiveness of the tools and methods will be assessed. The improved understanding of outbreaks in regions with little or no surveillance systems, mass migration settings or post-disaster settings may require special attention for emerging and re-emerging pathogens. The initiative will structure the European contribution to existing international activities and those under development.

The Commission considers that proposals requesting a contribution from the EU between the range of 15 to 20 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Better containment and mitigation of epidemics by competent authorities on the basis of a shared information system and global standards for rapid pathogen identification.
- Consequent improved resource efficiency and reduction of economic impact of outbreaks (related to health care costs, market losses); facilitation of international trade, increasing competitiveness of European food and agricultural sector; reinforcement of food chain sustainability and enhancement of food security.
- In line with the Union's strategy for international cooperation[8] in research and innovation, projects will contribute to implementing the "Global Research Collaboration for Infectious Disease Preparedness" and its objective to establish a research response within 48 hours of an outbreak.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 8 – 2014: Vaccine development for poverty-related and neglected infectious diseases: Tuberculosis

Specific challenge: Vaccines offer a safe and cost-effective way to protect large populations against infectious diseases, or at least to mitigate the clinical course of these diseases. Yet, many poverty-related and neglected infectious diseases continue to escape attempts to develop effective vaccines against them.

[8] COM(2012)497

Disappointing results of recent clinical trials point to bottlenecks in identifying viable candidate vaccines, which if unaddressed will continue to present significant risks of failure at relatively late stages of the development process.

The specific challenge will be to shift this "risk curve" in order better to select successful vaccine candidates (and discard those with a higher risk of failure) at an earlier stage of the vaccine development process.

Scope: Proposals will focus on strengthening the capacity for discovery and early development of new vaccine candidates for tuberculosis by addressing all of the following inter-related elements:

1. Establishment of a platform for the identification of (at least 10) new diverse and novel vaccine candidates for tuberculosis, and their pre-clinical and early clinical testing.

2. The major bottlenecks in vaccine development will be addressed; in particular better ways for early distinction between successful candidates and those that will eventually fail in late stage clinical trials. Proposals are thus expected to address areas such as *in vitro* and *in silico* testing, predictive animal models, predictive correlates of protection, phase 0 trials, first in man trials and innovative risk prediction methods. Based on specific gating and priority setting criteria the most promising new vaccine candidates for tuberculosis will be compared with other candidates and selected in an objective and transparent process according to their merits in line with effective vaccine portfolio management.

3. It is expected that the successful project will be part of the Global TB Vaccine Partnership and continue its vaccine development in the context of this initiative in collaboration with the European and Developing Countries Clinical Trials Partnership (EDCTP), and a pathway and commitment towards this must form an integral part of the proposal.

In line with the Union's strategy on international cooperation[9] in research and innovation, international cooperation is encouraged. The projects will also address the barriers and possible facilitators regarding the uptake and implementation of a new vaccine in low, middle and high income countries in different regions of the world.

The Commission considers that proposals requesting a contribution from the EU between the range of 15 to 20 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Reduction in the cost associated with late stage vaccine failure, increasing the number of other candidates which can be tested with the same resources, thus increasing the chance of discovery of an effective vaccine

[9] COM(2012)497

- Support to the Global TB Vaccine Partnership for the development of tuberculosis vaccines and, (currently under development in collaboration with European Investment Bank and Bill and Melinda Gates Foundation) including the establishment of close links with the European and Developing Countries Clinical Trials Partnership (EDCTP).

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 9 – 2015: Vaccine development for poverty-related and neglected infectious diseases – HIV/AIDS

Specific challenge: Vaccines offer a safe and cost-effective way to protect large populations against infectious diseases, or at least to mitigate the clinical course of these diseases. Furthermore, they may in combination with other treatment modalities contribute to an eradicative cure for HIV. Many poverty-related and neglected infectious diseases however continue to escape attempts to develop effective vaccines against them.

Disappointing results of recent clinical trials point to bottlenecks in identifying viable candidate vaccines, which if unaddressed will continue to present significant risks of failure at relatively late stages of the development process.

The specific challenge will be to shift this "risk curve" in order to better select successful vaccine candidates (and discard those with a higher risk of failure) at an earlier stage of the vaccine development process, for preventive as well as therapeutic vaccines.

Scope: Proposals will focus on strengthening the capacity for discovery and early development of new vaccine candidates for HIV/AIDS by addressing all of the following inter-related elements:

1. Establishment of a platform for the discovery and selection of (at least 10) new diverse and novel preventive or therapeutic vaccine candidates for HIV/AIDS, and support to their pre-clinical and early clinical testing.

2. The major bottlenecks in vaccine development will be addressed; in particular better ways for early distinction between successful candidates and those that will eventually fail in late stage clinical trials. Proposals are thus expected to pool expertise in the areas of *in vitro* and *in silico* testing, predictive animal models, predictive correlates of protection, phase 0 trials, first in man trials and innovative risk prediction methods. Based on these criteria the most promising new vaccine candidates for HIV/AIDS will be compared and selected in an objective and transparent process according to their merit.

3. It is expected that the successful project will continue its vaccine development in the context of the European and Developing Countries Clinical Trials Partnership (EDCTP), and a pathway and commitment towards this direction needs to be an integral part of the proposal.

In line with the Union's strategy on international cooperation[10] in research and innovation, international cooperation is encouraged. The projects will also address the barriers and possible facilitators regarding the uptake and implementation of a new vaccine in low, middle and high income countries in different regions of the world.

The Commission considers that proposals requesting a contribution from the EU between the range of 15 to 20 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Reduction in the cost associated with late stage preventive or therapeutic vaccine failure, increasing the number of other candidates which can be tested with the same resources, thus increasing the chance of discovery of an effective vaccine
- Establishment of close links to the European and Developing Countries Clinical Trials Partnership (EDCTP), for the further clinical development of the vaccine candidates identified in the present initiative.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

Improving diagnosis

PHC 10 – 2014: Development of new diagnostic tools and technologies: in vitro devices, assays and platforms

Specific challenge:

The development of new diagnostics (more sensitive, robust and selective) for improved clinical practice demands the translation of multidisciplinary scientific and technological knowledge from diverse fields into clinical applications.

Improved clinical decisions should lead to better health outcomes while contributing to the sustainability of the health care system.

Innovation in the diagnostics area relies on the development, translation and uptake of existing, new or evolving and often complex technologies.

A wide range of multidisciplinary competencies need to be brought together to develop and bring new diagnostics to the patient. This is also a field where many small European companies are active.

[10] COM(2012)497

Scope:

Proposals will focus on the development and application of new, innovative in vitro diagnostic tools and technologies (not novel applications of existing ones). Tools and technologies will improve over state of the art the performance of diagnosis, prediction, monitoring, intervention or assessment of therapeutic response based on in vitro devices, assays and platforms, with a significant impact on clinical decisions and health outcomes.

Additionally, proposals may include approaches based on high-throughput screening, nanotechnologies or microfluidics, data analysis methodology, or technologies for point-of-care diagnostics.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- New *in vitro* diagnostic tools and methods providing more accurate, more reliable, cost effective and earlier disease diagnosis, patient stratification and prognosis of disease outcome leading to improved clinical decisions and health outcomes.
- Contribution to the sustainability of health care systems.
- Growth of the European diagnostics sector, in particular for SMEs

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 11 – 2015: Development of new diagnostic tools and technologies: in vivo medical imaging technologies

Specific challenge:

The development of new diagnostics (more sensitive, robust and selective) for improved clinical practice demands the translation of multidisciplinary scientific and technological knowledge from diverse fields into clinical applications.

Innovation in the diagnostics area relies on the development, translation and uptake of existing, new or evolving, and often complex technologies. A wide range of multidisciplinary competencies need to be brought together to develop and bring new diagnostics to the patient. This is also a field where many European companies are active.

Scope: Proposals will focus on the development of innovative *in vivo* imaging tools and technologies (not novel applications of existing ones). Tools and technology should aim at

improving diagnosis, prediction, monitoring, image-based intervention or assessment of therapeutic response, with a significant impact on clinical decisions and health outcomes. Preference will be given to innovations that offer a clear advantage over existing tools and technologies. Development of *in vivo* medical imaging technologies should make use of existing high-tech engineering or physics solutions or innovative ideas and concepts coming from those fields.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- New *in vivo* diagnostic tools and methods providing more accurate, more reliable and earlier disease diagnosis, prediction or response to therapy, leading to improved clinical decisions and outcomes.
- Contribution to the sustainability of health care systems.
- Growth of the European diagnostics sector, in particular for SMEs

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 12 – 2014 and 2015: Clinical validation of biomarkers

Specific challenge:

Biomarkers are used in clinical practice to describe both normal and pathological conditions. They can also have a prognostic or a predictive power. They are therefore increasingly used in medicine and many potential biomarkers are proposed every year.

Only a few of them are however validated for use in a clinical setting. Such validation implies the demonstration of a link to a pertinent clinical endpoint or process, as well as a robust and appropriate analytical method.

The clinical validation of biomarkers will be increasingly important for the development of new diagnostics, and this is an area where many small European companies are active.

Improved clinical decisions should lead to better health outcomes while contributing to the sustainability of the health care system.

Scope:

The clinical validation of existing potential biomarkers (not the identification of new ones) is sought. This validation should provide evidence for: high analytical validity; appropriate sensitivity and specificity; clinical validity/ utility.

Both *in vivo* and *in vitro* potential biomarkers are eligible. Preference will be given to disease related biomarkers (i.e. diagnostic, susceptibility/risk, monitoring and prognostic biomarkers)

The SME instrument consists of three separate phases and a coaching and mentoring service for beneficiaries. Participants can apply to phase 1 with a view to applying to phase 2 at a later date, or directly to phase 2.

In phase 1, a feasibility study shall be developed verifying the technological/practical as well as economic viability of an innovative idea with considerable novelty to the industrial sector in which it is presented (new products, processes, services and technologies or new market applications of existing technologies). The activities could, for example, comprise risk assessment, market study, user involvement, intellectual property management, innovation strategy development, partner search, feasibility of concept and the like to establish a solid high-potential innovation project aligned to the enterprise strategy and with a European dimension. Bottlenecks in the ability to increase profitability of the enterprise through innovation shall be detected and analysed during phase 1 and addressed during phase 2 to increase the return in investment in innovation activities.

In phase 2, innovation projects will be supported that address the specific challenge described above and that demonstrate high potential in terms of company competitiveness and growth underpinned by a strategic business plan. Activities should focus on innovation activities such as demonstration, testing, prototyping, piloting, scaling-up, miniaturisation, design, market replication and the like aiming to bring an innovation idea (product, process, service etc) close to deployment and market introduction, but may also include some research. For technological innovation a Technology Readiness Levels of 6 or above (or similar for non-technological innovations) are envisaged.

In addition, in phase 3, SMEs can benefit from indirect support measures and services as well as access to the financial facilities supported under Access to Risk Finance of this work programme. *[Link to the Access to Risk Finance Part]*

Successful beneficiaries will be offered coaching and mentoring support during phase 1 and phase 2. This service will be accessible via the Enterprise Europe Network and delivered by a dedicated coach through consultation and signposting to the beneficiaries. The coaches will be recruited from a central database managed by the European Commission and have all fulfilled stringent criteria with regards to business experience and competencies. Throughout the three phases of the instrument, the Network will complement the coaching support by providing access to its innovation and internationalisation service offering. This could include, for example, depending on the need of the SME, support in identifying growth potential, developing a growth plan and maximising it through internationalisation; strengthening the leadership and management skills of individuals in the senior management team and

developing in-house coaching capacity; developing a marketing strategy or raising external finance.

The Commission considers that phase 2 proposals requesting a contribution from the EU between the range of 2 to 5 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. Funding for phase 1 will be provided in the form of a lump sum of 50.000 EUR

Expected impact:

- Increased clinical availability and exploitation of biomarkers for the benefit of the patient.
- Facilitation of entry of improved diagnostics in the clinic and the market.
- Support for the implementation of the Commission proposal for a revised *in vitro* diagnostic devices regulation[11].
- Enhancing profitability and growth performance of SMEs by combining and transferring new and existing knowledge into innovative, disruptive and competitive solutions seizing European and global business opportunities.
- Contribution to the sustainability of health care systems.
- Market uptake and distribution of innovations tackling the abovementioned specific challenge(s) in a sustainable way.
- Increase of private investment in innovation, notably leverage of private co-investor and/or follow-up investments.
- The expected impact should be clearly described in qualitative and quantitative terms (e.g. on turnover, employment, market seize, IP management).

Type of action: SME instrument (max. 100% funding)

The conditions for this topic are provided in the general conditions for this call. [*Link*]

[11] Proposal for a regulation of the European Parliament and Council on in vitro diagnostic medical devices COM(2012)541 final

Innovative treatments and technologies

PHC 13 – 2014: New therapies for chronic non-communicable diseases

Specific challenge: There is general consensus that chronic diseases are better managed through proper primary care interventions to avoid prolonged, costly treatment and hospitalisation. Nevertheless, while a considerable amount of knowledge has been generated by biomedical research in recent years, the development of new therapies is stagnating, in part due to a lack of clinical validation.

Scope: Clinical trial(s) supporting proof of concept in humans to assess the potential clinical efficacy of the novel therapeutic concept(s) / optimisation of available therapies (e.g. drug repurposing). The application may build on pre-existing pre-clinical research. A concise feasibility assessment justified by available published and preliminary results and supporting data is also to be provided. Considerations of effectiveness / potential clinical benefit (possibly including real world data) should be integrated in the application if relevant.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- New therapeutic strategies with the highest potential to generate advances in clinical practice for chronic diseases, including multi- or comorbidity, ready for further development.
- Early exclusion of candidate strategies unlikely to succeed.
- Contribute to the improvement of the therapeutic outcome of major chronic health issues with significant impact on burden of diseases both for individual patients and for health care systems.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 14 – 2015: New therapies for rare diseases

Specific challenge: A considerable amount of knowledge has been generated by biomedical research in recent years, yet most of the 6000-8000 rare diseases are lacking therapies despite many diseases being life-threatening or chronically debilitating.

Specific problems posed for rare diseases include the small and dispersed patient populations and the nature of the therapies proposed which are often highly specialised and novel

requiring the engagement of regulatory authorities during development. In addition the limited market for such therapies provides a low commercial return.

Scope:

Support will be given for development of new or improved therapeutic approaches, for repurposing of existing therapies, as well as for preclinical research, animal model development and GMP production.

Proposed treatments to be developed may range from small molecule to gene or cell therapy.

Clinical trials will only be supported in cases where "orphan designation" has been given and where the proposed clinical trial design takes into account recommendations from protocol assistance given by the European Medicines Agency and where a clear patient recruitment strategy is presented. A concise feasibility assessment justified by available published and preliminary results and supporting data is also to be provided. Considerations of effectiveness / potential clinical benefit should be integrated in the application if relevant.

Selected projects should contribute to the objectives of, and follow the guidelines and policies of the International Rare Diseases Research Consortium, IRDiRC.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Advancing the development of new therapeutic options for patients living with rare diseases.
- In line with the Union's strategy for international cooperation in research and innovation[12], projects will contribute to reaching the IRDiRC objective to deliver 200 new therapies for rare diseases by 2020.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 15 – 2014/15: Clinical research on regenerative medicine

Specific challenge: Translating basic knowledge on regenerative medicine into the clinic is held up by the difficulty in undertaking 'first in man' studies. Specific research is needed for

[12] COM(2012)497

proving safety, efficacy and repeatability of new treatments. The main players are academic and clinical centres, SME spin-offs and start-ups, and very often iterative dialogue with the authorities is needed before specific regulatory requirements can be established.

As a new therapeutic field lacking established business models, financing is a particular obstacle to clinical-stage research in regenerative medicine. The objective of this topic is to initiate a specific action to overcome this hurdle to in-patient research and to determine the potential of new regenerative therapies.

Scope: Proposals will focus on regenerative medicine techniques which are ready for clinical (in-patient) research. Proposers should have at the time of proposal submission the necessary ethical and regulatory authorisations to carry out the work or provide evidence of regulatory engagement and that such approval is close. Priority will be given to proposals closest to having approvals in place for clinical work to start. Since the objective is to test new regenerative therapies, proposals may address any disease or condition but a justification for the choice must be provided. Clinical work will represent a central part of the project.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Obtain results of in-patient regenerative medicine research so that new therapies can be taken to the next level of testing or, if not successful, can be discarded.
- Stimulate growth and competitiveness of European regenerative medicine including European small and medium sized enterprises and industry operating in the sector.
- Increase the attractiveness of Europe as a location of choice to bring forward new therapeutic options.
- Lever existing investments in fundamental research in regenerative medicine.
- New approaches to currently untreatable diseases.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 16 – 2015: Tools and technologies for advanced therapies

Specific challenge: For their successful application, new therapies, such as gene or cell therapies, tissue engineering or regenerative medicine often require technological innovation in the form of development of specific component tools and techniques.

These are needed at the early development stage of the therapy, such as isolation and multiplication of a cell or development of a scaffold, delivery of the therapy to the patient and for following-up the effect of the therapy in the patient.

In particular, achieving therapeutic scale production and GMP standards at reasonable cost is often underestimated. In addition, specific attention needs to be given to aspects such as miniaturisation, automation, biomaterials and scaffold construction while advanced methods and devices for targeted and controlled delivery, and monitoring technology, will be needed to bring these innovative treatments to the patient.

Since experience with the new therapies is by definition limited, achieving regulatory compliance for them is another challenge.

Scope: The term advanced therapies is used to mean gene therapy, cell therapy, tissue engineering, regenerative medicine and bio-artificial organs. These are biological approaches to therapy which often share common technologies.

Proposals should focus on refining a particular technological step or component needed by the therapeutic approach.

Establishing proof-of-concept for the new technology and carrying out preclinical research may be included if needed.

Regulatory aspects of the new technology should be addressed as appropriate.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Development of tools and technologies enabling establishment of new therapies or patient interventions
- Supporting regulatory compliant new technologies
- Boost the growth and the competitiveness of the European medical technology sector
- Combine new technology developments from different sectors for better, safer and customer friendly products
- Increase the attractiveness of Europe as a hub for innovative medical technologies

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 17 – 2014: Comparing the effectiveness of existing healthcare interventions in the elderly

Specific challenge: Effective health care for the rapidly growing elderly population in Europe is challenging and complex. This population is subject to frequent and numerous comorbidities, associated poly-pharmacy and impaired hepatic and renal function, as well as problems linked to access to care and compliance. In addition, while the elderly are overrepresented in terms of patient numbers, this group is underrepresented or even excluded from many clinical trials that generate the evidence-base for health care interventions.

Scope: Proposals will compare the use of currently available (pharmacological as well as non-pharmacological) healthcare interventions in the elderly (> 65 year) population (or subgroups thereof).

While there is no restriction on the diseases or interventions, priority will be given to interventions with high public health relevance, i.e. which are particularly frequent, have a high impact on the quality of life of the individual and/or are associated with significant costs or cost savings.

Issues of particular relevance for the target populations, such as poly-pharmacy and compliance, will be taken into account. Given the focus on existing interventions, projects will aim to contribute to decisions about the discontinuation of interventions that are less effective or cost-effective than others.

A comprehensive array of clinical and safety parameters, as well as socio-economic outcomes (e.g. quality of life, patient mortality, morbidity, costs, and performance of the health system) for chosen populations will be assessed. Agreed core outcome sets (CSO) should be used as endpoints in conditions where they already exist, in other cases attempts should be made to agree on such COS.

Randomised controlled trials, pragmatic trials, observational studies and meta-analyses may be considered for this topic. The study population will address gender balance where relevant.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Evidence base for more effective and safer interventions, and for enhanced compliance, in the elderly population, and the use of health technology assessment methodology in this target group. In particular:
    - Improvement of individual patient outcomes and health outcome predictability through tailoring of interventions

- Contribution to better guidelines development for chronic diseases and the management of comorbidities
- Support to regulatory guidance in this population and provision of more accurate information to patients and prescribers

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 18 – 2015: Establishing effectiveness of health care interventions in the paediatric population

Specific challenge: Knowledge about the overall benefit of healthcare interventions in the paediatric population is currently limited and may result in inappropriate interventions with potentially lifelong impact on health and well-being.

Increasing knowledge in the areas of intervention effectiveness and clinical research has the potential to achieve system-wide improvements in health care quality and health outcomes. Effectiveness research in children and adolescents is required which is targeted, designed, conducted, and reported in ways that include clinically important differences in the type and course of disease in children.

Scope: Proposals will focus on clinical research approaches providing a deeper understanding of effectiveness, efficacy and safety of healthcare interventions and the use of health technology assessment methods in the paediatric population.

In order to achieve this, applicants will propose a detailed programme based on clinical trials and/or real world data. The programme will address clinical, therapeutic (including pharmaco-dynamic and pharmaco-kinetic properties wherever relevant) and safety aspects of the healthcare interventions of interest, with a view to the identification and assessment of benefits and risks. Guidelines for best practice from healthcare associations and authorities must be taken in account when applicable.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Significantly decreasing treatment related risk in the paediatric population (e.g. by researching adverse drug reactions, medical device deficiencies, etc.)

- Establishing novel and/or more effective treatment schemes for healthcare interventions in the paediatric population
- Validating benefits of novel and/or frequently used health interventions in the paediatric population

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

Advancing active and healthy ageing

PHC 19 – 2014: Advancing active and healthy ageing with ICT: Service robotics within assisted living environments

Specific challenge: Citizens in an ageing European population are at greater risk of cognitive impairment, frailty and social exclusion with considerable negative consequences for their independence, quality of life, that of those who care for them, and for the sustainability of health and care systems.

The challenge is to develop new breakthroughs for active and assisted living based on advanced ICT solutions.

Scope: Focus will be on service robotics in assisted living environments which can help an ageing population to remain active and independent for longer. Work will build on advances in this domain, and will combine multi-disciplinary research involving behavioural, sociological, health and other relevant disciplines. Characteristics of the solutions developed will be their modularity, cost-effectiveness, reliability, flexibility in being able to meet a range of needs and societal expectations, applicability to realistic settings, safety and acceptability to end-users.

The Commission considers that proposals requesting a contribution from the EU between the range of 3 to 4 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Evidence for the benefits of service robotics developed, based on proof of concept and involvement of relevant stakeholders
- Reduction of admissions and days spent in care institutions, and prolongation of time spent living in own home when ageing with emerging functional impairments.

- Improvement in quality of life of older persons and of their carers
- Global leadership in advanced solutions supporting active and healthy ageing

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 20 – 2014: Advancing active and healthy ageing with ICT: ICT solutions for independent living with cognitive impairment

Specific challenge: Citizens in an ageing European population are at greater risk of cognitive impairment, frailty and social exclusion with considerable negative consequences for their independence, quality of life, that of those who care for them, and for the sustainability of health and care systems. The challenge is to deploy innovative and user led ICT pilot projects in support of independent living with cognitive impairments and translate promising results into scalable practice across Europe.

Scope: Pilots will build on common, flexible and open ICT solutions which can be adapted to specific users' needs, allowing them to live independently for longer while experiencing cognitive impairment. Pilot deployment across Europe will develop best-practice and viable business and financing models, as well as evidence for potential return on investment.

Innovation in organisational and business models for service delivery will be supported, as well as standardisation and interoperability work on required ICT platforms, services and data sources. The number of users involved should be sufficient to ensure statistical significance in impact analysis, with a minimum of 4 pilot sites in 4 countries.

The Commission considers that proposals requesting a contribution from the EU between the range of 2 to 3 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Based on quantitative and qualitative output indicators and impact data, each pilot is expected to demonstrate relevant contributions to the following expected impacts:
    - Clear evidence on return of investment, both for the private sector and in terms of societal benefits from ICT based solutions for cognitive impairments of older people;
    - Best practice for viable business and financing models which are scalable across Europe;

- Clear evidence on the improvements of efficiency of health and care systems
- Clear evidence of improvements to quality of life and active ageing for involved users and carers;
- Contribution to the competitiveness of the European ICT industry in the domain, through enhanced interoperability and scalable markets;

Type of action: Innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 21 – 2015: Advancing active and healthy ageing with ICT: Early risk detection and intervention

Specific challenge: Citizens in an ageing European population are at greater risk of cognitive impairment, frailty and social exclusion with considerable negative consequences for their quality of life, that of those who care for them, and for the sustainability of health and care systems.

The earlier detection of risks associated with ageing, using ICT approaches, can enable earlier intervention to ameliorate their negative consequences.

Scope: Early risk detection and intervention: ICT based solutions are sought which support active and healthy ageing by enabling early detection and minimisation of risks associated with ageing, including (but not limited to) cognitive impairment, frailty, depression and falls.

Such solutions will demonstrate the link between changes in behaviour and subsequent negative consequences of ageing by unobtrusive behavioural sensing, and large scale collection of data readily available in the daily living environment of older individuals.

In addition, ICT based interventions countering identified risks will be designed, as will innovative treatments and therapies based on early detection.

Work will build on multi-disciplinary research involving behavioural, sociological, health and other relevant disciplines, and will be driven by relevant user needs to ensure end-user acceptance. Full account will be taken of relevant data protection aspects.

The Commission considers that proposals requesting a contribution from the EU between the range of 3 to 4 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Evidence for the benefits of risk detection and intervention, based on proof of concept and involvement of relevant stakeholders
- Clear improvements of outcomes for individuals, care systems and wider society from new therapies and interventions based on early risk detection in comparison with current practices.
- Global leadership in ICT based innovation for active and healthy ageing.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 22 – 2015: Promoting mental wellbeing: in the ageing population

Specific challenge: Health and care of the rapidly growing older population in Europe and elsewhere poses a number of specific challenges. Among these, the burden posed by mental and neurological conditions on older citizens has a significant impact on their working capacity, quality of life and that of their care givers, and interacts with the course and treatment of comorbidities which are frequently associated with old age.

Although some mental disorders like depression, anxiety, insomnia, dementia, personality disorders and substance use-related disorders are not limited only to older people, they are often present in clinical forms specific to them, and may require adapted therapeutic approaches. In addition, non-age-specific mental illnesses may complicate or contribute to other, more specific age-related chronic disorders. The prevalence of these disorders is high and increasing, and difficulties in their treatment are compounded by the underrepresentation or even exclusion of older persons from many clinical trials in the field of psychiatry.

Scope: Proposals will include multi-disciplinary research to improve the understanding, prevention, early diagnosis, and treatment of mental conditions and disorders of older people. This may include a dimension of research into physical, psychological and social determinants of healthy ageing.

Proposals may address the role of external or internal determinants of mental health, including e.g. sensory deficits, chronic disease, substance use, socio-economic stressors (loneliness, poverty), or physical stressors. Clinical trials or comparative effectiveness research will contribute to the establishment of integrated preventative or therapeutic intervention strategies to improve mental health in the older population. Priority will be given to interventions with high public health relevance, i.e. addressing particularly frequent or severe situations, with a high impact on the quality of life of the individual and/or associated with a significant socio-economic burden.

Issues of particular relevance for the target populations, such as self-medication, poly-pharmacy and compliance, and gender specificities should also be taken into account.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Improved therapeutic management of older patients affected by mental conditions and disorders.
- Improve cognitive abilities of older people
- Establishment of preventative strategies favouring the mental dimension of healthy ageing.
- Reduction of the negative impact of mental disorders on comorbidities.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

Integrated, sustainable, citizen-centred care

PHC 23 – 2014: Developing and comparing new models for safe and efficient, prevention oriented, health and care systems:

Specific challenge: Public health (epidemiology, sociology, economics, etc.), biomedical and behavioural research have provided evidence for new approaches to prevention, primary care and treatment. Their integration into health services requires cooperation across sectors and between stakeholders, and challenges the current boundaries of healthcare and established norms of operation.

EU Member States have thus far had different responses to the need for reform, presenting an opportunity to learn how best to react to preserve and promote our population's health and avoid increases in health inequalities.

Scope: As action oriented research, proposals will develop new models for health systems that make these systems more patient-centred, prevention oriented, efficient, safe and sustainable.

The models' applicability and adaptation to different European health systems will be assessed, and their value, including individual and societal benefits, demonstrated.

Models can apply to different levels within the health system (micro – the patient interaction level, meso- the health care organization and community level, and macro - the policy level). They must be compared with alternatives (including existing models), capitalising on Europe's diversity. Views of relevant stakeholders such as policy makers and citizens should

be taken into account in the design of and evaluation of these models. Capacity building and awareness raising activities for the adoption and further use of models developed will be included.

Work will address the related challenge of ensuring appropriate and sufficient resources (human, financial, infrastructural, equipment (or consumables) and technology) for these new models and develop adequate governance mechanisms. Research can include methodological work in the field of health technology assessment, health systems performance assessment, health workforce analysis as well as indicators and measures to describe and monitor the quality of life of European citizens adequately, and will track costs.

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 6 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- On the basis of quantitative and qualitative indicators, evidence on new patient-centred, prevention oriented, safe and efficient models for health care systems and services will be produced.
- Evidence to be used by policy makers and decision makers in making improvements to health and care systems, health and other policies.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 24 – 2015: Piloting personalised medicine in health and care systems

Specific challenge: Research on new models of care organisation suggests that personalising medicine may have the potential to respond to, amongst others, the increasing burden of chronic disease and the complexity of co-morbidities, and in doing so contribute to the sustainability of health and care systems.

There is a need to demonstrate this potential in terms of sustainable benefits when personalised medicine is rolled out at a larger scale, and as a new model of care organisation. This demonstration is complicated by the diversity of European Union health systems.

Scope: Larger scale pilots of new models of care, based on the concept of personalised medicine[13] will be conducted in existing health care environments and will take into account Europe's diversity in health system organisation.

Research will be conducted in coordination with national/regional or local authorities engaging in health sector reform, with the design of new models taking into account the views of other relevant stakeholders, including policy makers and citizens. Behavioural, ethical, legal, and social implications will be addressed.

The health, economic and social impact of the implementation of these pilots on individual patients, whole or stratified population groups, and their impact at the level of health care systems will be assessed. The organisational and resource requirements of the piloted models (data, personnel and financing) will be tracked, providing evidence on methods of implementation and benefits of the reform while ensuring safety, equity and cost efficiency. Appropriate measures for knowledge transfer and capacity building will be put in place.

The Commission considers that proposals requesting a contribution from the EU between the range of 12 to 15 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: On the basis of quantitative and qualitative indicators, evidence for a validated model of organisation of care based on the concept of personalised medicine will be produced, to be used by policy makers and decision makers in making improvements to health and care systems.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 25 – 2015: Advanced ICT systems and services for Integrated Care

Specific challenge: Research on new models of care organisation demonstrates that advanced ICT systems and services may have the potential to respond to, amongst others, the increasing burden of chronic disease and the complexity of co-morbidities, and in doing so contribute to the sustainability of health and care systems.

The challenge in re-designing health and care systems is to develop integrated care models that are more closely oriented to the needs of the patients and older persons: multidisciplinary,

[13] Personalised medicine refers to a medical model using molecular profiling for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention

well-coordinated, anchored in community and home care settings, and shifting from a reactive approach to proactive and patient-centred care.

Scope: To go beyond the current state of art in tele-health and tele-care systems by developing new approaches for integrated care supported by ICT systems and services. Proposals will address barriers from technological, social and organisational points of view in the following domains:

- Development of robust, privacy compliant, accurate and cost-effective systems that facilitate monitoring of patient status, patient activity and compliance with therapy;
- Fusion, analysis and interpretation of patient and care provider data, to improve decision making among formal and informal care givers and patients;
- Multi-channel and multi-actor interaction and exchange of knowledge in integrated care settings, across digital collaborative platforms;
- Development of patient-oriented services to support patient empowerment, self-care, adherence to care plans and treatment at the point of need;
- Development of new patient pathways, new training programmes for the care workforce and new organisational models to improve the coordination of care services as well as the skills and collaboration of health professionals, social carers and informal care givers;
- Personalisation of care management programmes to specific characteristics of patients' profiles, through analysis of multimodal data, risk stratification algorithms for chronic diseases and multi-morbidity conditions, predictive algorithms of patient's status, and personalisation tools for patients and;
- The creation of new knowledge for the management of co-morbidities and for addressing poly-pharmacy.

The design process of such ICT systems and services shall entail participation of a wide range of users, developers and stakeholders, including medical doctors, nurses, social workers, patients as well as programmers and interaction designers. Validation will provide proof-of-concept with both qualitative parameters and quantitative success measures.

The Commission considers that proposals requesting a contribution from the EU between the range of 3 to 5 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Reduced admissions and days spent in care institutions, and improvements in the daily activities and quality of life of older persons through effective use of ICT and better coordination of care processes.

- Strengthened evidence base on health outcomes, quality of life and care efficiency gains from the use of ICT in integrated care.
- Improved cooperation and secure information exchange among the actors involved in health, social and informal care services.
- Improved interaction between patients and their carers, and more active participation of patients and their relatives in care processes.
- Improved usability and adaptability of ICT systems for integrated care, taking account of the complex relationship between digital technologies and their social and human context of application.
- Reinforced medical knowledge with respect to management of co-morbidities.
- Strengthened European industrial position in ICT products and services by measurable indicators such as new business areas, start-ups and protected intellectual property

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 26 – 2014: Self-management of health and disease: citizen engagement and mHealth

Specific challenge: Empowering citizens to manage their own health and disease will result in more cost-effective healthcare systems by improving utilisation of healthcare, enabling the management of chronic diseases outside institutions, improving health outcomes, and by encouraging healthy citizens to remain so.

Several clinical situations would be prevented or better monitored and managed with the participation of the patient him or herself. Care sciences may complement the medical perspective without increasing the cost. This requires research into socio-economic and environmental factors, dietary impact and cultural values, behavioural and social models, attitudes and aspirations in relation to personalised health technologies, mobile and/or portable and other new tools, co-operative ICTs, new diagnostics, sensors and devices (including software) for monitoring and personalised services and interventions which promote a healthy lifestyle, wellbeing, mental health, prevention and self-care, improved citizen/healthcare professional interaction and personalised programmes for disease management. Support for knowledge infrastructures is also required, as well as the combination of predictive personalised models with personal health systems and other sources of data.

Scope: Proposals may focus on patients or healthy persons. Health management will be addressed in a holistic approach, from healthy lifestyle, dietary habits interlinked with disease management, placing the patient in the centre and putting increased emphasis on health education, secondary prevention and self-management of individual conditions, including co-morbidities. Implementation of programs or applications for different target populations to

capture gender- and age-dependent differences in health, behaviour and handling of devices is encouraged.

Proposals are invited which address this specific challenge by focusing on one of the two elements below:

(i) citizen engagement in health, wellbeing and prevention of diseases.

Projects shall enable individuals to become co-managers of their health and wellbeing (including physical and mental wellbeing, equality, health literacy, life style factors such as nutrition and smoking) with the help of ICT, tools and personalised services. The focus is on the following elements:

- The creation of a supportive environment for healthy behaviour including support to behavioural change e.g., mathematical, dynamic modelling of behaviour with quantitative, testable models especially in real world settings and application of the sciences in designing interventions or game based physical training with motion tracking based feedback;
- Health promotion, health literacy and disease prevention;
- Activities will envisage developing a multi-stakeholder ecosystem (of health and care professionals, patients, nutrition - and pharmaceutical industries, public healthcare authorities, health IT, mHealth actors, health insurers and regulators, etc…) to develop a 'co-production of health' business model – an evidence based, general, alternative way of creating and augmenting personalised health, supported by information exchange and utilisation and;
- A migration path towards comprehensive solutions that could be incorporated into health care processes would be an advantage.

(ii) mHealth applications for disease management

Projects will focus their research on application development for disease management with the following characteristics:

- Strong emphasis on co-designing and user needs as a key driver;
- Knowledge management systems to analyse and compile the data collected by applications on individuals' health and activities in order for such information to be used by the persons themselves, health professionals and public health monitoring authorities;
- Guidance for patients, families and patients' social environment on chronic disease management supported by mHealth;
- Economic aspects of encouraging secondary prevention and addressing avoidable negative health and wellbeing outcomes;
- Public health or health promotion interventions addressed to large sectors of population through mHealth applications and;

- Co-operative ICTs to support co-operative management of health and disease among patients and eco-health systems.

The Commission considers that proposals requesting a contribution from the EU between the range of 3 to 5 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: In both cases (i) and (ii)

- Improved self-management of health, disease prevention, management of diseases and/or expenditure.
- Strengthened evidence base on health outcomes, quality of life, care efficiency gains and economic benefits from the use of ICT in new care models, in compliance with data protection requirements.
- Increased confidence in decision support systems for wellbeing and disease / patient management.
- Strengthened evidence and improved knowledge about individuals' behaviour related to wellbeing, disease prevention or management facilitating the creation of new personalised behavioural health interventions.

For (i)

- Validated programmes for health promotion and disease prevention
- Ecosystem and new business models for promotion and co-production of health

For (ii)

- Improved service offering and business concepts and models
- Impact in several of the following facets of mHealth e.g., patient safety, contribution to or revision of (guidelines of) relevant legal frameworks, medical guidelines, harmonisation (across borders), standards, co-ordination of therapies, recognition of mHealth as a reimbursable cost, improved accessibility, liability, inter-operability, more reliable connectivity, patient empowerment, improved patient-health professional interaction, maturing personalised health systems, sustainability, usability and user-acceptance.
- Improved interaction between patients, their relatives and care givers, facilitating more active participation of patients and relatives in care processes.
- Improving the management of disease by reducing the number of severe episodes and complications.
- Increased level of education and acceptance by patients and care givers of ICT solutions for personalised care.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 27 – 2015: Self-management of health and disease and patient empowerment supported by ICT

Specific challenge: Empowering citizens and patients to manage their own health and disease can result in more cost-effective healthcare systems by enabling the management of chronic diseases outside institutions, improving health outcomes, and by encouraging healthy citizens to remain so. Several clinical situations would be prevented or better monitored and managed with the participation of the patient him or herself. Care sciences may complement the medical perspective without increasing the cost.

This requires research into socio-economic and environmental factors and cultural values, behavioural and social models, attitudes and aspirations in relation to personalised health technologies, mobile and/or portable and other new tools, co-operative ICTs, new diagnostics, sensors and devices (including software) for monitoring and personalised services and interventions which promote a healthy lifestyle, wellbeing, mental health, prevention and self-care, improved citizen/healthcare professional interaction and personalised programmes for disease management.

Support for knowledge infrastructures is also required, Implementation of programs or applications for different target populations to capture gender- and age-dependent differences in health, behaviour and handling of devices is encouraged.

This topic is a continuation of PHC 26 – 2014) giving more and different opportunities to develop solutions and services for self-management of health and diseases.

Scope:

Solutions will be developed and tested with the use of open innovation platforms such as large scale demonstrators for health and service innovation. Proposals will involve health procurers and support them in their efforts to lower costs, and reduce difficulties associated with limited numbers of health professionals by utilising the capacity and potential of the patient as a co-producer of health. The topic will use pre-commercial procurement to maximise the engagement of innovation in healthcare organisations following the community building and road-mapping activity in FP7 call 10 CSA on innovation in health procurement[14].

Proposals will aim to empower patients to manage their pre-existing conditions. Health management will be addressed holistically, including healthy lifestyle interlinked with disease management, placing the patient in the centre and putting increased emphasis on health

[14] http://ec.europa.eu/research/participants/portal/page/call_FP7;efp7_SESSION_ID=QJb3S2ZR4c5R8YGRdcXg6sMvRGhp5MnfdJ6hwS2s2Zdph80JKMYL!1216744746?callIdentifier=FP7-ICT-2013-10&specificProgram=COOPERATION#wlp_call_FP7

education, secondary prevention and self-management of individual conditions, including co-morbidities.

The projects will address a) personalised guidance to patients based on their profiles and the use of wearable/portable devices and improved individual/healthcare-professional interaction, b) engagement of patients as active members in managing their diseases, in particular addressing chronic diseases, co-morbidities, treatment adherence, rehabilitation, self-diagnostics and self-care and c) decision support systems interoperable and/or maintaining integrity with electronic health records.

The Commission considers that proposals requesting a contribution from the EU between the range of 3 to 5 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Improving the participation of the patient in the care process.
- Improving the management of a disease by reducing the number of severe episodes and complications.
- Increasing the level of education and adherence of individuals, patients and care givers related to application of ICT for personalised care.
- Improved interaction between patients, their relatives, providers of health-, social-, and informal care givers.
- Strengthened evidence base on health outcomes, quality of life, care efficiency gains and economic benefits from the use of ICT in new care models.
- Reinforced medical knowledge with respect to efficient management of comorbidities.
- Increased confidence in decision support systems for disease/patient management.
- Involvement of health care providers/authorities with increased commitment in the deployment of innovative services empowering the patient.

Type of action: Pre-commercial procurement

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 28 – 2015: Self-management of health and disease and decision support systems based on predictive computer modelling used by the patient him or herself

Specific challenge: Several clinical situations would be prevented or better monitored and managed with the participation of the patient him or herself. In order to promote the self-management, predictive personalised models can be combined with personal health systems and other sources of data (clinical, biological, therapeutic, behavioural, environmental or

occupational exposure, lifestyle and diet etc.) and used by the patient him or herself, in order to raise individual awareness and empower the patient to participate in the management of his or her health, with application in lifestyle, wellbeing and prevention, in monitoring of the disease etc. This will improve the quality of life of patients and the self-management of disease and lifestyle.

Scope: Proposals will focus on predictive systems based on computer modelling and will develop decision support systems (DSS) that will be used by the individual. The DSS shall include the collection of various data (patient, clinical, biological, therapeutic, behavioural, environmental or occupational exposure, physical training and performance, lifestyle and diet, environmental data, social data etc.). Connected existing predictive models will process these data in real-time to predict how the health of the patient will evolve in the near future and such predictions, accompanied with all relevant information regarding their uncertainties and limits will be used by the patient / citizen him or herself for self-management of health and wellbeing. These DSS could also help to improve interactions between individuals / health professionals and co-decision making in healthcare. Combination with monitoring personal health systems and other technologies and sources of data, as e.g., tools for data collection on external factors potentially linked to disease are possible.

The Commission considers that proposals requesting a contribution from the EU between the range of 3 to 5 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Improving the participation of the patient in the care process.
- Improving the management of a disease by reducing the number of severe episodes and complications.
- Increasing the importance of the prevention sector in healthcare using predictive modelling.
- Boosting the development of personal devices used for self-management of health.
- Improving individual self-control of health and of disease prevention

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 29 – 2015: Public procurement of innovative eHealth services

Specific challenge: The sustainability of pilot and demonstration solutions and services is broadly perceived as one of the biggest challenges in streamlining healthcare delivery processes and in improving cost efficiency while maintaining or improving patient safety. The

pace of development has been slow and penetration of ICT still has high growth potential in healthcare compared to other public or private sectors.

This activity facilitates public purchasing of innovative solutions in healthcare which have not yet been deployed on a large scale.

Scope: The projects shall improve sustainable deployment of new or improved services by healthcare service procurers in line with the eHealth Action Plan[15]. Examples of target outcomes for healthcare delivery could be addressing early hospital discharge, delivery of healthcare in remote, sparsely populated and difficult to access regions, eHealth services for mobile EU patients, and pre/post operation care outside the hospital environment.

The intended scope of the PPI pilot(s) is to specify, purchase and deploy ICT based solutions which can deliver sustainable, new or improved healthcare services and improve the ecosystem in which procurement approaches for innovative healthcare solutions are successfully applied.

Proposals should be driven by clearly identified procurement needs of healthcare organisations:

- Solutions should be based on a complete set of common specifications for technology and end to end services;
- The implementation phase should have the ambition to reach a large scale across multiple regions of Europe;
- Proposals must engage public and/or private procurers from each country participating (at national, regional or local level) that have responsibilities and budget control in the relevant area of care or supply of services;
- Wherever possible the work should build on and contribute to relevant standards to ensure interoperability and take into account best practices and relevant standardisation efforts as well as provide appropriate safeguards against relevant ethical and privacy issues;
- The work will include a non-confidential, comprehensive socio-economic evidence base for ICT investments in the field (including e.g. cost-benefit analysis, assessment of impacts, return on investments, medical evidence, patient safety gain and user satisfaction) to facilitate the development of sustainable business models and;
- Good practice will be made available for replication in other regions, for example detailed plans for larger-scale sustainable uptake as well as reference material including guidelines, manuals and educational materials.

[15] ec.europa.eu/digital-agenda/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century

The Commission considers that proposals requesting a contribution from the EU between the range of 4 to 5 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Contribution to regulatory and legal process development addressing possible barriers to procurement of innovative solutions in healthcare.
- Growing awareness and successful use of public procurement by the procurers to boost innovation in the application of ICT in the sector concerned.
- Support to interoperability and defragmentation of the market.
- Sustainable implementation of services and creation of economic conditions that support long-term development.
- More forward-looking, concerted, public sector approach to eHealth.
- Reduced fragmentation of public sector demand across a number of EU Member - or Associated States by enabling public purchasers to collectively implement PPI strategies, which due to their nature are better addressed jointly, or which they would not have been able to tackle independently.
- Increased opportunities for wide market uptake and economies of scale for the supply side for ICT based solutions and services by forming critical mass on the public demand side.

Type of action: Public procurement of innovative solutions

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 30 – 2015: eHealth Sectoral Inducement Prize[16]

Specific challenge: This prize will reward the development of an interactive health and well-being app. The rules of the contest will be established and published[17] by the European Commission, which will launch and manage the contest and award the prizes based on the judgement of independent experts.

eHealth and well-being are areas with high growth potential and considerable possibilities for innovation, notably by unlocking the exchange of health data. However, the challenges of the

[16] Note that the implementation mechanism for prizes remains to be determined and so future iterations of this work programme may see their inclusion in the 'other actions' section of this work programme. In that case, additional practical details will be included, but the essential goals of the prize will remain as described above.

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

economic crisis, market fragmentation and other barriers are limiting the benefits of eHealth for healthcare, health systems, the economy and citizens.

The objective of this inducement prize is to unlock the eHealth market with apps that would support citizens in being more active in treating their conditions, and physicians in communicating with their patients.

Scope:

The prize will be called 'App for the better health and wellbeing of the EU citizen'.

Participants in the competition must be legally established in one or several EU Member States.

The prize will be awarded, after closure of the competition, to the contestant who or which in the opinion of the jury provides a solution that best addresses the cumulative criteria that will be published on competition launch, but which are likely to include:

The solution ensures that citizens can securely store and access their health and well-being data. These data can be transmitted seamlessly to healthcare professionals.

The application shall provide a health and well-being scoreboard to users in order to help them to improve their health and well-being

The solution should be available in at least 3 official EU languages

The solution should be able to retrieve information from other existing sources, in particular from other health and well-being apps.

Note also that applications that work on only one operating system will not be considered. Similarly, the solution should be developed by the contestant.

The prize purse (EUR 2 million) will be distributed among the winners (of which there may be more than one).

Expected impact:

Engage European citizens in their health and well-being

Develop effective approaches to continuously collect / monitor health and well-being data

Develop ICT solutions for better interactions between citizens & healthcare professionals

Type of action: Inducement prize

The conditions for this topic are provided in the general conditions for this call. [*Link*]

Improving health information, data exploitation and providing an evidence base for health policies and regulation

PHC 31 – 2015: Digital representation of health data to improve disease diagnosis and treatment

Specific challenge: Digital personalised models, tools and standards with application for some specific clinical targets are currently available. There is however a need for greater integration of patient information, for example of multi-scale and multi-level physiological models with current and historical patient specific data and population specific data, to generate new clinical information for patient management. Any such integrative digital representation (Digital Patient) must also allow meaningful knowledge extraction and decision support.

Scope: Work will propose new decision support systems based on a complex integration of heterogeneous data sources and subject-specific computer models. This will enable an integrated data analysis, and will present a highly visual data representation, using user-friendly interactive exploratory interfaces in order to assure usability and acceptability.

They will be used by healthcare professionals for personalised prediction and decision in prevention, diagnosis or treatment and should take into account data protection and ethical considerations. The models should be already available, multi-level and multi-scale and will be integrated with the individual and population data relevant for the targeted clinical situations, e.g. the required molecular and cellular data, including genomics and epi-genomics, in vivo and in vitro imaging data, or data on administration of therapeutics and on nutrition/exposure to environmental factors and will be linked when relevant with computer models of personalised physiology, functional disorders and other diseases. The proposed systems should take advantage of the personal medical data accumulated over time. Importance will be attached to the standardisation of data formats. Integration of data coming from other technologies and key-enabling technologies is encouraged.

The Commission considers that proposals requesting a contribution from the EU between the range of 3 to 5 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Better coherent use of health data available for a subject in conjunction with the existing medical knowledge in clinical decision making
- Better management of complex clinical situations.
- Enabling use of the same information by different medical services and the other relevant healthcare professionals.
- Better control and inter-service coordination in the management of the patient health.

- Providing a consistent view of a patient's care needs.

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 32 – 2014: Foresight for health policy development and regulation

Specific challenge: The complex interactions between multiple determinants of health and wellbeing are not well understood. These include but are not limited to air quality, greenhouse gas emissions, traffic and congestion, ambient noise, built environment, urban sprawl, sustainable food systems, waste, lifestyle, behaviour, occupation, demographic change, socio-economic factors, globalisation of exchanges of goods and people and so on.

Adding to the complexity, currently used measures and indicators of health status and quality of life are inadequate to capture the effect of these interactions and there is a lack of comparable health related data as produced by different health information systems. Furthermore, the co-existence of a multitude of analytical frameworks, often not multi-factorial in nature, limits the comprehensiveness of the assessment.

Foresight is a powerful tool in providing a systematic and structured approach for understanding stress factors and facilitators affecting health and wellbeing that are at play, analysing the range of possible outcomes and for helping to define policy options

Scope: Proposals should identify key driving forces- (external and internal to the health systems) likely to influence health and wellbeing in Europe and beyond in the future. Research should help understand the inter-relationships between these factors; analyse their economic and social impact and suggest alternative policy options to respond to the challenges they pose. Proposals should present a comprehensive, structured and participatory framework of analysis, integrating key factors impacting health and demand for health services taking Europe's diversity into account.

Use should be made of current techniques for foresight such as horizon scanning, trend monitoring, and analysis based on epidemiological surveillance (of health and health determinants), weak signals analysis, expert opinion (to create collective intelligence), scenario development, back-casting and wildcards (to help define alternative futures).

Research should further include more quantitative analysis, such as economic and other modelling and sensitivity analysis to measure variation in impact of different factors. Work will include the identification and validation of relevant measures & indicators and the development of (common) standards. It will capitalise on existing good practices in Europe as well as international level experiences.

The usefulness of current health data and statistics for these modelling exercises should be assessed and suggestions for improvement made. Networking between centres with existing expertise in foresight, both public and private, and partnerships with centres aspiring to develop this expertise is desired.

It is expected that successful projects will collaborate and a pathway and commitment towards this will be an integral part of the proposal.

The Commission considers that proposals requesting a contribution from the EU between the range of 2 to 3 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: Through the use of a validated analytical framework with a robust set of indicators, the ability to model and track the impact of various factors (internal and internal to the health systems) on population health will be improved. Work should serve as a basis for policy dialogue, facilitating timely decision making in the EU MS and beyond with regards to health sector reform and guide investments in health care to improve population health. Work undertaken will also provide guidance for future (public) health research

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 33 – 2014: Advancing bioinformatics to meet biomedical and clinical needs

Specific challenge: Recent technological advances in molecular biology, biomedical sciences and systems biology have enabled a greatly increased rate of data generation and of many different types of data. Furthermore, these new technologies are gradually becoming much less expensive and more accessible to individual laboratories and clinics – thus the rate of data generation at a local level is also set to increase dramatically. Similarly, although current bioinformatics is characterized by this large scale data accumulation and more sophisticated tools, a truly integrative perspective is lagging somewhat.

Currently available bioinformatics tools and approaches are thus not sufficient to enable data collection, storage, organisation, integration, analysis and exploitation in biomedical research and the in clinic of such diverse and complex data. Furthermore, the emerging area of network bioinformatics needs a higher level of acknowledgement in Europe in order to maintain scientific competitiveness. It is proposed to promote specific research actions to ensure that bioinformatics capabilities are not only made adequate for the current data challenge but also to meet future biomedical and clinical needs. SME interest in the field is high.

Scope: Proposals will focus on research, including the development of new mathematical, statistical and computational approaches, to address specific bottlenecks in bioinformatics that

hold back better understanding and use of biomedical and clinical research data. The needs include, but are not limited to: better data capture, organisation and storage; improved data analysis and processing methodologies; new approaches for data integration (e.g. different types and sources, integration of the time component); new approaches to data standardisation, including development of both preclinical and clinical standard operating procedures, ensuring data consistency and sharing while also complying with data protection requirements; improving accessibility and user-friendliness of biomedical and clinical research data. Close links between developers and envisaged end- users of the new approaches must be ensured from the start of all projects, as must widespread dissemination of the new tools and approaches. Commercial development of new methodologies should be encouraged where appropriate.

The Commission considers that proposals requesting a contribution from the EU between the range of 2 to 3 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Widespread dissemination of the new bioinformatics tools to maximise the accessibility and utility of biomedical data in research and medicine
- Increased commercial products in bioinformatics (e.g. data services).
- Increased research & innovation opportunities in this SME-intensive field
- Building on European excellence to make the EU a location of choice for advanced bioinformatics research

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 34 – 2015: New approaches to improve predictive human safety testing

Specific challenge: Current approaches to assessing and predicting the safety of chemicals in humans, particularly tests done in animal models, are expensive and time consuming and often of limited relevance. Better approaches are needed to improve the efficiency of predictive toxicological testing to meet regulatory requirements. Key areas of toxicological concern for human health include carcinogenicity, reproductive effects, developmental effects, immune system and allergies, neuro- and organ toxicity. Safety testing is of worldwide concern – markets are global – therefore, international cooperation could be an important element in addressing the challenge.

Scope: Proposals will capitalise on advances in biomedical research, together with advances in computational biology and chemistry, high-throughput technologies, and systems biology

approaches to understand complex biological pathways of toxicological relevance and to identify early markers predictive of toxicological effects with the objective to develop and validate routine, animal-free, toxicity testing approaches for chemical products (excluding radio-chemicals).

The research could include the development of methodologies for confirmatory testing of mechanistic hypotheses to improve understanding of toxicity mechanisms. Proposals should involve, amongst others, the research communities, SMEs, industry and regulatory agencies as appropriate, and should demonstrate efficient mechanisms for the co-ordination of activities and exchange of information. In line with the Union's strategy for international cooperation[18] in research and innovation, cooperation is encouraged with similar initiatives in the USA, Japan and elsewhere, and would be highly beneficial from scientific and economic standpoints.

The Commission considers that proposals requesting a contribution from the EU between the range of 10 to 15 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- More effective, faster, cheaper human toxicological testing to better meet regulatory needs
- Improved toxicological knowledge to encourage "read across" for use in different regulatory domains (chemicals, cosmetics, drugs, food…).
- Commercial exploitation of the developed toxicological testing methods, products and services.
- Advancement of international co-operation in the field of predictive toxicology and human safety testing

Form of funding: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

PHC 35 – 2014: eHealth interoperability

Specific Challenge: There are a number of challenges to effective eHealth service deployment in Europe, each of which is to be addressed by an individual CSA as below.

(i) There is little stakeholder consensus on a common reference information model for eHealth deployment in Europe, and it seems unlikely that international consensus can be

[18] COM(2012)497

reached for common (clinical) reference standards in a reasonable timeframe and budget. It is therefore reasonable to ask whether competing / overlapping standards can co-exist in a common eHealth European interoperability framework; this is of relevance to the MoU on eHealth between the EC and the US department of Health and Human services.

(ii) The Directive on patients' rights in cross-border healthcare (Directive 2011/24/EU) pursues the objective to enhance safety and continuity of cross-border treatment through interoperable access to patients' summary data and interoperable ePrescriptions. The challenge in ePrescription is how medicines can be communicated in the cross border setting. There is neither a common data model nor a common vocabulary for medicinal or pharmaceutical products throughout Europe.

(iii) The clinical domain is probably among the most complex from a semantic point of view. Vocabularies, terminologies, classification and coding systems, ontologies have been developed by different stakeholders to address different needs in different subdomains. The semantic health report had already demonstrated the central role that SNOMED CT[19] could play as a core terminology to solve semantic interoperability issues, provided "evidence-based results of SNOMED CT's fitness for purpose are assessed". The epSOS pilot project has retained SNOMED CT as one of the constituents of its master value sets catalogue which ensures semantic interoperability across the borders in the frame of the pilot. More recently, the eHealth Network called on the Commission to play a more active role in assessing the value of SNOMED CT for eHealth deployments in Europe. A detailed analysis on the advantages and disadvantages, as well as the impact of using SNOMED CT as the core terminology at the EU level is needed.

(iv) The Connecting Europe Facility will provide the funding and the governance framework to deploy cross border eHealth Services, among other digital services, until 2020. The intention is to migrate progressively the Connecting Europe facility from a publicly funded initiative to a self-financed operation. There is a need to identify the right business model and plan which would identify sustainable sources of revenue and all the costs which the operations of such services would generate. Gathering evidence that interoperability contributes to lowering the cost of health systems is an important element for decision makers when they have to envisage eHealth investments.

Scope: (i) The proposal should at minimum build on existing CEN, ISO, and HL7 standards. The need for a formal standardization activity in the area should be demonstrated, as well as a realistic roadmap with concrete deliverables. Alternative scenarios should be envisaged. Proposals should build on existing initiatives and EU projects in the area. Large involvement of stakeholders (including at least Member States, Industry and international standards development organisations (SDOs)), consensus building and endorsement of the work carried

[19] http://www.ihtsdo.org/snomed-ct

on and the submitted deliverables will be considered as a key success factor. Contribution to the EU eHealth Interoperability Framework should be demonstrated. The successful proposal should support large scale deployments of eHealth services (including cross border) in Europe and contribute to the implementation of the EU-US MoU and roadmap.

(ii) There is a need to investigate the possibility of combining existing or developing a new European or international standard which would need to address the following issues:

- Unambiguous definition and description of medicinal and pharmaceutical products, including unique identification.
- Handling of substitution

A proposal should be submitted by a consortium gathering relevant international standards development organisations, member states' public authorities and fora and consortia which have a demonstrated expertise to perform the work.

The successful proposal should build on existing standard vocabularies, terminologies and ontologies and demonstrate that it will contribute to the adoption of existing or the development of international standards

(iii) The analysis should cover the use of SNOMED CT as a core terminology to solve semantic interoperability issues for cross border but also national and regional eHealth deployments in the EU. The assessment shall cover aspects such as costs (license or membership, but also operational, translations, mapping to local terminologies, maintenance, training,…), fitness to clinical requirements, legal, technical and operational, benefits, governance, impact on the different stakeholders including patients and healthcare providers, for the cross border as well as for the national and regional scenarios. It will compare the SNOMED scenario with at least two scenarios: a) do nothing at the EU level and b) define a semantic interoperability framework without SNOMED CT. It will assess whether SNOMED CT satisfies the criteria listed in the annex II of the EU standardization regulation. The analysis should take into account advice and guidelines from the eHealth Network but also developments related to the EU-US roadmap.

Proposals for this section should not last longer than one year.

(iv) The proposal should build on existing work done by projects such as epSOS[20] and SemanticHealthNet[21] which will have developed key building blocks which will help to address the challenge. The epSOS pilot project has been piloting two basic use cases (ePrescription and Patient Summary) and successful proposals are expected to identify and agree on a roadmap of use cases that should be deployed on large scale in the future after the epSOS use cases. The successful proposal will demonstrate the value proposition of

[20] http://www.epsos.eu/

[21] http://www.semantichealthnet.eu/

healthcare providers with regard to interoperability and assess sustainable incitement schemes that would encourage healthcare providers to encode health data and provide it in an interoperable way and to invest in interoperable eHealth systems.

It should gather a large multidisciplinary group of stakeholders from the Member States, Regions, SDO, sectoral fora and consortia, industry, health insurance companies, key interoperability experts, patients associations, health care providers associations, and any other stakeholders which will be deemed necessary. It should deliver a full business plan going beyond 2020 including all revenue streams and cost items.

The Commission considers that projects requesting a contribution from the EU in the range of EUR 1 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

(i) Convergence in the use of eHealth Standards in Europe and in the world. Contribution to the eHealth Interoperability Framework and to large scale deployment of eHealth Services (including cross border) in Europe. In line with the Union's strategy for international cooperation in research and innovation[22], projects will contribute to the implementation of the EU-US roadmap

(ii) The proposal should provide practical solutions to solve the specific challenge and enable large scale deployments of cross border ePrescription services in the EU. It is also expected to contribute to the EU-US roadmap and MoU.

(iii) Contribute to better semantic interoperability of eHealth services in Europe, to building a European eHealth Interoperability Framework and to prepare the deployments of eHealth Services in the frame of the Connecting Europe Facility.

(iv) The proposal will contribute to the planning and road-mapping of the CEF for that which concerns the deployment of cross border eHealth services. It will also contribute to help the member states and the eHealth Network to prioritise use cases to be deployed at national level and better plan their own national deployments.

Type of action: Coordination and support actions

The conditions for this topic are provided in the general conditions for this call. [*Link*]

[22] COM(2012)497

PHC36 – 2015: Inducement prize – topic TBD[23]

Specific challenge: In addition to topic PHC30, and building on the experience gained with the 'Vaccine inducement prize'[24], provision is included here for an inducement prize, the subject of which will be determined on the basis of the outcome of the on-going study "Development and design of inducement prize competitions in key areas under Horizon 2020" (starting Q4 2014).

Scope: TBD as indicated above

Form of funding: Inducement prize

The conditions for this topic are provided in the general conditions for this call. [*Link*]

[23] Note that the implementation mechanism for prizes remains to be determined and so future iterations of this work programme may see their inclusion in the 'other actions' section of this work programme. In that case, additional practical details will be included, in addition to the essential goals of the prize which will be included according to the template above, following conclusion of the study undertaken by RTD C.

[24] http://ec.europa.eu/research/health/vaccine-prize_en.html

CONDITIONS FOR THIS CALL AND THE PRIZES

Publication date[25]: 11th December 2013
Deadline(s) (2014)[26]:

PHC 1 - 2014 PHC 5 - 2014 PHC 6 - 2014 PHC 10 – 2014 PHC13 - 2014 PHC 17 - 2014 PHC 23 - 2014 PHC 33 - 2014	Stage 1 – XXX at 17.00.00 Brussels time			
PHC 15 - 2014 PHC 19 - 2014 PHC 20 - 2014 PHC 26 - 2014 PHC 32 - 2014 PHC 35 – 2014	Single stage - XXX at 17.00.00 Brussels time			
PHC 1 - 2014 PHC 5 - 2014 PHC 6 - 2014 PHC 7 - 2014 PHC 8 - 2014 PHC 10 – 2014 PHC 13 - 2014 PHC 17 - 2014 PHC 23 - 2014 PHC 33 - 2014	Stage 2 - XXX at 17.00.00 Brussels time Single stage – XXX at 17.00.00 Brussels time (PHC 7 and PHC8 only)			
PHC 12 - [SME instrument][27] Open call cut-off dates	Phase 1 XX/XX/2014 Phase 2 XX/XX/2014	Phase 1 XX/XX/2014 Phase 2 XX/XX/2014	Phase 1 XX/XX/2015 Phase 2 XX/XX/2015	Phase 1 XX/XX/2015 Phase 2 XX/XX/2015

Indicative budget :

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

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

[27] These dates will not be the same as those for the other SME instrument topics elsewhere in Horizon 2020 but will rather be synchronised with the PHC call deadlines. Precise modalities remain under discussion.

- EUR 546.30 million from the 2014 budget[28]
- EUR 560.10 million from the 2015 budget[29]

[*Link to the relevant option on "margin of manoeuvre*"]

	2014 EUR million	*2015* *EUR million*	
PHC 1 - 2014	54.00		Two stage
PHC 2 - 2015		*36.00*	Two stage
PHC 3 - 2015		*30.00*	Two stage
PHC 4 - 2015		*18.00*	Two stage
PHC 5 - 2014	24.00		Two stage
PHC 6 - 2014	15.00		Two stage
PHC 7 - 2014	15.00 (with an additional 5.00 million from SC2)		Single stage + hearing
PHC 8 - 2014	22.00		Single stage + hearing
PHC 9 – 2015		*22.00*	Two stage
PHC 10 - 2014	48.00		Two stage
PHC 11 - 2015		*48.00*	Two stage
PHC 13 - 2014	60.00		Two stage
PHC 14 - 2015		*60.00*	Two stage
PHC 16 – 2015		*36.00*	Two stage
PHC 15 – 2014/15	36.00	*36.00*	2014 – one stage, one deadline 2015 – one stage, two deadlines

[28] Subject to the adoption of the draft budget 2014 by the Budgetary Authority without modifications of the appropriations foreseen on the corresponding budget line (08.020301 and 09.040301) or the availability of appropriations in 2014 under the rules of provisional twelfths referred to in Article 315 of TFEU.

[29] These amounts will be included in the financial decision for 2015. At this stage it also includes EUR 3 million for prizes though their modalities are still worked on and they might be separated from the call.

	2014 EUR million	*2015* *EUR million*	
PHC 17 – 2014	48.00		Two stage
PHC 18 – 2015		*26.00*	Two stage
PHC 19 – 2014	24.60		Single stage
PHC 20 – 2014	10.00 (70%)		Single stage
PHC 21 – 2015		*21.00*	Single stage
PHC 22 – 2015		*18.00*	Two stage
PHC 23 – 2014	30.00		Two stage
PHC 24 - 2015		*30.00*	Two stage
PHC 25 - 2015		*21.00*	Single stage
PHC 26 - 2014	59.60		Single stage
PHC 35 - 2014	4.00		Single stage
PHC 27 - 2015		*15.00 (PCP)*	Single stage
PHC 28 - 2015		*20.00*	Single stage
PHC 31 - 2015		*20.00*	Single stage
PHC 29 - 2015		*10.00 (PPI)*	Single stage
PHC 32 - 2014	6.00		Single stage
PHC 33 – 2014	24.00		Two stage
PHC 34 – 2015		*30.00*	Two stage
PHC 12 – 2014 and 2015	66.10	*45.10*	SME instrument[30]
PHC 30 – 2015		*2.00*	Inducement prize

[30] Assuming the ability to run phases 1 and 2 in both years.

	2014 EUR million	*2015* *EUR million*	
PHC 36 – 2015 Inducement prize		*1.00*	Inducement prize
TOTALS	546.30	*545.10*	

Eligibility conditions[31],[32]:

PHC 1 - 2014 PHC 5 - 2014 PHC 6 - 2014 PHC 7 - 2014 PHC 8 - 2014 PHC 10 – 2014 PHC 13 - 2014 PHC 15 - 2014 PHC 17 - 2014 PHC 19 - 2014 PHC 23 - 2014 PHC 26 - 2014 PHC 32 - 2014 PHC 33 - 2014	The standard eligibility conditions for research and innovation actions apply. Please read carefully the provisions *[Link to the annex on standard eligibility conditions]* under Annex X before the preparation of your application.
PHC 20 - 2014	The standard eligibility conditions for innovation actions apply. Please read carefully the provisions *[Link to the annex on standard eligibility conditions]* under Annex X before the preparation of your application.
PHC 35 - 2014	The standard eligibility conditions for Coordination and Support actions (CSA) apply. Please read carefully the provisions *[Link to the annex on standard eligibility conditions]* under Annex X before the preparation of your application.
PHC12 [SME instrument]	The standard eligibility conditions for the **SME instrument** apply to this topic. *[Link to the annex of the standard eligibility conditions for SME instrument]*
	Please read carefully the provisions under Annex X *[Link to the annex on standard eligibility conditions]* before the preparation of your application.

Evaluation criteria:

[31] *In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects supported under all topics in calls under the Societal Challenge 'Health, demographic change and well-being'.*

[32] *Beneficiaries will be allowed to charge the cost of clinical trials on the basis of unit costs if the Commission adopts an ad hoc decision determining the method to be used.*

PHC 1 - 2014 PHC 5 - 2014 PHC 6 - 2014 PHC 7 - 2014 PHC 8 - 2014 PHC 10 – 2014 PHC 13 - 2014 PHC 15 - 2014 PHC 17 - 2014 PHC 19 - 2014 PHC 23 - 2014 PHC 26 - 2014 PHC 32 - 2014 PHC 33 - 2014	The standard evaluation criteria for research and innovation actions apply. Please read carefully the provisions [*Link to the annex on standard evaluation criteria*] under Annex X before the preparation of your application.
PHC 20 - 2014	The standard evaluation criteria for innovation actions apply. Please read carefully the provisions [*Link to the annex on standard evaluation criteria*] under Annex X before the preparation of your application.
PHC 35 - 2014	The standard evaluation criteria for Coordination and Support actions (CSA) apply. Please read carefully the provisions [*Link to the annex on standard evaluation criteria*] under Annex X before the preparation of your application.
PHC 12 [SME instrument]	The specific award criteria for the **SME instrument** apply to this topic. *[Link to the annex of the specific award criteria for SME instrument]* Please read carefully the provisions under Annex X [*Link to the annex on standard evaluation criteria]* before the preparation of your application.

Evaluation procedure: [*Link to the annex on standard evaluation procedure*]

- Proposal page limits and layout:

PHC 1 - 2014 PHC 5 - 2014 PHC 6 - 2014 PHC 7 - 2014 PHC 8 - 2014 PHC 10 – 2014 PHC 13 - 2014 PHC 15 - 2014 PHC 17 – 2014 PHC 19 - 2014 PHC 20 - 2014 PHC 23 - 2014	NN pages (noting difference between single and two stage)

PHC 26 - 2014 PHC 32 - 2014 PHC 33 - 2014 PHC 35 - 2014	
PHC 12 - 2014 [SME instrument]	Phase 1 :max. 10 pages Phase 2: max. 30 pages

- Indicative timetable for evaluation and grant agreement[33]:

	Information on the outcome of the evaluation (*single stage*)	Information on the outcome of the evaluation (*second stage)*	Indicative date for the signing of grant agreements	
PHC 1 - 2014 PHC 5 - 2014 PHC 6 – 2014 PHC 10 – 2014 PHC 13 - 2014 PHC 17 - 2014 PHC 23 - 2014 PHC 32 - 2014 PHC 33 – 2014	Maximum 5 months from the final date for submission.	For the evaluation of topic PHC7 - 2014, the Commission will organise hearings at stage 2 with applicants as part of the panel deliberations for all proposals above threshold. Maximum 5 months for the final date submission to the second stage	Maximum 3 months from the date of applicants having been informed of their success in evaluation.	
PHC 7 - 2014 PHC 8 - 2014 PHC 15 – 2014 PHC 19 - 2014	For the evaluation of topic PHC8 – 2014, the	N/A	Maximum 3 months from the date of applicants	

[33] Should the call publication postponed, the dates in this table should be adjusted accordingly.

	Information on the outcome of the evaluation (*single stage*)	Information on the outcome of the evaluation (*second stage)*	Indicative date for the signing of grant agreements	
PHC 20 - 2014 PHC 26 - 2014 PHC 35 - 2014	Commission will organise hearings at stage 1 with applicants as part of the panel deliberations for all proposals above threshold. Maximum 5 months from the final date for submission.		having been informed of their success in evaluation.	
PHC12 [SME instrument]	Applicants will be informed of the outcome of the evaluation two months after the corresponding deadlines set out above for phase 1 and three months after the corresponding deadlines set out above for phase 2.		Grant agreements are planned to be signed within 3 months after the corresponding deadlines set out above for phase 1 and within 6 months after the corresponding deadlines set out above for phase 2.	

Consortia agreements: Consortia agreements are mandatory[34] for all multi-beneficiary actions.

[34] When not mandatory, a justification will be provided in this section

Call co-ordination activities

H2020-HCO-2014/2015

HCO 1 – 2014: Innovation Partnership: Support for the European Innovation Partnership on Active and Healthy Ageing

Specific Challenge: The strategic implementation plan (SIP) of the European innovation partnership on active and healthy ageing (EIP-AHA) has identified a number of priority action areas. In a subset of these, stakeholder action groups have developed action plans for implementing innovative services for the ageing population. Another subset of priority action areas addresses domains whose readiness towards implementation is maturing and may soon give rise to additional action plans.

The Strategic Implementation Plan has invited, among others, the European Commission to establish favourable framework conditions to implement the actions outlined in the Plan. The European Commission, in its Communication "Taking forward the Strategic Implementation Plan of the European Innovation Partnership on Active and Healthy Ageing", committed to take account of relevant priorities of the Plan, together with input from other stakeholders, for future research and innovation work programmes and instruments.

Support is therefore required in facilitating: the execution of action plans, the establishment of favourable framework conditions for the deployment of the intended innovative services, and the future development of further action plans and priority areas.

Scope: The aim is to provide coordinated support to the activities of the European Innovation Partnership on Active and Healthy Ageing concerning the following aspects:

Support the existing action groups in implementing their action plans. The support may relate for example to coordination of action group activities, communication among partners and dissemination of results;

Support the development of new action plans coming from more priority action areas identified in the strategic implementation plan of the EIP-AHA, and subsequently, support the newly formed action groups in the same way as described above;

In collaboration with relevant stakeholders, including those from civil society, identify any new areas that can be regarded as future priority action areas, and develop a roadmap of research priorities, which are needed in the context of the existing and future priority action areas;

Work together with the European Commission, with relevant legislative and standardisation initiatives and with national, regional and local authorities in developing recommendations for more favourable regulatory and standardisation conditions, innovative procurement and incentive mechanisms.

The Commission considers that proposals requesting a contribution from the EU within the range of EUR 1 to 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

Each proposal will present quantitative or qualitative indicators to quantify the potential impact along the points listed below.

• Enhanced communication among EIP-AHA stakeholders, enhanced coordination of activities in the Action Groups of EIP-AHA and enhanced communication of their results.

• Identification of priority areas for research and innovation actions in the domain of Active and Healthy Ageing.

• Accelerated progress in the establishment of favourable framework conditions to implement the actions outlined in the Action Plans of the EIP-AHA.

Type of action: Coordination and support actions

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO 2 – 2014: Joint Programming: Coordination Action for the Joint Programming Initiative (JPI) "More Years, Better Lives - the Challenges and Opportunities of Demographic Change"

Specific challenge: Following the implementation of the actions foreseen by the Commission's Communication on Joint Programming to tackle Europe's major societal challenges, the Competitiveness Council has welcomed the progress made by EU Member States in Joint Programming Initiatives (JPIs) launched so far. Several Council Conclusions on Joint Programming[35] invite the Commission to support JPIs via Coordination and Support Actions.

The JPI "More Years, Better Lives - the Challenges and Opportunities of Demographic Change" enhances coordination and collaboration between national research programmes related to demographic change. It enables Member States to pursue common visions and a strategic research agenda on demographic change.

In this specific challenge, coordination and support is sought for the implementation of the joint programming pursued by national governments.

[35] Council Conclusions of 12 October 2010, of 26 November 2010 and of 8 December 2011

Scope:

The action will ensure the coordination of exchange on national programmes on demographic change as well as facilitate the effective governance of the JPI. It will also monitor national research activities in the area and provide support for the implementation of the Strategic Research Agenda of the JPI MYBL[36] in particular through;

- Coordination and organisation of potential joint calls;
- Alignment of national research programmes and activities to the JPI's Strategic Research Agenda;
- Integration and enhanced accessibility of national data related to active and healthy ageing, demographics, and statistics, to support evidence-based policy making and effective cross-policy actions; common usage of databases and infrastructures where appropriate;
- Investigate novel forms of implementation of SRA.

The action will provide for dissemination and awareness actions, liaison with relevant EU level initiatives, collaboration with international initiatives and third countries as well as supporting the development and dissemination of policy guidelines based on the JPI's outcomes.

The Commission considers that proposals requesting a contribution from the EU within the range of EUR 1 to 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Effective governance and support to the implementation of the JPI MYBL
- A stronger international dimension of the JPI
- Better coordination of research programmes in demographic change and dissemination of policy guidelines based on the JPI's outcome
- Alignment of national research programmes and activities with the JPI's Strategic Research Agenda and coordination with Horizon 2020 objectives
- Avoiding unnecessary duplication of research and infrastructure investment at national level
- Fostering a transnational, multi-disciplinary approach to demographic change and using of the potential of societal change in Europe

[36] Methods of collaboration shall follow the "Voluntary guidelines on framework conditions" adopted by the High Level Group on Joint Programming (GPC) on 11 November 2012.

- Facilitating implementation measures based on the Strategic Research Agenda of the JPI

Type of action: Coordination and support actions

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO 3 – 2015: Support for the European Reference Networks: Efficient network modelling and validation

Specific Challenge: Article 12 of Directive 2011/24/EU establishes the legal framework for creating a system of European Reference Networks in the EU. Centres of Expertise will be able to collaborate, coordinate and share their knowledge across borders. This collaboration is essential to ensure efficiency of health systems and access to high quality health care, especially for patients who suffer from conditions that require a particular concentration of resources or expertise, such as rare diseases, highly expensive treatments or where the number of professionals in a certain field is low.

Although many efforts and resources have been devoted to support research projects in the area of healthcare there is a clear lack of evidence with regard to efficient and validated models of organisation of complex networks as is the case of ERNs. Increasing complexity of the healthcare system and the interactions among the different players along with the introduction of new technologies highlights the need for more research to allow new healthcare system models to address effectively all potential system needs, states and variables.

There is a need to promote and support the development of a demonstration and validation project on this innovative model of cooperation and work between highly specialized healthcare providers, which will foster transfer of knowledge to clinical and organisational practice (e.g. e-health, healthcare related information systems, and clinical trials).

Support is therefore required in facilitating:

- Favourable framework conditions for the establishment and functioning of the European Reference Centres for the deployment of the intended innovative networking activities and services for patients and healthcare professionals across the EU;

- The design and validation of a model of network organisation that will be based in system modelling research methodologies and will imply building technical

foundations and knowledge and integrating these with the organizational, technical, and cultural aspects of a European Reference Network System and the identification of best practices and their effective implantation in several areas related with the mandate of the Directive.

Scope: The aim is to provide coordinated support to the activities of the European Reference Networks under the framework of Directive concerning the following aspects:

- Validation of a model for the optimal organisation, governance, maintenance and continuous monitoring and evaluation of the European Reference Networks and its centres. Such methodology would then be integrated into the legal framework;

- Support the existing European Reference Networks in implementing their goals. The support may relate for example to coordination of ERN collaborative activities, communication among partners and other healthcare providers and centres and dissemination of results;

- Support the development of new Networks based on already identified needs by the Commission, health authorities and experts;

- In collaboration with relevant stakeholders, identify any new conditions and diseases that can be regarded as future Priority Networks and develop a roadmap of Networks priorities, which are needed in the context of the Directive of Cross border Healthcare;

- The identification and implementation of validated specific networking tools and solutions in the following areas (Improving the research capacity; current models on the use and impact of guidelines & protocols, integrated and standardised IT platform including telemedicine and other communication resources, validation of training models in highly specialised care (simulation).

The Commission considers that proposals requesting a contribution from the EU in the range of EUR 0.5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: Implementation of a validated system methodology for the optimal organisation, governance, maintenance and continuous monitoring and evaluation of the European Reference Networks and their centres.

Such methodology would then be integrated into the legal framework and monitored by The Commission.

European Reference Networks will be established and supported in order to reach the goals as provided in Directive 2011/24/EU

The organisational and resource requirements of the piloted models (data, personnel and financing) will be tracked, creating evidence on benefits and ensuring equity and cost efficiency.

Each proposal will present quantitative or qualitative indicators to quantify the potential impact along the points listed below.

- Effectiveness of the model and tools validated in the Network in terms of efficiency, performance and outcomes of the Networks and Centres. An independent and external evaluation methodology will be used
- Satisfaction of patients and healthcare providers
- Number and type of effective tools and methods developed.
- Deliverables for each of the specific domain of the project.

Type of action: Coordination and support action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO 4 – 2014: Support for international infectious disease preparedness research

Specific Challenge: Human health worldwide is increasingly threatened by potential epidemics caused by existing, new and emerging infectious diseases (including from antimicrobial resistant pathogens). An infectious epidemic can strike anywhere, and at any time globally. In order to save lives, the research response needs to be quick, flexible, comprehensive and global and therefore is beyond the capacity of any single country or even the European Union (EU). Besides being a major threat to human health, such epidemics are a severe burden on the global economy with an impact on competitiveness, growth and jobs. In response to these challenges a global, multi-funder initiative has been launched. Support is therefore required in building, maintaining and coordinating a global consortium of funding organisations working towards the goal of preparing for a rapid joint global research response to any new outbreak.

Scope: The support action should provide organisational support to the implementation of the global research collaboration for infectious diseases preparedness consortium (GloPID-R), in close collaboration with the European Commission, research funding agencies from Member States and from third countries involved.

The support action should assist the GloPID-R executive committee, notably for the organisation of and reporting on meetings (e.g. *ad hoc* meetings of working groups), support information exchange among all members of the participating bodies, facilitate coordination

among relevant research projects and initiatives as well as communicate progress of relevant research funded under Horizon 2020 and by consortium members. This action should also include support activities with relevant stakeholders groups and with the public at large (e.g. development of website, communication materials, etc.)

The Commission considers that proposals requesting a contribution from the EU between the range of EUR 2 to 3 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

In line with the Union's strategy for international cooperation[37] in research and innovation, the project will contribute to implementing the Global Research Collaboration for Infectious Disease Preparedness.

Reinforced international cooperation in funding of research in new and emerging infectious diseases aiming to ensure a rapid and effective research response in case of an outbreak.

Effective operations of the global research collaboration for infectious disease preparedness consortium (GloPID-R) for 5 years.

Better mutual information and complementarity of funding/research initiatives worldwide in the area of emerging infectious diseases.

Decreased legal, regulatory, and financial barriers to the rapid mounting of a joint global research response

Type of action: Coordination and support action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO 5 – 2014: Global Alliance for Chronic Diseases: prevention and treatment of type 2 diabetes

Specific challenge: In the past twenty years the global death rate from diabetes has doubled and the World Health Organisation (WHO) is predicting that this will increase by two thirds by 2030. It is currently estimated that 347 million people worldwide suffer from diabetes with more than 80% from low-and middle-income countries. Of those suffering from diabetes, type 2 comprises 90% of this population around the world. Halting the rise in prevalence of diabetes has been identified as one of the 9 WHO non communicable diseases global voluntary targets to be met by Member States by 2025

[37] COM(2012)497

With the burden of this chronic non-communicable disease ever-increasing the Global Alliance for Chronic Diseases (GACD) partnership has agreed to launch a call for proposals on the prevention and treatment of type 2 diabetes, with a focus on implementation and intervention research in low- and middle-income countries and in vulnerable populations in high income countries.

Scope: This call for proposals is focused on type 2 diabetes. The aim of this call is to fund projects that will generate new knowledge on interventions and their implementation for the prevention and treatment of type 2 diabetes in low and middle income countries, and in vulnerable populations in high income countries. The emphasis of this initiative is on existing approaches to prevention and control of type 2 diabetes rather than development of new treatments. Proposals can address prevention or treatment of specific complications of type 2 diabetes.

Research proposals can focus on a wide range of prevention and/or treatment strategies. This might include programmes addressing (one of or combinations of):

- Changes to lifestyle and behaviour resulting from the provision of an environment that supports and promotes better health. This might include community-wide approaches, or other strategies targeting individuals at high risk. For example, population prevention strategies designed to address unhealthy diets and physical inactivity as risk factors for diabetes;

- Structural interventions or policies designed to promote improved health outcomes. For example, evaluating the contribution of public policies to diabetes prevention efforts, or monitoring the potential effects of such policies if adopted and implemented;

- Delivery of relevant health care and health interventions;

- Approaches to implementing accessibility of or adherence to, pharmaceutical, nutritional or other promising or proven interventions.

Proposals should focus on implementation research, to examine what works, for whom and under what contextual circumstances, and how interventions can be adapted and scaled up in ways that are accessible and equitable. Proposals can address prevention or treatment of specific complications of type 2 diabetes. Projects addressing gestational diabetes are within the scope of this call. Projects can focus on specific societal groups but a clear justification should be provided as to why the group has been chosen and how the choice will assist the funders in delivering their aim to address health inequities at a local and/or global level. Proposal should focus on implementation research into interventions for prevention and treatment of type 2 diabetes that are applicable in low resource settings. However, in some settings, the project may need to incorporate work to establish baseline data on prevalence of diabetes and its risk factors to evaluate the impact of the intervention. Research into these aspects can be incorporated into the proposed work if it does not duplicate existing evidence available.

All proposals must:

- Focus on research into implementation of prevention and/or treatment strategies derived from existing knowledge and research.
- Develop an improved understanding of the key barriers and facilitators at local and national levels that affect the prevention and treatment of type 2 diabetes.
- Include an assessment of equity and gender gaps in diabetes prevention and treatment.
- Demonstrate a sound understanding of the local health system context.
- Provide evidence of a health economics dimension such as cost effectiveness of the proposed intervention and its scalability.
- Describe a clear proposed pathway to embedding the intervention into policy and practice after the study which addresses how:
    - Local and/or national policy makers will be engaged both at the start of the project as well as the end.
    - The project outcomes/evidence will be utilised for the scaling up of the intervention on a local, national and international level.
    - Future scaled-up implementations will fit within the local social, cultural and economic context.
    - Identify obstacles such as inequities and equity gaps including gender that will be taken into account in the design of an implementation strategy.
- Be proposed by a multidisciplinary project team, including local researchers as co-investigators where applicable.
- Include local stakeholders such as patient groups or community groups.
- The following types of proposals DO NOT fall within the scope of this call:
    - Replication of effectiveness studies and clinical trials testing the efficacy or effectiveness of new or established pharmacological agents (or combination of agents) which have wider effects than those relating to type 2 diabetes.
    - Aetiological or mechanistic studies of type 2 diabetes.
    - Phase I or Phase IIa trials.

The Commission considers that proposals requesting a contribution from the EU between the range of EUR 1 to 3 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Reducing health inequalities and inequities, including gender, in the prevention and treatment of type 2 diabetes in both a local and global context.
- Pursuing knowledge translation and exchange approaches that are designed to maximize the public health benefits of research findings within different health contexts.
- Providing evidence to inform local health service providers, policy and decision makers on the effective scaling up of the interventions at the local, national and regional levels. For example, applicants could address affordability for users and the financial implications for implementing organisations and funders or might assess scalability to various socio-political contexts.
- Contribute to the Global Alliance for Chronic Diseases.
- Appropriate leveraging of existing programmes and platforms (e.g. research, data, and delivery platforms).
- Contribute to the WHO Global Action Plan on NCDs (2013-2020) as projects will demonstrate alignment with international and/or national commitments to halt the rise in prevalence of type 2 diabetes.
- Contribute to the United Nations Millennium Development Goals.

The GACD aims to develop a network of researchers that can enhance cumulative learning across individual projects, and work towards understanding how socio-economic, cultural, geopolitical and policy contexts have influenced results and how findings might be adapted and applied in different settings. The funded researchers will meet annually to discuss their research and share information and data in order to develop approaches to standardise data collection, and wherever feasible to use these standardised approaches in their respective projects

Type of action: Research and innovation action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO 6 – 2015: Global Alliance for Chronic Diseases: subject to be confirmed

Specific challenge: The timetable for the process by which the GACD defines annual priorities for calls does not permit the insertion of 2015 topic details at this time. These will be provided when this work programme is updated in Q4 2014. Proposals should nevertheless be of a similar type (research and innovation) and size (EUR 2-3 million) to those called for in

HCO 5. Further details will be provided at the same time as the inclusion of details of the 2015 financing decision in this work programme.

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO7 – 2014: ERA-NET: Joint Programming - Establishing synergies between the Joint Programming on Neurodegenerative Diseases Research and Horizon 2020

Specific challenge: The EU Joint Programming Initiative on Neurodegenerative Diseases Research, in particular Alzheimer's (JPND), was established in 2009 as the pilot of the Member State-led Joint Programming Initiatives and enables Member States to work together on this considerable challenge.

JPND addresses the challenge of age-related neurodegenerative diseases through research collaboration across the participating 27 countries. The objective is to establish, align and build on national research programmes to increase the effectiveness and impact of research efforts.

Implementation of the JPND Research Strategy is now at a critical moment as it needs now to be scaled-up and synergies must be established with Horizon 2020 as was also called for by the Council in its conclusions of 8 December 2011[38]. The scope of the Research Strategy requires coordinated action not only amongst the participating countries but also with the EC for producing the necessary critical mass. Moreover, for achieving the highest impact possible, there is the need for less fragmentation, better coordination and alignment amongst the countries participating in the JPND.

Scope: The proposal should coordinate national and regional programmes for research in the area of neurodegenerative diseases research by implementing a transnational call with EU co-funding with a view to scale-up the implementation of the JPND Research Strategy. This call should aim at furthering the understanding of the '*Identification of genetic, epigenetic and environmental risk and protective factors for neurodegenerative diseases*', and/or of the '*Longitudinal cohorts in neurodegenerative disease research*' and/or of the '*Advanced experimental models of neurodegenerative diseases*'.

Moreover, the proposal should also aim at promoting the strategic alignment of research activities related to neurodegenerative diseases across Europe, such as developing and aligning national research plans and strategies, making data bases more accessible and interoperable, harmonisation of measurements and methodologies, networking of already existing structures and studies, training etc.

The successful proposal should demonstrate the expected impact on national and transnational programmes as well as the leverage effect on European research and competitiveness, and should plan the development of key indicators for supporting this.

The proposal is encouraged to implement other joint activities including training and additional joint calls without EU co-funding.

The Commission considers that proposals requesting a contribution from the EU between the range of EUR 3 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Funding of research projects on a topic identified by the JPND implementation plan or by their action groups, which needs to be addressed at European level and which is complementary to topics of the EC work programmes;
- Leverage transnational excellent research with EU-added value in the area of neurodegenerative diseases;
- Increased commitment of participating countries to the implementation of the JPND SRA;
- Establishment and alignment of national and regional plans and initiatives on neurodegenerative diseases;
- Strengthened exchange and better interoperability between existing European infrastructures and data bases;
- Enhancement and/or better exploitation of national or EC-supported activities.

Type of action: ERA-NET Co-fund

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO8 – 2014: ERA-NET: Aligning national/regional translational cancer research programmes and activities

Specific challenge: The challenges in the area of translational cancer research can only be met by an effective cooperation at transnational level avoiding the duplication of efforts, ensuring the availability of critical mass, efficiently using available resources, exchanging knowledge, producing more significant results of higher quality and impact, and sharing data and infrastructures.

Significant progress has been made in this respect by existing initiatives. However there is still the need for better coordination, data sharing and alignment of national programmes and

activities in the above mentioned area. Finally, there is still a large difference of research intensity between countries, preventing some less research-intensive countries from participating in transnational activities.

Scope: The proposal should coordinate national and regional programmes for research in the area of translational cancer research by implementing a transnational call with EU co-funding.

Moreover, the proposal should also aim at the better collaboration and alignment of national programmes and activities and should provide concrete plans for decreasing fragmentation, for data sharing, for addressing hurdles for effective coordination, for involving stakeholders and relevant existing initiatives, and for encouraging the participation of less research-intensive countries. The proposal should consider and may build on previous EU-funded projects supporting ERA-NETs.

The successful proposal should demonstrate the expected impact on national and transnational programmes as well as the leverage effect on European research and competitiveness, and should plan the development of key indicators for supporting this.

The proposal is encouraged to implement other joint activities including training and additional joint calls without EU co-funding.

The Commission considers that proposals requesting a contribution from the EU between the range of EUR 3 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Stepping up funding of transnational collaborative research projects in the area of translational cancer research;
- Identification of common research priorities and research needs, also taking into account developments on the international level where relevant;
- Establishment and/or implementation of a common strategic research agenda;
- Development and alignment of national and regional plans;
- Streamlined national or regional practices in organising research funding;
- Increased interoperability of national research programmes;
- Prioritisation of transnational research;
- Sharing of data and knowledge;
- Networking of infrastructures and databases;

- Increased collaboration between less research-intensive and more research-intensive countries; leverage excellent research in previously less research-intensive countries;
- Contribution to the establishment of the ERA by addressing issues related for example to administrative hurdles, IPR management and different practices regarding resource sharing.

Type of action: ERA-NET Co-fund

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO9 – 2014: ERA-NET: Collaboration and alignment of national programmes and activities in the area of brain-related diseases and disorders of the nervous system

Specific challenge: The challenges in the areas of brain-related diseases can only be met by an effective cooperation at transnational level avoiding the duplication of efforts, ensuring the availability of critical mass, efficiently using available resources, exchanging knowledge, producing more significant results of higher quality and impact, and sharing data and infrastructures.

Significant progress has been made in this respect by existing initiatives. However there is still the need for better coordination, data sharing and alignment of national programmes and activities in the above mentioned areas. Finally, there is still a large difference of research intensity between countries, preventing some less research-intensive countries from participating in transnational activities.

Scope: Proposals will coordinate national and regional programmes for research in the area of brain-related diseases by implementing a transnational call with EU co-funding.

Moreover, proposals will also aim at improved collaboration and alignment of national programmes and activities and will provide concrete plans for decreasing fragmentation, for data sharing, for promoting common data elements for the establishment of patient registries, for addressing hurdles for effective coordination, for involving stakeholders and relevant existing initiatives, and for encouraging the participation of less research-intensive countries. The proposal should consider and may build on previous EU-funded projects supporting ERA-NETs.

The successful proposal should demonstrate the expected impact on national and transnational programmes as well as the leverage effect on European research and competitiveness, and should plan the development of key indicators for supporting this.

The proposal is encouraged to implement other joint activities including training and additional joint calls without EU co-funding.

The Commission considers that proposals requesting a contribution from the EU between the range of 3 and 5 million euro would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Stepping up funding of transnational collaborative research projects in the areas of brain-related diseases;
- Identification of common research priorities and research needs, also taking into account developments on the international level where relevant;
- Establishment and/or implementation of a common strategic research agenda;
- Development and alignment of national and regional plans;
- Streamlined national or regional practices in organising research funding;
- Increased interoperability of national research programmes;
- Prioritisation of transnational research;
- Sharing of data and knowledge;
- Networking of infrastructures and databases;
- Increased collaboration between less research-intensive and more research-intensive countries; leverage excellent research in previously less research-intensive countries;
- Contribution to the establishment of the ERA by addressing issues related for example to administrative hurdles, IPR management and different practices regarding resource sharing.

Type of action: ERA-NET Co-fund

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO10 – 2014: ERA-NET: Systems medicine to address clinical needs

Specific challenge: The rise of genomics and the accumulation of large amounts of data potentially provide medicine with many new opportunities. With this abundance of different types of data has come the realisation that a full understanding of human development and disease processes requires research that integrates and interprets data at system level.

Through the FP7 co-ordination action CaSyM, health research funders, clinicians, researchers, medical educators and industry, have agreed a road map that prioritises areas where a systems approach is needed to address clinical questions and solve clinical problems. EU policy makers also recognise the need for systems medicine in the drive to make personalised medicine a reality (Commission draft report on use of –omics technologies in the development of personalised medicine).

Scope: The proposal should aim to coordinate national and regional programmes for research in the area of systems medicine. It should implement a transnational call with EU co-funding with a view to support multinational innovative research initiatives on the research priorities identified in the CaSyM action.

The successful proposal should demonstrate the expected impact on national and transnational programmes as well as the leverage effect on European research and competitiveness, and should plan the development of key indicators for supporting this.

The consortium is encouraged to implement other joint activities including training and additional joint calls without EU co-funding.

The Commission considers that proposals requesting a contribution from the EU between the range of EUR 3 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: This ERA-NET will:

- improve cooperation and synergies between national and regional efforts, including mutual opening of national programmes,
- suggest new paths for clinical research aiming at delivering better prevention and more efficient and personalised therapies throughout life
- support the European Policy for the development of personalised medicine
- improve knowledge of health and disease focussed on helping clinical decision making
- make best use of national and EU funding in relevant areas of research and ensure better use of limited resources
- develop training activities and European curriculum for systems medicine

Type of action: ERA-NET Co-fund

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO 11 – 2014: ERA NET: Rare Disease research implementing IRDiRC objectives

Specific challenge**:** Maximising scarce resources and coordinating research efforts are key elements for success in the area of rare diseases, characterised by scattered knowledge and relatively small patient populations. Transnational cooperation and coordination to pool resources and avoid duplication of efforts while developing common standards and research priorities is therefore essential. The International Rare Diseases Research Consortium (IRDiRC) was launched in 2011 to strengthen international collaboration in the area with the aim of delivering 200 new therapies for rare diseases and means to diagnose most of them by the year 2020[39]. An ERA-NET focused on funding research according to IRDiRC objectives and priorities should be an implementation tool for the realisation of the IRDiRC 2020 goals.

Scope: The proposal should coordinate national and regional programmes for research on rare diseases by preparing and implementing a transnational call with EU co-funding research with a view to implement IRDiRC[40] objectives and identified priorities. This call should aim at furthering the understanding of disease mechanisms and natural history of rare diseases with the objective to develop new diagnostic tools and treatments. Selected projects should adhere to the policies and guidelines of IRDiRC.

Moreover, the proposal should be complementary to other funding programmes and activities on European and international level.

The successful proposal should demonstrate the expected impact on national and transnational programmes and IRDiRC objectives as well as the leverage effect on European research and competitiveness, and should plan the development of key indicators for supporting this.

The proposal should also aim at implementing other joint activities including training and additional joint calls without EU co-funding.

The Commission considers that proposals requesting a contribution from the EU between the range of EUR 3 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- In line with the Union's strategy for international cooperation in research and innovation[41], the project will contribute to reaching the overall goals of IRDiRC;

[39] www.irdirc.org
[40] The IRDiRC policies and guidelines document is available on: http://www.irdirc.org/?page_id=12
[41] COM(2012)497

- Deepened and extended coordination of national and transnational research in the field of rare diseases resulting in a substantial contribution to the overall goals of IRDiRC;
- Streamlined national/regional and international practices in organising research funding;
- Increased interoperability of national research programmes;
- Increased sharing of data and knowledge;
- Increased networking of infrastructures and databases.

Type of action: ERA-NET Co-fund

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO12 – 2015: ERA-NET: Generating programmes and activities on antibiotic resistance by the Joint Programming on Antimicrobial Resistance

Specific challenge: Antibiotic resistance is a global problem. It is considered by the World Health Organization as one of the three greatest threats to human health for the next decades. In Europe, however, research on the resistance to antibiotics and on how to make sustainable use of antibiotics is fragmented. In addition, few countries have specific programs dedicated to this field of research.

The Joint Programming Initiative (JPI) on Anti-Microbial Resistance (AMR) provides an excellent opportunity for joint research of the EU Member States addressing the emerging problem of antibiotic resistance in human and veterinary medicine. Indeed, the currently funded research projects in national or trans-national programs are usually the result of calls initiated within other research areas rather than from research programmes specifically focusing on AMR. Consequently, the variable and non-permanent resources of trans-national organisations and individual countries are insufficient to provide the long-term funding opportunities that are required to solve the major research questions concerning AMR. In addition, research activities on AMR are not harmonised between countries; which may lead to duplications in the research being performed in different countries.

The 18 participating countries of this JPI aim to accomplish the coordination of European research on AMR in close collaboration with the funding instruments of the EU; specifically Horizon 2020, Innovative Medicines Initiative (IMI) and the ERA-NET Infect-ERA.

This will create the necessary critical mass and develop the most advanced scientific approaches to tackle the problem of AMR, reverting its increasing trend, in the way forward defined by the Strategic Research Agenda which is to be adopted by the JPIAMR in December 2013.

This transnational cooperation will enhance the societal impact that is required in this area, promoting knowledge dissemination among multiple sectors of the society that are implicated – patients, clinical, veterinarians, pharmacists, food producers and representatives of the pharmaceutical industry.

Scope: The proposal will be instrumental for efficient joint research funding in the area of AMR. The ERA-NET will be a necessary instrument for the implementation of the Strategic Research Agenda by implementing transnational calls on scientific proposals about antibiotic resistance, particularly among bacteria that can cause life-threatening infection during hospitalization.
This call should aim at furthering the understanding of molecular mechanisms and strategies of microbes to adapt to antibiotics and immune system and using of vaccination approaches.

The final aim of the research funded will have to lead to sustainable use of antibiotics to treat infectious diseases and to a decrease in the number of patients with resistant infections in Europe. To do so, the project will create a collaborative European research area where the best resources and capabilities are coordinated.

The one of the strategies against AMR is to improve the use of currently available antibiotics by minimizing the overuse and misuse of antibiotics in clinical medicine as well as in veterinary and food production settings. Another important strategy is to prevent spreading of resistant organisms. In parallel, new types of antibiotics need to be developed using different approaches and introduced to the market. It has, however, proven difficult to find new leads for these antibiotics and investments in antibiotic development appear yet to be economically unattractive from an industrial perspective. Therefore, alternatives to antibiotics, of which the development of vaccines for human and veterinary use may be another approach, need to be developed. In addition, we need to stem the emergence and spread of AMR. This will entail a mix of policy measures in human and veterinary medicine and innovations.

The proposal is encouraged to implement other joint activities including collaborative actions with the World Health Organisation or the pharmaceutical industry (among others) as well as additional joint international calls without EU co-funding (e.g. with Canada).

The Commission considers that proposals requesting a contribution from the EU between the range of EUR 3 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Leverage transnational research by funding research proposals on a topic identified by the JPIAMR from its Strategic Research Agenda and implementation plan.

- Stimulate and increase research into the causes, prevention, diagnosis and treatment of infections caused by resistant organisms and force the EU added value in the area of antibiotics.
- Enhancement and/or better exploitation of current research funding activities at national, European and international level.
- Catalysing and strengthening the development of national and trans-national strategies in JPI AMR countries.
- Establishment and alignment of existing national strategies.
- Increased visibility, also at a political level, of the burden of AMR and the benefits of research to economy and society.

Type of action: ERA-NET Co-fund

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO13 – 2015: ERA-NET: Cardiovascular disease or HIV/AIDS

Specific challenge: The specific challenge to be addressed will focus either on cardiovascular disease or HIV / AIDS and depends on the input of the SC1 shadow programme committee. A decision will be taken during the next meeting of this group, taking place on the 11th October 2013.

Scope: As above

The Commission considers that projects requesting a contribution from the EU between the range of EUR 3 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: As above

Type of action: ERA-NET Co-fund

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO14 – 2014: New approaches to bridge the divide in European health research and innovation

Specific challenge: The research and innovation potential of the Member States remain very different, with large gaps between “innovation leaders” and “modest innovators”. This divide is equally present in Europen health research and innovation.

Two major European instruments – the Research Framework Programme and the Structural Funds – attempt to address this issue and although from distinct perspective but with the same strategic goals of serving the Europe2020 strategy for smart, sustainable and inclusive growth.

There is no one-size-fits-all solution, therefore, health research specific new approaches are needed that take into account the individual differences of the less performing RDI regions and provide tailor-made recommendations.

Scope: To tackle successfully the divide in European health research, both evidence based analysis and remedial actions are needed.

On analysis, proposals may examine the current health research activities in the less performing RDI regions/countries, looking also into past national and European funding, private investments, preparing SWOT analyses. Strategies of these regions can be studied, and specific indicators can be identified to measure development. Consortia are also expected to create a networking platform where companies, research organisations, universities, national authorities and managers of H2020 and structural funds can talk to each other to identify the needs, obstacles, bad and good practices, opportunities.

For remedial actions proposals should come up with new approaches to unlock excellence in those regions.

Proposals are expected to build the on existing instruments (RIS3 - Research and Innovation Strategies for Smart Specialisation)

The Commission considers that projects requesting a contribution from the EU in the range of EUR 1 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: Within the health R&I domain, the action(s) would contribute to three important Horizon 2020 goals:

- Widening participation
- Bridging the innovation divide
- Synergies between H2020 and Structural Funds

Deep knowledge could be gained from the thorough analyses which would serve to evidence-based policy making.

The networking effect could help the less innovative countries and regions to join their efforts.

Type of action: Coordination and Support Action

The conditions for this topic are provided in the general conditions for this call. [*Link*]

HCO 15 – 2014: Mobilisation and mutual learning action plan in the area of societal challenge 1

Specific challenge: Ensuring that research and innovation in this societal challenge is not only excellent, but also relevant and responsive to the needs of all is important, not least in ensuring the uptake of results.

Scope: Mobilisation and Mutual Learning Action Plans (MML for short) are one means of ensuring the engagement of all relevant groups and aim to tackle research and innovation related challenges by creating partnerships with a variety of perspectives, knowledge and experience.

MMLs are Coordination and Support Actions (CSA) with at least 10 countries that allow discussion and cooperation between science and society at different stages of the research and innovation process. MMLs comprise at least one of each of the following types of partners: research performing or funding organisations, industry/businesses, policy makers, Civil Society Organisations. The consortium may include as well media, education establishments, science academies, museums, science centres, etc. Ensuring a balanced distribution of roles and responsibilities between the different types of participants will be evaluated under evaluation criterion 2.

The Commission considers that projects requesting a contribution from the EU in the range of EUR 1 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact: The MML will contribute to the implementation of 'Science with and for Society' issues (public engagement, ethics, gender perspectives, science education, communication and access to and dissemination of scientific information) in the area of health. It will develop a common communication and implementation strategy to further the implementation of the MML outcomes and recommendations. It will contribute to relevant EU related initiatives and policy developments at local, national and European levels.

Type of action: Coordination and support action

CONDITIONS FOR THIS CALL

Publication date[42]: December 11th 2013
Deadline[43]:

HCO 1 - 2014 HCO 2 - 2014 HCO 4 - 2014 HCO 5 - 2014 HCO 7 - 2014 HCO 8 - 2014 HCO 9 - 2014 HCO 10 - 2014 HCO 11 - 2014 HCO 14 – 2014 HCO 15 - 2014	XXX at 17.00.00 Brussels time

Indicative budget :

- EUR 43.00 million from the 2014 budget[44]
- EUR 22.50 million from the 2015 budget[45]

[*Link to the relevant option on "margin of manoeuvre*"]

	2014 EUR million	*2015* *EUR million*	
HCO 1 – 2014	2.00		Single stage
HCO 2 – 2014	2.00		Single stage
HCO 3 – 2015		*0.50*	Single stage
HCO 4 – 2014	3.00		Single stage
HCO 5 -2014	9.00		Single stage

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

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

[44] Subject to the adoption of the draft budget 2014 by the Budgetary Authority without modifications of the appropriations foreseen on the corresponding budget line (08.020301 and 09.040301) or the availability of appropriations in 2014 under the rules of provisional twelfths referred to in Article 315 of TFEU.

[45] These amounts will be included in the financial decision for 2015.

HCO 6 -2015		*12.00*	Single stage
HCO 7 - 2014	5.00		Single stage
HCO 8 - 2014	5.00		Single stage
HCO 9 - 2014	5.00		Single stage
HCO 10 - 2014	5.00		Single stage
HCO 11 – 2014	5.00		Single stage
HCO12 - 2015 *(see HCO13)*		*5.00*	Single stage
HCO13 – 2015 *Note that 3 ERA Net have been proposed by SC1 Programme Committee. Only 2 will be supported and will occupy spaces HCO12 and 13, and will focus on AMR, CVD or HIV (i.e. 2 from 3). TBC 11 October*		*5.00*	Single stage
HCO14 - 2014	1.00		Single stage
HCO 15 - 2014	1.00		Single stage
TOTALS	43.00	*22.50*	

Eligibility conditions[46]:

HCO 5 - 2014	The standard eligibility conditions for Research and innovation actions apply. Please read carefully the provisions [*Link to the annex on standard*

[46] *In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects supported under all topics in calls under the Societal Challenge 'Health, demographic change and well-being'.*

	eligibility conditions] under Annex X before the preparation of your application.
HCO 1 - 2014 HCO 2 - 2014 HCO 4 - 2014 HCO 14 - 2014 HCO 15 – 2014	The standard eligibility conditions for Coordination and Support actions (CSA) apply. Please read carefully the provisions *[Link to the annex on standard eligibility conditions]* under Annex X before the preparation of your application.
HCO 7 - 2014 HCO 8 - 2014 HCO9 - 2014 HCO10 - 2014 HCO11 - 2014	The standard eligibility conditions for ERANET Cofund apply. Please read carefully the provisions *[Link to the annex on standard eligibility conditions]* under Annex X before the preparation of your application.

Evaluation criteria:

HCO 1 - 2014 HCO 2 - 2014 HCO 4 - 2014	The standard evaluation criteria apply. Please read carefully the provisions *[Link to the annex on standard evaluation criteria]* under Annex X before the preparation of your application.
HCO 5 - 2014 HCO 7 - 2014 HCO 8 -2014 HCO 9 - 2014 HCO 10 - 2014 HCO 11 - 2014 HCO 14 - 2014 HCO 15 - 2014	The standard evaluation criteria for Coordination and Support actions (CSA) apply. Please read carefully the provisions *[Link to the annex on standard eligibility conditions]* under Annex X before the preparation of your application.
	The standard evaluation criteria for ERANET Cofund apply. Please read carefully the provisions *[Link to the annex on standard eligibility conditions]* under Annex X before the preparation of your application.

Evaluation procedure: *[Link to the annex on standard evaluation procedure]*
- Proposal page limits and layout:

HCO 1 - 2014 HCO 2 - 2014 HCO 4 - 2014 HCO 5 - 2014 HCO 7 – 2014 HCO 8 - 2014 HCO 9 - 2014 HCO 10 - 2014 HCO 11 - 2014 HCO 14 - 2014 HCO 15 - 2014	NN pages

- Indicative timetable for evaluation and grant agreement[47]:

	Information on the outcome of the evaluation (*single stage*)	Information on the outcome of the evaluation (*second stage)*	Indicative date for the signing of grant agreements	
HCO 1 - 2014 HCO 2 - 2014 HCO4 - 2014 HCO 5 - 2014 HCO 7 - 2014 HCO 8 – 2014 HCO 9 - 2014 HCO 10 - 2014 HCO 11 - 2014 HCO 14 - 2014 HCO 15 - 2014	*Maximum 5 months from the final date for submission*	*Maximum 5 months from the final date for submission to second stage*	*Maximum 3 months from the date of informing applicants*	

Consortia agreements: Consortia agreements[48] are mandatory for all multi-beneficiary actions

[47] Should the call publication postponed, the dates in this table should be adjusted accordingly.

[48] When not mandatory, a justification will be provided in this section

Fast track to Innovation pilot

Fast track to Innovation Topic

It is to be noted that the following information is provided at this stage only to facilitate the familiarisation with this topic. The Commision will provide in due course full details, together with the announcement of the relevant calls, on the Fast track to Innovation Topic.

The general aspects of this topic are as follows:

> Under this Fast Track to Innovation (FTI) pilot, proposals for innovation actions linked to any technology field will be invited, on the basis of a continuously open call (with its first cut-off date in 2015) and a bottom-up-driven logic.
>
> Any legal entity may participate and proposals may be submitted at any time. The Commission shall initiate three cut-off dates per year to evaluate proposals. Time between a cut-off date and signature of the grant agreement or notification of the grant decision shall not exceed six months. No more than 5 legal entities shall participate in an action. The amount of the grant shall not exceed EUR 3 million.
>
> Proposals shall be ranked according to the impact, quality and efficiency of implementation and excellence, with the criterion of impact given a higher weighting. Factors such as time sensitivity and the international competitive situation shall be taken into sufficient account when evaluating the impact of a proposal, to allow for flexibility according to the various specificities within different fields of applied research.

Other actions (not subject to calls for proposals)

HOA1 – 2014/2015: Subscription fee: Human Frontier Science Programme Organisation

Scope: An annual subscription to the international Human Frontier Science Programme Organisation (HFSPO)[49] will allow EU non-G8 Member States to fully benefit from the Human Frontier Science Programme (HFSP) and provide increased visibility for European research, as well as contributing to the implementation of the Union's strategy for international cooperation[50] in research and innovation.

Type of action: Subscription
Indicative budget: EUR 4 765 000 from the 2014 budget[51] and of EUR 4 861 000 from the 2015 budget[52]

HOA2 – 2014/2015: Tenders for programme evaluation, studies and impact assessment; and for conferences, events and outreach activities.

Scope: Calls for tender may be published to support the monitoring and evaluation of previous Framework Programme activities of relevance to this societal challenge, and of the societal challenge itself. These tenders may call for the monitoring and evaluation of entire programmes or of specific parts thereof. Likewise, calls for tender may be published to support studies and / or impact assessment exercises intended to define future challenge priorities.

Conferences and other events of relevance to this societal challenge will also be organised. These include but are not limited to the organisation of events addressing eHealth and events related to the European Innovation Partnership on Active and Healthy Ageing. Some of these events may in 2014 be organised by the Greek Presidency (as a 'named beneficiary') receiving a maximum of EUR 300,000, with the same amount being allocated under the same conditions for another Presidency event in 2015.

Other communications activities will also be supported through existing Framework Contracts or via the launch of new calls for tenders.

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

[50] COM(2012)497

[51] Subject to the adoption of the draft budget 2014 by the Budgetary Authority without modifications of the appropriations foreseen on the corresponding budget line (08.020301 and 09.040301) or the availability of appropriations in 2014 under the rules of provisional twelfths referred to in Article 315 of TFEU.

[52] These amounts will be included in the financial decision for 2015.

The precise nature of all these activities will be detailed in the corresponding terms of reference.

Type of action: Public procurement
Indicative budget: EUR 5.00 million from the 2014 budget[53]; EUR 2.80 million from the 2015 budget[54].

HOA3 – 2014/15: Independent experts assisting in proposal evaluations and project reviews

Independent experts are required for assisting in proposal evaluations, project reviews and evaluation (project level, not programme – see OA2) and monitoring of SC1.

Type of action: Expert contracts

Indicative budget: EUR 8.00 million from the 2014 budget[55]; EUR 8.00 million from the 2015 budget[56].

HOA4 – 2014: Global Alliance for Chronic Diseases

Scope: The European Commission will make a contribution towards activities of the Global Alliance for Chronic Diseases (GACD). This will enable the European Commission to take part in GACD, which brings together leading health research funding agencies of key countries (currently USA, Australia, UK, Canada, China, India, and South Africa) to coordinate research activities addressing on a global scale the prevention and treatment of chronic, non-communicable diseases such as cardiovascular diseases (mainly heart disease and stroke), diabetes, mental health and cancer. Recommendations of GACD are expected to have a fundamental value for future orientation of public health research policy. This will also contribute to the implementation of the Union's strategy for international cooperation[57] in research and innovation. Funding will be provided through an action grant to the secretariat of the GACD, hosted by University College London (UCL), Gower Street 1, WC1E 6BT, London, UK.

[53] Subject to the adoption of the draft budget 2014 by the Budgetary Authority without modifications of the appropriations foreseen on the corresponding budget line (08.020301 and 09.040301) or the availability of appropriations in 2014 under the rules of provisional twelfths referred to in Article 315 of TFEU.

[54] These amounts will be included in the financial decision for 2015.

[55] Subject to the adoption of the draft budget 2014 by the Budgetary Authority without modifications of the appropriations foreseen on the corresponding budget line (08.020301 and 09.040301) or the availability of appropriations in 2014 under the rules of provisional twelfths referred to in Article 315 of TFEU.

[56] These amounts will be included in the financial decision for 2015.

[57] COM(2012)497

Form of funding: Subscription

Indicative budget: EUR 180 000 from the 2014[58] budget

HOA5 – 2014: National Contact Points

Specific challenge: Facilitate trans-national co-operation between NCPs within this [Societal challenge/Part] with a view to identifying and sharing good practices and raising the general standard of support to programme applicants, taking into account the diversity of actors that make up the constituency of this societal challenge.

Scope: Support will be given to a network of formally nominated NCPs in the area of this societal challenge. The activities will be tailored according to the nature of the area, and the priorities of the NCPs concerned. Various mechanisms may be included, such as benchmarking, joint workshops, enhanced cross-border brokerage events, specific training linked to this societal challenge as well as to gender dimension of Research and Innovation, and twinning schemes. Special attention will be given to enhance the competence of NCPs, including helping less experienced NCPs rapidly acquire the know-how accumulated in other countries.

The focus throughout should be on issues specific to this societal challenge.

Proposals can only include NCPs from EU Member States, and Associated Countries, who have been officially appointed by the relevant national authorities.

The consortium should have a good representation of experienced and less experienced NCPs.

If certain NCPs wish to abstain from participating, this fact should be explicitly documented in the proposal. These NCPs are nevertheless invited and encouraged to participate in the project activities, and are eligible for reimbursement of their participation.

Participation of NCPs from third countries is welcome, but these NCPs are not eligible for reimbursement for their participation.

The Commission expects to receive and fund a single proposal under this heading.

Expected impact: An improved and professionalised NCP service across Europe, thereby helping simplify access to Horizon 2020 calls, lowering the entry barriers for newcomers, and raising the average quality of proposals submitted. A more consistent level of NCP support services across Europe.

Funding scheme: Coordination and support action

[58] Subject to the adoption of the draft budget 2014 by the Budgetary Authority without modifications of the appropriations foreseen on the corresponding budget line (08.020301 and 09.040301) or the availability of appropriations in 2014 under the rules of provisional twelfths referred to in Article 315 of TFEU.

Indicative budget: EUR 2.00 million[59] from the 2014 budget

HOA6 – 2014: Stem cell research outreach

Specific challenge: Stem cell research offers hope for untreatable and life-threatening disease, however the use of these cells raises ethical concerns which vary across Europe and which make the research the subject of great debate among scientists, clinicians, religious groups, business interests and the public in general.

In order to inform the general public about this research, its results and perspectives, the EU has supported under FP7 a coordination and support action called Eurostemcell, whose centrepiece is a multi-lingual website, the European Stem Cell Information Portal www.eurostemcell.org

The debate about stem cell research during the run-up to H2020 coupled with new scientific discoveries that are opening up new treatment approaches and applications demonstrate the continuing need to provide information and scientific outreach to the European public.

University of Edinburgh is identified as the beneficiary to carry out this work because it has set up the existing web portal, kept it up-to-date and fed it with new material during the course of FP7. The portal built up by the beneficiary during FP7 meets the requested communication and outreach objectives effectively. The objective is to ensure continuation of the existing portal.

Scope: The information portal has developed into the premier European reference site for stem cell information and discourse. The consortium comprises the principal stem cell laboratories across Europe, including new member states, and additionally offers outstanding expertise in ethical and societal concerns and in evaluating clinical outcomes. This coalition provides unparalleled expertise across the field of stem cell biology and regenerative medicine, and is uniquely placed to achieve the vision of a trusted and accessible European stem cell information resource that promotes and facilitates public dialogue.

Expected impact:

Continuation of Eurostemcell web portal as a European reference point for stem cell research;

Dissemination of results of EU projects and other stem cell research to general audiences;

Multi-lingual provision of factual information about stem cell research, including ethical and societal considerations;

[59] Subject to the adoption of the draft budget 2014 by the Budgetary Authority without modifications of the appropriations foreseen on the corresponding budget line (08.020301 and 09.040301) or the availability of appropriations in 2014 under the rules of provisional twelfths referred to in Article 315 of TFEU.

Provision of trusted high quality information on stem cells accessible to citizens and stakeholders across Europe;

Stronger European presence on web-based information on stem cell research;

Better information flow between European stem cell researchers;

Strengthen European efforts to exploit scientific results in stem cell research for the benefit of patients.

Legal entity: University of Edinburgh

Type of action: Grant to identified beneficiary (University of Edinburgh, UK)

Evaluation criteria: This action will be evaluated based on the evaluation criteria set out in Article 14 of the Horizon 2020 Rules for Participation.

Rate of co-financing: The maximum possible rate of co-financing is set out in Article 22 of the Horizon 2020 Rules for Participation.

Type of action: Grant to identified beneficiary (University of Edinburgh, UK)

Indicative budget: EUR 0.60 million from the 2014[60] budget

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Indicative budget for other actions:

- EUR 20.55 million from the 2014 budget
- EUR 21.66 million from the 2015 budget

[60] Subject to the adoption of the draft budget 2014 by the Budgetary Authority without modifications of the appropriations foreseen on the corresponding budget line (08.020301 and 09.040301) or the availability of appropriations in 2014 under the rules of provisional twelfths referred to in Article 315 of TFEU.