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ANNEX 11 TO THE DECISION

HORIZON 2020

WORK PROGRAMME 2014 – 2015

8. Health, demographic change and wellbeing

(European Commission Decision C(2013)XXX of 10 December 2013)

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Introduction

The Horizon 2020 societal challenge of ‘health, demographic change and wellbeing’ (SC1) for the years 2014 and 2015 includes 34 topics in the ‘personalising health and care’ focus area call (15 in 2014 only, 17 in 2015 only and 2 which are open in both years) and 15 topics in the ‘co-ordination activities’ call (10 in 2014 and 5 in 2015). 8 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, in particular through topic PHC 12 which makes use of the new SME instrument.

Societal challenge 1 is also implemented by the continuation and extension of a variety of activities not included in this work programme, the innovative medicines initiative¹ (IMI), the European and developing countries clinical trials partnership² (EDCTP) and the active and

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

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

assisted living programme³ (AAL). Topics in this work programme also respond to the priorities of the European Innovation Partnership on Active and Healthy Ageing⁴ (EIP-AHA).

³ <http://www.aal-europe.eu/why-another-aal-programme/>

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

Call for personalising health and care

H2020-PHC-2014/2015

Proposals are invited against the following topics:

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 and evolution of common diseases and disabilities result from varying degrees of interaction between the genetic make-up of individual human beings and behavioural, environmental, occupational, nutritional and other modifiable lifestyle factors. This applies from the earliest stages of development throughout life.

Understanding these factors, their interactions and the extent to which they contribute to disease development is important for the development of preventive and therapeutic measures supporting good health, prolonged active independence and a productive working life, not least in the context of changing demographic patterns and the ageing of the European population. In particular, proposals will contribute to improving risk identification and validation, and will allow better diagnosis, risk-based prevention strategies and policies.

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

EITHER:

- i. The identification of health trends and determinants, their validation, and the validation of risk factors for disease and disability, through the generation, integration and validation of data derived from relevant disciplines (e.g. molecular, behavioural, nutritional, clinical, environmental epidemiology; exposure sciences; genetics, epigenetics, 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 and active ageing (from early stages of development onwards) and of health deterioration caused by time, disease accumulation and the abovementioned risk factors and their interactions.

In both cases, sex and gender differences should be taken into account.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 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, proposals should 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.

For option:

- i. This should provide evidence for risk identification, underpinning future preventive, diagnostic and therapeutic strategies and policies

For option:

- ii. This should provide a better understanding of pathways of healthy ageing, underpinning future strategies for the promotion of healthy ageing, targeted disease prevention and clinical interventions

Type of action: Research and Innovation actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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. biology, medicine, mathematics, computational technologies) for implementing systems (bio) medicine approaches.

Scope: Proposals should focus on 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, taking due account of gender, and their clinical potential thoroughly investigated.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 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 detection, 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 should 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 in both males and females.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 behavioural change. This requires a multi-sector approach that aims to improve health by addressing such factors as housing; water and sanitation systems; transportation; exposure to chemicals and their mixtures; communication, education and information; occupational factors, physical activity, food production and distribution, and the physical, natural and social environments.

Scope: Given the breadth of sectors, the scope of this topic is limited to the integration of environment, climate and health sectors (including but not limited to air quality, water and sanitation, chemicals, occupational factors, etc.).

Using a multidisciplinary approach and involving relevant stakeholders such as policy makers, the private sector, civil society organisations etc., proposals should address all of the following elements:

- Develop inter-sector interventions (and/or policy initiatives) to promote health or prevent disease based on known environmental stressors. These inter-sector interventions will address key environmental stressors for which changes in relevant EU and international policies related to environment, climate and health would have the greatest impact. In the development of these interventions, age and gender aspects should be taken into account where appropriate.
- Document success characteristics of the abovementioned inter-sector interventions, including those factors that help to 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 and their impact on reducing inequalities.

In line with the Union’s strategy for international cooperation in research and innovation⁵, research activities will be developed as a European contribution to existing international activities and those under development.

⁵ COM(2012)497

The Commission considers that proposals requesting a contribution from the EU of between 4 and 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, climate 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,
- Contribution to the EU commitment to the Rio+20 agenda and the new UN Sustainable Development Goals (SDGs), as well as to the Parma declaration 2010.

Type of action: Research and Innovation actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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.

Scope: Proposals should address all of the following elements:

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 should 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 should take into account age and gender aspects where appropriate.
- The assessment of the behavioural, ethical, regulatory and social implications, as well as of the cost-effectiveness of the programme;

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 of between 4 and 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 should 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 and across Europe. The gender dimension should be taken into account where relevant.

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

Proposals should 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 should be paid from the outset to the further development and dissemination of methodological expertise, including capacity building across Europe, in order that the expertise generated is fully exploited.

The Commission considers that proposals requesting a contribution from the EU of between 2 and 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

PHC 7 – 2014: Improving the control of infectious epidemics and foodborne outbreaks through rapid identification of pathogens (see also societal challenge 2)

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, economic 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 of pathogens should be generated, stored and analysed in combination with clinical, microbiological, epidemiological, additional gene- and transcriptome-based analyses and other data (e.g.: differing responses in women and men) for risk assessment (RA) in an appropriate information system for all sectors (public health, food, animal health).

Proposals should improve pathogen monitoring by rapid identification, comparison, and geographical mapping, including bio-tracing approaches. Proposals should include predictive models on RA, to identify ‘high-risk’ areas and disease-emergence patterns. Proposals should ensure links and consistency with existing networks and databases (TESSY, RASFF, EWRS, EFSA/ECDC⁶ molecular testing database) and data protection requirements. Access to the system should be granted to relevant animal, food safety and human health service stakeholders.

Harmonised standards for sampling, sequencing, sex-disaggregated representative (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 should be assessed. Better 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. Proposals should cooperate with existing EU projects and international activities and those under development.

The Commission considers that proposals requesting a contribution from the EU of between 15 and 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;

⁶ 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

reinforcement of food chain sustainability and enhancement of food security, reduced carbon footprint.

- In line with the Union’s strategy for international cooperation⁷ in research and innovation, proposals should contribute to implementing the ‘Global Research Collaboration for Infectious Disease Preparedness’ and its objectives.

Type of action: Research and Innovation actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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.

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 should 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 several 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 should therefore 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, taking into account potential sex-specific differences. 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.

⁷ COM(2012)497

3. The successful proposal shall 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 cooperation⁸ in research and innovation, international cooperation is encouraged. The proposals 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 of between 15 and 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
- Contribution to the implementation of 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 eradicated cure for HIV. Many poverty-related and neglected infectious diseases however 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 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 should 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 several 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 should be addressed; in particular better ways for early distinction between successful candidates and those that will eventually fail in late stage clinical trials. Proposals should therefore 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, taking into account sex-specific differences. 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. The successful proposal shall 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 must form an integral part of the proposal.

In line with the Union’s strategy on international cooperation⁹ in research and innovation, international cooperation is encouraged. The proposals 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 of between 15 and 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

⁹ COM(2012)497

- Establishment of close links with 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 are required to develop and bring new diagnostics to the patient. This is also a field where many small European companies are active.

Scope:

Proposals should focus on the development and application of novel *in vitro* diagnostic tools and technologies (including assays and platforms). The novel application of existing tools and technologies is excluded. These tools and technologies should improve the performance of diagnosis, prediction, monitoring, intervention or assessment of therapeutic response, 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 of between 4 and 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:

- Innovative, more accurate, more reliable and cost effective *in vitro* diagnostic tools and technologies for earlier disease diagnosis, patient stratification and/or 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 are required to develop and bring new diagnostics to the widest range of patients. This is also a field where many European companies are active.

Scope: Proposals should focus on the development of innovative *in vivo* imaging tools and technologies. The novel application of existing tools and technologies is not included. 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. Proposals should focus on 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 and if appropriate, new developments in the field of imaging agents.

The Commission considers that proposals requesting a contribution from the EU of between 4 and 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, less invasive, 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

PHC 12 – 2014 and 2015: Clinical validation of biomarkers and/or diagnostic medical devices

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. Priority should be given to validation of biomarkers with high potential for short term uptake into clinical practice.

In addition, validation of the clinical performance of new diagnostic devices can be supported, either in combination with the biomarker validation, or against existing standards.

Both *in vivo* and *in vitro* potential biomarkers are eligible. Preference will be given to the validation of 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 proposals 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 of between 2 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. 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.
- New diagnostic devices
- 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 regulation¹⁰.
- 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 related to this topic are provided at the end of this call and in the General Annexes

Innovative treatments and technologies

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

Specific challenge: Chronic non-communicable diseases represent a significant burden on individuals and healthcare systems. Innovative, cost effective therapeutic approaches are required to provide the best quality of care when prevention fails. 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.

¹⁰ Proposal for a regulation of the European Parliament and Council on in vitro diagnostic medical devices COM(2012)541 final

Scope: Clinical trial(s) supporting proof of concept in humans to assess the potential clinical efficacy of the novel therapeutic concept(s) and / or optimisation of available therapies (e.g. drug repurposing). The application may build on pre-existing pre-clinical research and additional results from large scale databases. A concise feasibility assessment justified by available published and preliminary results and supporting data should also be provided. Considerations of effectiveness and 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 of between 4 and 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, adapted where relevant to the differing needs of men and women, 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 in therapy development 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:

Proposals may address one or more of the following: 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 shall 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. The orphan medicinal product must have been granted the EU orphan designation¹¹ at the latest on the date of the call closure. 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 proposals 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 of between 4 and 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 innovation¹², proposals should contribute to reaching the IRDiRC objective to deliver 200 new therapies for rare diseases by 2020.

Type of action: Research and Innovation actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

¹¹ The European register of designated Orphan Medicinal Products is available from <http://ec.europa.eu/health/documents/community-register/html/alforphreg.htm>

¹² COM(2012)497

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 proving safety, efficacy and repeatability of new treatments. The (very often iterative) dialogue between the relevant authorities and those developing regenerative medicine approaches 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 should focus on regenerative medicine therapies 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. Preference will be given to proposals which have or are 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 should represent a central part of the project.

The Commission considers that proposals requesting a contribution from the EU of between 4 and 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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, are 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 encompasses 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 of between 4 and 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 to be the focus of proposals, preference will be given to proposals focusing on interventions with high public health relevance, i.e. which are particularly frequent, have a high negative impact on the quality of life of the individual and/or are associated with significant costs or where savings can be achieved.

Issues of particular relevance for the target populations, for example, poly-pharmacy, vaccine efficacy, compliance, and under-diagnosed or untreated pain should be taken into account. Given the focus on existing interventions, proposals 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 health and socio-economic outcomes (e.g. quality of life, patient mortality, morbidity, costs, and performance of the health system) for chosen populations should be assessed. Agreed core outcome sets (CSO) should be used as endpoints in conditions where they already exist, in other cases efforts should be made to agree on such COS.

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

The Commission considers that proposals requesting a contribution from the EU of between 4 and 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
- Improvement of guideline development for 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 acute or 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 should 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 should propose a detailed programme based on clinical trials and/or real world data. The programme should address clinical, therapeutic (including pharmacodynamic and pharmacokinetic 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 of between 4 and 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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: Proposals should focus on service robotics in assisted living environments which can help an ageing population to remain active and independent for longer. Proposals should build on advances in this domain, and should combine multi-disciplinary research involving behavioural, sociological, health and other relevant disciplines. Characteristics of the solutions developed should 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 (including gender aspects).

The Commission considers that proposals requesting a contribution from the EU of between 3 and 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 should 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 should develop best-practice and viable business and financing models, as well as evidence for potential return on investment.

Proposals should focus on innovation in organisational and business models for service delivery, 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 (including gender balanced relevance), with a minimum of 4 pilot sites in 4 countries.

The Commission considers that proposals requesting a contribution from the EU of between 2 and 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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: Proposals should focus on early risk detection and intervention: specifically ICT based solutions 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.

Proposals should 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.

Proposals should also design ICT based interventions countering identified risks, as well as innovative treatments and therapies based on early detection.

Proposals should build on multi-disciplinary research involving behavioural, sociological, health and other relevant disciplines, and should be driven by relevant user needs to ensure

end-user acceptance (including gender aspects). Full account should be taken of relevant data protection aspects.

The Commission considers that proposals requesting a contribution from the EU of between 3 and 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 and may have their origins in events experienced earlier in the lifespan, they are often present in clinical forms specific to older people, 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 should 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, environmental and social determinants of healthy ageing.

Proposals may address the role of external or internal determinants of mental health, including e.g. behaviour, resilience, sensory deficits, chronic disease, substance use, socio-economic stressors (e.g. loneliness, poverty, violence, trauma and conflicts), or other physical and environmental stressors. Clinical trials or comparative effectiveness research should contribute to the establishment of integrated preventative or therapeutic intervention strategies to improve mental health in the older population. Preference 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 of between 4 and 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.
- Maintenance of 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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, biomedical, social 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 population health, mitigate the effects of the economic crisis and avoid increases in health inequalities.

Scope: As action oriented research, proposals should develop new, or improve on existing, models for health systems, in order to make these systems more patient-centred, prevention oriented, efficient, resilient to crises, safe and sustainable.

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

Models may 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. The gender dimension should be duly addressed. Capacity building and awareness raising activities for the adoption and further use of models developed should be included.

Proposals should 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. Proposals may 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, taking into account the diverse socio-demographic groups and cultural backgrounds, and should track costs.

The Commission considers that proposals requesting a contribution from the EU of between 4 and 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 for new patient-centred, prevention oriented, safe and efficient models for health care systems and services.
- 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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

Specific challenge: Personalised medicine¹³ has 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.

If this potential is to be realised at a larger scale it must first be demonstrated in terms of sustainable benefits, and as a new model of care organisation. Demonstration is however complicated by the diversity of European Union health systems.

Scope: Pilots of new models of care, based on the concept of personalised medicine will be conducted in existing health care environments and should take into account Europe's (national and regional) diversity in health system organisation.

Proposals should envisage 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, social implications as well as the gender dimension should 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 should be assessed. The organisational and resource requirements of the piloted models (data, personnel and financing) should be tracked, providing evidence on methods of implementation and benefits of reform while ensuring safety, equity and cost effectiveness. Appropriate measures for knowledge transfer and capacity building should be put in place.

The Commission considers that proposals requesting a contribution from the EU of between 12 and 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 actions

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

The conditions related to this topic are provided at the end of this call and in the General Annexes

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.

One challenge in re-designing health and care systems is to develop integrated care models that are more closely oriented to the needs of patients and older persons: multidisciplinary, well-coordinated, anchored in community and home care settings, and shifting from a reactive approach to proactive and patient-centred care.

Scope: Proposals should 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 should address barriers from technological, social (including gender) 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 should provide proof-of-concept with both qualitative parameters and quantitative success measures.

The Commission considers that proposals requesting a contribution from the EU of between 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:

- 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 or both. Health management should be addressed in a holistic approach, from healthy lifestyle, dietary habits interlinked with disease management, and adherence to medical plans, placing the patient in the centre and putting increased emphasis on health education, patient empowerment, secondary prevention and self-management of individual conditions, including co-morbidities and frailty. Implementation of programs or applications for different target populations to capture gender- and age-dependent differences in health, behaviour and handling of devices should be included.

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

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

Proposals 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;
- The development of 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.

(ii) mHealth applications for disease management

Proposals should 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, care-givers, families and patients' social environment on chronic disease management supported by mHealth;
- Patient adherence to and compliance with medical recommendations
- Economic aspects of encouraging secondary prevention and addressing avoidable negative health and wellbeing outcomes;
- Screening for pre-frailty states
- 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 of between 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: 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) only

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

For (ii) only

- 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 should be developed and tested with the use of open innovation platforms such as large scale demonstrators for health and service innovation. Proposals should 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. Proposals should use pre-commercial procurement to maximise the engagement of innovation in healthcare organisations following the community building and road-mapping activity in the seventh framework programme call 10 CSA on innovation in health procurement¹⁴.

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

Proposals should address all of the following elements 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 of between 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:

- 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.

¹⁴ http://ec.europa.eu/research/participants/portal/page/call_SEVENTH_FRAMEWORK

PROGRAMME;eSeventh Framework

Programme_SESSION_ID=QJb3S2ZR4c5R8YGRdcXg6sMvRGhp5MnfdJ6hws2s2Zdph80JKMYL!12167447

46?callIdentifier=SEVENTH_FRAMEWORK_PROGRAMME-ICT-2013-

10&specificProgram=COOPERATION#wlp_call_SEVENTH_FRAMEWORK_PROGRAMME

- 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 co-fund actions.

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 should focus on predictive systems based on computer modelling and will develop decision support systems (DSS) that will be used by the individual. The DSS should 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 should 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 should be used by the patient / citizen him or herself for self-management of health and wellbeing. These DSS should also help to improve interactions between individuals / health professionals and co-decision making in healthcare. Proposals may also include 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.

The Commission considers that proposals requesting a contribution from the EU of between 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:

- 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 proposals should improve sustainable deployment of new or improved services by healthcare service procurers in line with the eHealth Action Plan¹⁵. Examples of target outcomes for healthcare delivery may include 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 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.

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

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 shall 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 shall 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.

The Commission considers that proposals requesting a contribution from the EU of between 4 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:

- As applicable, 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 co-fund actions.

The conditions related to this topic are provided at the end of this call and in the General Annexes

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

PHC 30 – 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: Proposals should focus on new decision support systems (DSS) based on a complex integration of heterogeneous data sources and subject-specific computer models. This should enable an integrated data analysis, and should present a highly visual data representation, using user-friendly interactive exploratory interfaces in order to assure usability and acceptability.

Proposals should enable the use of DSS by healthcare professionals for personalised prediction and decision in prevention, diagnosis or treatment and should take into account data protection and ethical considerations, as well as those pertaining to the inherent uncertainties and limits of prediction. 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. Proposals should include the standardisation of data formats and the integration of data coming from other technologies and key-enabling technologies.

The Commission considers that proposals requesting a contribution from the EU of between 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:

- Better coherent use of health data available for a subject in conjunction with the existing medical knowledge in clinical decision making
- Design of predictive and therapeutic interventions
- 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

PHC 31 – 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, climate change, traffic and congestion, ambient noise, built environment, urban sprawl, sustainable food systems, waste, lifestyle, behaviour, occupation, demographic change, cultural characteristics, 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, 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. Proposals should contribute to the understanding of 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 and quantifying key factors impacting health, health inequalities and demand for health services taking Europe's diversity into account. Use of Copernicus data, products and information may be considered where relevant.

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 signal analysis, expert opinion (to create collective intelligence), scenario development, back-casting and wildcards (to help define alternative futures).

Proposals should include quantitative analysis, such as environment, health, economic and other modelling and sensitivity analysis to measure variation in impact of different factors. Proposals should include the identification and validation of relevant measures & indicators and the development of (common) standards. Proposals should capitalise on existing good practice 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. Proposals should also include networking between centres with existing expertise in (health) foresight, both public and private, and partnerships with centres aspiring to develop this expertise.

If more than one proposal is successful, proposals should collaborate.

The Commission considers that proposals requesting a contribution from the EU of between 2 and 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 standardised indicators, the ability to model and track the impact of various factors (internal and external to the health systems) on population health will be improved.
- 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.
- Guidance for future (public) health research

Type of action: Research and Innovation actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

PHC 32 – 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 the production of many different types of data. Furthermore, these new technologies are gradually becoming much less expensive and more accessible to individual laboratories and clinics. The rate of data generation at a local level is therefore set to increase dramatically.

Currently available bioinformatics tools are however insufficient to maximise the use of these new, diverse and complex data. Deficiencies exist in data collection, storage, organisation, integration, analysis and exploitation is therefore not optimal. Network bioinformatics requires support in Europe in order to maintain scientific competitiveness.

Scope: Proposals should ensure that bioinformatics capabilities are not only made adequate for the current data challenge but are also able to meet future biomedical and clinical needs. Proposals should focus on the development of new mathematical, statistical and computational methods, to address specific bottlenecks in bioinformatics that hold back better understanding, integration 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, and interoperability; 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 methods must be ensured from the start of all successful proposals, as must widespread dissemination of the new methods. Commercial development should be encouraged where appropriate.

The Commission considers that proposals requesting a contribution from the EU of between 2 and 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:

- Accelerate the translation of the results into clinical research
- Widespread dissemination of the new bioinformatics methods 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

PHC 33 – 2015: New approaches to improve predictive human safety testing

Specific challenge: Current approaches assessing and predicting the safety of chemicals in humans are expensive and time consuming, and are often of limited relevance. Better approaches are needed to improve the efficiency of predictive toxicological testing to meet regulatory requirements. Safety testing is of worldwide concern and therefore international cooperation may be an important element in addressing the challenge.

Scope: Proposals should capitalise on advances in all relevant fields of science to understand complex biological pathways of toxicological relevance and to identify early markers predictive of toxicological effects with the objectives of developing and validating routine, non-animal approaches for toxicity testing of chemical products (excluding radio-chemicals).

The research may 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 cooperation¹⁶ in research and innovation, cooperation is encouraged with similar initiatives in the USA and elsewhere, and would be highly beneficial from scientific and economic standpoints.

The Commission considers that proposals requesting a contribution from the EU of between 10 and 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

¹⁶ COM(2012)497

- Improved toxicological knowledge to encourage "read across" for use in different research and regulatory domains.
- 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.
- Reduced use of animals in safety testing.

Form of funding: Research and Innovation actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

PHC 34 – 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 Co-ordination and Support Action 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 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, and 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 CT¹⁷ could play as a core terminology to solve semantic interoperability issues, provided that "evidence-based results of SNOMED CT's fitness for purpose are assessed". The epSOS pilot project

¹⁷ <http://www.ihtsdo.org/snomed-ct>

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. Proposals should ensure sufficient involvement of stakeholders (including at least Member States, Industry and international standards development organisations (SDOs)), consensus building and endorsement of the work carried out and of the submitted deliverables. 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) Proposals should investigate the possibility of combining existing or developing a new European or international standard which address the following issues:

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

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

Proposals should build on existing standard vocabularies, terminologies and ontologies and demonstrate a likely contribution to the adoption of existing, or the development of new international standards

(iii) Proposals should investigate 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. Proposals should 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. Proposals should 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. Proposals should assess whether SNOMED CT satisfies the criteria listed in the annex II of the EU standardization regulation. Proposals should take into account advice and guidelines from the eHealth Network but also developments related to the EU-US roadmap.

Proposals for section (iii) should have a duration of no longer than one year.

(iv) The proposal should build on existing work done by projects such as epSOS¹⁸ and SemanticHealthNet¹⁹ 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 should 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. Proposals should demonstrate the value proposition of 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.

Proposals 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. Proposals should deliver a full business plan going beyond 2020 including all revenue streams and cost items.

The Commission considers that proposals requesting a contribution from the EU of up to 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

¹⁸ <http://www.epsos.eu/>

¹⁹ <http://www.semantichealthnet.eu/>

cooperation in research and innovation²⁰, proposals will contribute to the implementation of the EU-US roadmap

(ii) Practical solutions to solve the specific challenge and enable large scale deployments of cross border ePrescription services in the EU. Contribution 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) Contribution to the planning and road-mapping of the CEF for that which concerns the deployment of cross border eHealth services. Contribution to help the EU Member States and the eHealth Network to prioritise use cases to be deployed at national level and to better plan their own national deployments.

Type of action: Coordination and support actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

²⁰ COM(2012)497

CONDITIONS FOR THIS CALL

Publication date: 11th December 2013

Deadline(s) (2014)^{21, 22}: 11th March 2014 (stage one of two stage call), 15th April 2014 (single stage call), 19th August 2014 (stage two of two stage call), **TBD (SME instrument topic)**

PHC 1 - 2014 PHC 5 - 2014 PHC 6 - 2014 PHC 10 – 2014 PHC13 - 2014 PHC 17 - 2014 PHC 23 – 2014 PHC 31 - 2014 PHC 33 - 2014	Stage 1 – 11 th March 2014 at 17.00.00 Brussels time	Stage 2 – 19 th August 2014 at 17.00.00 Brussels time		
PHC 7 - 2014 PHC 8 - 2014 PHC 15 - 2014 PHC 19 - 2014 PHC 20 - 2014 PHC 26 - 2014 PHC 32 - 2014 PHC 34 – 2014	Single stage – 15 th April 2014 at 17.00.00 Brussels time			
PHC 12 - [SME instrument] 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: EUR 554.30 million from the 2014 budget^{23,24}, EUR 542.10 million from the 2015 budget²⁵

²¹ The Director-General responsible may delay this deadline by up to two months.

²² Any deadlines provided in brackets are indicative and are subject to a separate financing decision for 2015.

²³ Of which EUR 5.00 million from the societal challenge ‘Food security, sustainable agriculture and forestry, marine and maritime and inland water research and the bioeconomy’.

²⁴ Subject to the availability of the appropriations provided for in the draft budget for 2014 after the adoption of the budget for 2014 by the budgetary authority or if the budget is not adopted as provided for in the system of provisional twelfths.

²⁵ The budget amounts are indicative and will be subject to a separate financing decision to cover the amounts to be allocated for 2015.

HORIZON 2020 – WORK PROGRAMME 2014-2015

Health, demographic change and wellbeing

	2014 EUR million	2015 <i>EUR million</i>	
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 and hearing
PHC 8 - 2014	25.00		Single stage and hearing
PHC 9 – 2015		22.00	Single stage and hearing
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
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

HORIZON 2020 – WORK PROGRAMME 2014-2015

Health, demographic change and wellbeing

	2014 EUR million	2015 <i>EUR million</i>	
PHC 23 – 2014	30.00		Two stage
PHC 24 - 2015		<i>30.00</i>	Two stage
PHC 25 - 2015		<i>21.00</i>	Single stage
PHC 26 - 2014	59.60		Single stage
PHC 27 - 2015		<i>15.00 (PCP)</i>	Single stage
PHC 28 - 2015		<i>20.00</i>	Single stage
PHC 29 - 2015		<i>10.00 (PPI)</i>	Single stage
PHC 30 - 2015		<i>20.00</i>	Single stage
PHC 31 - 2014	6.00		Single stage
PHC 32 – 2014	24.00		Two stage
PHC 33 – 2015		<i>30.00</i>	Two stage
PHC 34 - 2014	4.00		Single stage
PHC 12 – 2014 and 2015	66.10	<i>45.10</i>	SME instrument
TOTALS	549.30	<i>542.10</i>	

HORIZON 2020 – WORK PROGRAMME 2014-2015

Health, demographic change and wellbeing

Eligibility and admissibility conditions^{26, 27}: The conditions are described in parts B and C of the General Annexes to the work programme, with the following exceptions:

Evaluation criteria, scoring and threshold: The criteria, scoring and threshold are described in part H of the General Annexes to the work programme.

Evaluation procedure: The procedure for setting a priority order for proposals with the same score is given in part H of the General Annexes.

The full evaluation procedure is described in the relevant guide associated with this call.

- Indicative timetable for evaluation and grant agreement²⁸:

	Information on the outcome of the evaluation (<i>single stage</i>)	Information on the outcome of the evaluation (<i>second stage</i>)	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		Maximum 5 months from the final date for submission to the second stage.	Maximum 3 months from the date of informing applicants.	
PHC 7 - 2014 PHC 8 - 2014 PHC 15 – 2014 PHC 19 - 2014 PHC 20 - 2014 PHC 26 – 2014 PHC31 - 2014 PHC 34 - 2014	Maximum 5 months from the final date for submission. For the evaluation of topics PHC7 –	N/A	Maximum 3 months from the date of informing applicants.	

²⁶ 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’.

²⁷ 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.

²⁸ Should the call publication postponed, the dates in this table should be adjusted accordingly.

HORIZON 2020 – WORK PROGRAMME 2014-2015

Health, demographic change and wellbeing

	Information on the outcome of the evaluation (<i>single stage</i>)	Information on the outcome of the evaluation (<i>second stage</i>)	Indicative date for the signing of grant agreements	
	2014 and PHC8 – 2014, the Commission will organise hearings at stage 1 with applicants as part of the panel deliberations for all proposals above threshold.			
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: In line with the Rules for Participation and the Model Grant Agreement, participants in Research and Innovation actions or in Innovation actions are required to conclude a consortium agreement prior to grant agreement.

Call co-ordination activities

H2020-HCO-2014/2015

Proposals are invited against the following topics:

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 EIP-AHA has invited, among others, the European Commission to establish favourable framework conditions to implement the actions outlined in the SIP. 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 SIP, 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: Proposals should provide coordinated support to the activities of the EIP-AHA as follows:

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 of between EUR 1 and 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:

Proposals should present quantitative or qualitative indicators to quantify the potential impact of the following.

- 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 related to this topic are provided at the end of this call and in the General Annexes

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 Programming²⁹ 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

²⁹ Council Conclusions of 12 October 2010, of 26 November 2010 and of 8 December 2011

related to demographic change. It enables Member States to pursue common visions and a strategic research agenda on demographic change.

Proposals should provide coordination and support for the implementation of the joint programming pursued by national governments.

Scope:

Proposals should ensure the coordination of exchange on national programmes on demographic change as well as facilitate the effective governance of the JPI. Proposals should also monitor national research activities in the area and provide support for the implementation of the Strategic Research Agenda of the JPI MYBL³⁰ 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.

Proposals should 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 of between EUR 1 and 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

³⁰ 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.

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

Type of action: Coordination and support actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 such as 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.

The demonstration and validation project of ERN as an 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) is required.

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 build technical foundations and knowledge and integrating these with the organisational, technical, and cultural aspects of a European Reference Network System, and the identification of best practice and its effective implementation in several areas related with the mandate of the Directive.

Scope: Proposals should 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 their 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 of between EUR 1 and 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: 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 methodologies should 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 should 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.

Type of action: Coordination and support actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 those which are resistant to antimicrobial agents. 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. 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, the global research collaboration for infectious disease preparedness (GloPID-R). 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: Proposals should provide organisational support to the implementation of GloPID-R, in close collaboration with the European Commission, research funding agencies from

Member States and from non-EU countries. Proposals should map GloPID-R relevant networks worldwide.

Proposals 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 the development of a strategic research agenda as well as the coordination among relevant research projects and initiatives. Proposals should also communicate progress of relevant research funded under Horizon 2020 and by consortium members. Proposals should also include support activities with relevant stakeholders groups and with the public at large (e.g. development of website, communication materials, etc.). Proposals should involve non-EU regions particularly affected by emerging epidemics.

The Commission considers that proposals requesting a contribution from the EU of between 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 cooperation³¹ 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

³¹ COM(2012)497

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

With the burden of this chronic non-communicable disease ever-increasing the Global Alliance for Chronic Diseases (GACD) partnership, of which the EC is a member, 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: Proposals must focus on type 2 diabetes. Proposals should 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. Proposals must focus on existing approaches to prevention and control of type 2 diabetes rather than development of new treatments. Proposals may address prevention or treatment of specific complications of type 2 diabetes.

Proposals may focus on a wide range of prevention and/or treatment strategies. This may 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 may 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 may address prevention or treatment of specific complications of type 2 diabetes. Proposals may also focus on gestational diabetes.

Proposals may 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, proposals may incorporate work to establish baseline data on prevalence of diabetes and its risk factors to evaluate the impact of the intervention. Proposals may include these aspects if they do 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.
- Proposals shall not include:

- 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 of between 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 proposals 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 should 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 actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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 related to this topic are provided at the end of this call and in the General Annexes

HCO7 – 2014: ERA-NET: 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 the 27 participating EU Member States to work together on the challenge of age-related neurodegenerative diseases. JPND allows the establishment, alignment and building on of national research programmes to increase the effectiveness and impact of research efforts.

The JPND Research Strategy must now 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 2011³². 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: Proposals should coordinate national and regional programmes for research in the area of neurodegenerative diseases research by implementing a transnational call with EU co-funding resulting in grants to third parties, with a view to scale-up the implementation of the JPND Research Strategy. This call shall be defined as follows: *'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*’.

Proposals should also promote 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.

Proposals 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.

Proposal should 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 of a minimum of EUR 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 proposals 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 related to this topic are provided at the end of this call and in the General Annexes

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, by ensuring the availability of critical mass, by efficiently using available resources, by exchanging knowledge, by 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. There is however still the need for better coordination, data sharing and alignment of national programmes and activities in the above mentioned area.

Scope: Proposals should coordinate national and regional programmes for research in the area of translational cancer research by implementing a transnational call with EU co-funding resulting in grants to third parties.

Proposals 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. The proposal should consider and may build on previous EU-funded projects supporting ERA-NETs.

Proposals 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.

Proposals should 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 of a minimum EUR of 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;
- 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 related to this topic are provided at the end of this call and in the General Annexes

HCO9 – 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 disease processes requires research that integrates and interprets data at the system level.

Through the seventh framework programme, 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: Proposals should aim to coordinate national and regional programmes for research in the area of systems medicine. Proposals should implement a transnational call with EU co-funding, resulting in grants to third parties, with a view to support multinational innovative research initiatives on the research priorities identified in the CaSyM action.

Proposals 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.

Proposals should 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 of a minimum of EUR 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 related to this topic are provided at the end of this call and in the General Annexes

HCO 10 – 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 2020³³. 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: Proposals should coordinate national and regional programmes for research on rare diseases by preparing and implementing a transnational call with EU co-funding, resulting in

³³ www.irdirc.org

grants to third parties, with a view to implement IRDiRC³⁴ 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 proposals should adhere to the policies and guidelines of IRDiRC.

Proposals should be complementary with other funding programmes and activities on European and international level.

Proposals 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.

Proposals 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 of a minimum of 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 innovation³⁵, the project will contribute to reaching the overall goals of IRDiRC;
- 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 related to this topic are provided at the end of this call and in the General Annexes

³⁴ The IRDiRC policies and guidelines document is available on: http://www.irdirc.org/?page_id=12

³⁵ COM(2012)497

HCO11 – 2015: 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 abovementioned areas.

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

Proposals should 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. Proposals should consider and may build on previous EU-funded projects supporting ERA-NETs.

Proposals 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.

Proposal should 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 a minimum of 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;
- 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 related to this topic are provided at the end of this call and in the General Annexes

HCO12 – 2015: ERA-NET: 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 19 participating countries of the AMR 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, reversing its increasing trend, in the way forward defined by the Strategic Research Agenda which is to be adopted by the JPIAMR in early 2014.

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:

Proposals should be central to the effective coordination of joint research funding in the area of AMR. Proposals should coordinate national and regional programmes in order to implement the Strategic Research Agenda (SRA) of the JPI AMR through a transnational call with EU co-funding resulting in grants to third parties.

This transnational call topic should be in line with one or more of the priority areas of the SRA and is expected to lead to a lower, smarter use of antibiotics in veterinary and clinical settings and to a significant reduction of the risk that antibiotic-resistance poses to public health.

Proposal should 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 of a minimum of 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 related to this topic are provided at the end of this call and in the General Annexes

HCO13 – 2015: ERA-NET: Cardiovascular disease

Specific challenge: Cardiovascular diseases (CVD) are the largest cause of death in the EU and account for 40% of deaths or 2 million deaths per year. Overall CVD is estimated to cost the EU economy almost €110 billion a year, and they are also one of the leading causes of long term sickness and loss to the labour market. CVD is therefore a major health problem in every country in Europe.

Despite this overall burden, research into CVD is fragmented. In addition, few countries have specific programs dedicated to this field of research.

The challenges in the area of cardiovascular 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.

Scope: Proposals should coordinate national and regional programmes for research in the area cardiovascular research by implementing a transnational call with EU co-funding resulting in grants to third parties. Moreover, proposals 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.

Proposals 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.

Proposals should 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 of a minimum of 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 cardiovascular 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;
- 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 related to this topic are provided at the end of this call and in the General Annexes

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 European health research and innovation.

Two major European instruments – the Research Framework Programme and the Structural Funds – attempt to address this issue, albeit from distinct perspectives, 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, new approaches specific to health research and innovation 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. Proposals may address either analysis or remedial actions, or both.

Proposals should examine the current health research activities in the less performing RDI regions/countries, looking into determinants influencing the health R&I performance. Strategies of these regions (RIS3 – Research and Innovation Strategies for Smart Specialisation) can be studied, and specific indicators can be identified to measure development. Proposals should reveal the factors underlying the divide, identify common patterns and individual differences within these regions. Outcomes should include suggested European and local actions to alleviate differences in health R&I.

For remedial actions, proposals should develop new approaches to unlock excellence in those regions.

Proposals should 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, best practice, opportunities.

The Commission considers that proposals requesting a contribution from the EU of up to EUR 500.000 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

Type of action: Coordination and Support Actions

The conditions related to this topic are provided at the end of this call and in the General Annexes

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) 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 also include media, education establishments, science academies, museums, science centres, etc. Ensuring a balanced distribution of roles and responsibilities between the different types of participants shall be evaluated under evaluation criterion 2.

The Commission considers that proposals requesting a contribution from the EU of up to 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 actions

CONDITIONS FOR THIS CALL

Publication date: December 11th 2013

Deadline^{36, 37}: 15th April 2014

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

Indicative budget :

- EUR 38.00 million from the 2014 budget³⁸
- EUR 29.00 million from the 2015 budget³⁹

[\[Link to the relevant option on "margin of manoeuvre"\]](#)

	2014 EUR million	2015 <i>EUR million</i>	
HCO 1 – 2014	2.00		Single stage
HCO 2 – 2014	2.00		Single stage
HCO 3 – 2015		2.00	Single stage
HCO 4 – 2014	3.00		Single stage
HCO 5 -2014	9.00		Single stage
HCO 6 -2015		12.00	Single stage

³⁶ The Director-General responsible may delay this deadline by up to two months.

³⁷ Any deadlines provided in brackets are indicative and subject to a separate financing decision for 2015.

³⁸ Subject to the availability of the appropriations provided for in the draft budget for 2014 after the adoption of the budget for 2014 by the budgetary authority or if the budget is not adopted as provided for in the system of provisional twelfths.

³⁹ The budget amounts are indicative and will be subject to a separate financing decision to cover the amounts to be allocated for 2015.

HORIZON 2020 – WORK PROGRAMME 2014-2015

Health, demographic change and wellbeing

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 – 2015		5.00	Single stage
HCO12 - 2015		5.00	Single stage
HCO13 – 2015		5.00	Single stage
HCO14 - 2014	1.00		Single stage
HCO 15 - 2014	1.00		Single stage
TOTALS	38.00	29.00	

Eligibility and admissibility conditions: The conditions described in parts B and C of the General Annexes to the work programme, with the following exceptions.

Evaluation criteria, scoring and threshold: The criteria, scoring and threshold are described in part H of the General Annexes to the work programme.

Evaluation procedure: The procedure for setting a priority order for proposals with the same score is given in part H of the General Annexes.

The full evaluation procedure is described in the relevant guide associated with this call.

- Indicative timetable for evaluation and grant agreement:

	Information on the outcome of the evaluation (<i>single stage</i>)	Information on the outcome of the evaluation (<i>second stage</i>)	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 14 - 2014	Maximum 5 months from the final date for submission	<i>n/a</i>	Maximum 3 months from the date of informing applicants	

HORIZON 2020 – WORK PROGRAMME 2014-2015

Health, demographic change and wellbeing

HCO 15 - 2014				
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Consortia agreements: In line with the Rules for Participation and the Model Grant Agreement, participants in Research and Innovation Actions or in Innovation Actions are required to conclude a consortium agreement prior to grant agreement.

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 Commission 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^{40 41}

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

Scope: An annual subscription to the international Human Frontier Science Programme Organisation (HFSP⁴²) 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 cooperation⁴³ in research and innovation.

Type of action: Subscription

Indicative budget: EUR 4 765 000 from the 2014 budget⁴⁴ and of EUR 4 861 000 from the 2015 budget⁴⁵

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, as well as to support dissemination and exploitation of project results. 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

⁴⁰ The budget amounts for 2014 are subject to the availability of the appropriations provided for in the draft budget for 2014 after the adoption of the budget for 2014 by the budgetary authority or if the budget is not adopted as provided for in the system of provisional twelfths.

⁴¹ The budget amounts for 2015 are indicative and will be subject to a separate financing decision to cover the amounts to be allocated for 2015.

⁴² The European Union is a member of the HFSP Organisation (HFSP⁴²) and has funded HFSP under previous Framework Programmes

⁴³ COM(2012)497

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.

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.

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 budget⁴⁶; EUR 2.80 million from the 2015 budget⁴⁷.

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 budget⁴⁸; EUR 8.00 million from the 2015 budget⁴⁹.

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

⁴⁶ 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.

⁴⁷ These amounts will be included in the financial decision for 2015.

⁴⁸ 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.

⁴⁹ These amounts will be included in the financial decision for 2015.

contribute to the implementation of the Union's strategy for international cooperation⁵⁰ 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.

Form of funding: Subscription

Indicative budget: EUR 180 000 from the 2014⁵¹ budget

HOA5 – 2014: National Contact Points

Specific challenge: Facilitate trans-national co-operation between NCPs within this societal challenge with a view to identifying and sharing good practice 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. Liaison with other support structures is encouraged.

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

Only NCPs from EU Member States and Associated Countries (and other countries only where fully justified) which have been officially appointed by the relevant national authorities are eligible to participate in and receive funding for this action.

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

Submission of a single proposal is encouraged. NCPs from EU Member States or Associated Countries choosing not to participate should be identified and the reason explained in the proposal. These NCPs are nevertheless invited and encouraged to participate in the project activities, and are eligible for reimbursement of their participation.

The Commission will only fund one proposal under this heading.

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.

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 actions

Indicative budget: EUR 2.00 million⁵² 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 the seventh framework programme 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 the seventh framework programme. The portal built up by the beneficiary during the seventh framework programme 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

⁵² 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.

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;

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.

Type of action: Coordination and support actions (grant to identified beneficiary: University of Edinburgh, UK).

Evaluation criteria: The criteria, scoring and threshold are described in part H of the General Annexes to the work programme.

Evaluation procedure: The procedure for setting a priority order for proposals with the same score is given in part H of the General Annexes.

The full evaluation procedure is described in the relevant guide associated with this call

Rate of co-financing: 100%

Indicative budget: EUR 0.60 million from the 2014⁵³ budget

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.

HOA7 – 2015: eHealth Sectoral Inducement Prize⁵⁴

Specific challenge: This prize will reward the development of one or more interactive health and well-being apps. The rules of the contest will be established and published⁵⁵ by the European Commission, which will launch and manage the contest and award the prize(s) 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 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(s) who 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 should ensure that citizens can securely store and access their health and well-being data. These data can be transmitted seamlessly to healthcare professionals.

The application should 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.

⁵⁴ Precise details concerning this prize will be supplied during 2014 and this text must be viewed as indicative only. Furthermore, the launch of the contest is subject to the availability of appropriations following the vote of the budget for the year 2015.

⁵⁵ On its ‘participant portal’ (<http://ec.europa.eu/research/participants/portal/page/home>) but also actively publicised elsewhere to maximise participation.

The prize purse (EUR 2 million) will be distributed in line with the guidance of the jury who may choose to reward more than one winner.

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

HOA8 – 2015: Inducement prize – topic TBD⁵⁶

Specific challenge: In addition to topic PHC30, and building on the experience gained with the ‘Vaccine inducement prize’⁵⁷, 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

Expected impact: TBD as indicated above

Type of action: Inducement prize

⁵⁶ Precise details concerning this prize will be supplied during 2014 and this text must be viewed as indicative only. Furthermore, the launch of the contest is subject to the availability of appropriations following the vote of the budget for the year 2015

⁵⁷ http://ec.europa.eu/research/health/vaccine-prize_en.html