Draft Horizon 2020 Work Programme 2016-2017
in the area of "Health, demographic change and well-being"

Important notice:

This paper is made public just before the adoption process of the work programme to provide potential participants with the currently expected main lines of the work programme 2016-2017. It is a working document not yet endorsed by the Commission and its content does not in any way prejudge the final decision of the Commission.

The adoption and the publication of the work programme by the Commission are expected in mid-October 2015. Only the adopted work programme will have legal value.

This adoption will be announced on the Horizon 2020 website and on the Participant Portal. Information and topic descriptions indicated in this working document may not appear in the final work programme; and likewise, new elements may be introduced at a later stage. Any information disclosed by any other party shall not be construed as having been endorsed by or affiliated to the Commission.

The Commission expressly disclaims liability for any future changes of the content of this document.

Table of contents

Introduction

The headline goal of the 'Health, Demographic Change and Well-being' Societal Challenge is better health for all. Its main policy objectives are to improve health and well-being outcomes, to promote healthy and active ageing, to promote market growth, job creation, and the EU as a global leader in the health area. The challenges to this goal derive from the ageing of European population and lifestyle patterns, which, if not actively managed through a life-course approach, will increase the burden of chronic diseases on individuals, on existing health and care systems and on society. This will also result in increase of public expenditure coupled with labour force and productivity losses.

The overall strategic orientation for the 'Health, Demographic Change and Well-being' Work Programme 2016-2017 is 'promoting healthy ageing and personalised healthcare'. It directly links with what has been successfully initiated in the years 2014-2015. The programme will implement several research priorities: personalised medicine, rare diseases, human bio-monitoring, mental health, comparative effectiveness research, advanced technologies, e/m-health, robotics, patient empowerment, active and healthy ageing, data security, big data, valorisation, anti-microbial resistance, infectious diseases including vaccines, maternal and child health and the silver economy. In addition, Pilot 1 'Smart Living Environments for Ageing Well' of the focus area call on 'Internet of Things' is jointly implemented by the "Health, Demographic Change and Well-being" Societal Challenge and the "Leadership in enabling and industrial technologies Information and Communication Technologies" (ICT LEIT) (see topic IoT-01–2016: Large Scale Pilots in part 17 of the Work Programme). Those priorities will support the development of evidence-based health and care policies, resulting from scientific research data, ICT solutions and good practices in interventions improving efficiency and quality of health and care systems.

Activities supported under this Societal Challenge offer a unique opportunity to improve the quality of life of EU citizens, to position the EU as a central player in the global context and to stimulate the high quality of European research and innovation (R&I) and industrial competitiveness by mobilising relevant European R&I performers, both public and private. The 'Health, Demographic Change and Well-being' Work Programme 2016-2017 will therefore contribute to the Commission priorities on: 'A new boost for jobs, growth and investment', 'A stronger global player' and 'A connected digital single market'.

The 'Health, Demographic Change and Well-being' Work Programme 2016-2017 makes use of the whole range of instruments available: collaborative research and innovation actions, SME instrument, prizes, innovative financing, programme co-fund, ERA-NET Co-Funds, coordinated and support action including support for Joint Programming Initiatives (JPIs). It also builds strong links and synergies with activities undertaken by the Innovative Medicines Initiative 2[1] (IMI2), the European and Developing Countries Clinical Trials Partnership 2[2]

[1] http://www.imi.europa.eu/content/imi-2

[2] http://www.edctp.org/

(EDCTP2) and the Active and Assisted Living Joint Programme 2[3] (AAL2). Topics in this work programme also respond to the priorities of the European Innovation Partnership on Active and Healthy Ageing[4] (EIP-AHA).

The 'Health, Demographic Change and Well-being' Work Programme 2016-2017 integrates the principle of responsible research and innovation in all its activities, including addressing gender/sex differences as well as ethics, social sciences and humanities (SSH) whenever relevant.

Health challenges are global and applicants are therefore encouraged to include the international dimension in their proposal where relevant. The use of European health research infrastructures (including e-infrastructures) is also encouraged when appropriate, e.g. research infrastructures established as a European Research Infrastructure Consortium (ERIC) or identified on the roadmap of the European Strategy Forum on Research Infrastructures (ESFRI). Projects submitting a Data Management Plan are invited to identify the existing European research data infrastructures that may be used and how these may be mobilised, in particular for long-term data curation and preservation.

Finally the programme should allow for further building of clinical research infrastructure and evidence with regard to efficient and validated models of organisation of complex networks such as European Reference Networks of healthcare providers established by Article 12 of Directive 2011/24/EU[5].

A novelty in Horizon 2020 is the Pilot on Open Research Data which aims to improve and maximise access to and re-use of research data generated by projects. While certain Work Programme parts and calls have been explicitly identified to participate in the Pilot on Open Research Data, individual projects funded under the other Work Programme parts and calls can choose to participate in the Pilot on a voluntary basis. Participating projects will be required to develop a Data Management Plan (DMP), in which they will specify what data the project will generate, whether and how it will be exploited or made accessible for verification and re-use, and how it will be curated and preserved. Further guidance on the Pilot Open Research Data[6] and Data Management[7] is available on the Participant Portal.

[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

[5] http://ec.europa.eu/health/ern/policy/index_en.htm

[6] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf

[7] Template for data management plan can be found on p. 5-6 of http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

Call - Personalised Medicine

H2020-SC1-2016-2017

1.1 UNDERSTANDING HEALTH, WELL-BEING AND DISEASE

Proposals are invited against the following topic(s):

SC1-PM-01-2016: Multi omics for personalised therapies addressing diseases of the immune system

Specific Challenge: Despite much progress in 'omics' and epidemiological research in recent years, the knowledge on the combined role of genetic and non-genetic factors in health and disease is still limited, thus hampering the full development potential of personalised medicine[8].

There is increasing evidence that interactions with the environment, as reflected in genome-epigenome-proteome-metabolome-microbiome crosstalk, play an important role in disease development and progression. International initiatives such as the International Cancer Genome Consortium (ICGC), the International Human Epigenome Consortium (IHEC) and the International Human Microbiome Consortium have generated high quality comprehensive large scale data catalogues and maps. The challenge is to build on the existing high quality data deposited in relevant databases (e.g. but not limited to: http://epigenomesportal.ca/ihec/, http://docs.icgc.org/data-portal) and combine these data and knowledge with lifestyle and environmental data, thus accelerating the translation into novel targeted or personalized interventions. These objectives cannot be accomplished on an individual country level which calls for broad transnational collaboration.

Scope: The scope of this topic is to integrate and use high quality genome, epigenome, proteome, metabolome, microbiome data produced by large scale international initiatives with innovative imaging, functional, structural and lifestyle/environmental data, and combine these with disease-oriented functional analysis to contribute to the understanding of health and disease with the final objective of selecting relevant biomarkers for clinical validation that will lead to the development of new targeted therapies for diseases of the immune system. Proposals must build on data from IHEC and, as appropriate, on data from other international initiatives. Proposals should address relevant ethical implications, take into account sex and gender differences and include a section on research data management. International

[8] Personalised medicine refers to a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) 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 term "personalised medicine" is used throughout this Work Programme with this definition in mind.

cooperation is requested. Proposals addressing rare diseases of the immune system are excluded.

The Commission considers that proposals requesting a contribution from the EU of between EUR 12 and 15 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:

- Translate big data and basic research results into clinical applications.
- Contribute to exploiting data from IHEC and, as appropriate, data from other international initiatives.
- Identify and select new biomarkers for clinical validation in stratified patient populations
- Develop new targeted therapies for diseases of the immune system with high prevalence.
- In line with the Union's strategy for international cooperation in research and innovation proposals should create strategic synergies between scientists across disciplines, sectors and around the globe.

Type of Action: Research and Innovation action

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

SC1-PM-02-2017: New concepts in patient stratification

Specific Challenge: Despite the major advances in understanding disease in the post-genomic era, still a majority of all drugs are effective in only a limited number of patients. From a clinical perspective, implementing knowledge-based decisions on what therapeutics to use for which patients and, if relevant, in which combinations, are extremely challenging. The aspiration to provide more effective therapeutic interventions tailored to the individual or groups of individuals with common molecular phenotypes remains unfulfilled because of the variable response of individuals to such interventions.

Patient stratification aims at grouping patients into disease sub-groups, where the specific pathological processes involved are better defined (clinical/molecular phenotypes). This will lead to the development of targeted therapies, optimizing the intervention to individual patients, thus achieving greater success in treating or curing the patient.

Scope: Proposals should deliver novel concepts for disease-mechanism based patient stratification to address the needs for stratified or personalised therapeutic interventions. The proposals should integrate multidimensional and longitudinal data and harness the power of -omics, including pharmacogenomics, systems biomedicine approaches, network analysis and

of computational modelling. The new concepts of stratification should be validated in pre-clinical and clinical studies taking into account sex and gender differences. Applicants are encouraged to actively involve patient associations. The proposals should consider regulatory aspects of clinical practice and commercialisation opportunities. Proposals should focus on complex diseases having high prevalence and high economic impact.

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:

- New models for patient stratification to inform clinical decision making.
- Accelerate the translation of biomedical and clinical research results to medical use.
- Increased cost-effectiveness of the novel concepts in comparison to already established practices.
- Increased research and innovation opportunities in this innovative industries-driven field, particularly small or medium-sized enterprises (SMEs).

Type of Action: Research and Innovation action

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

SC1-PM-03–2017: Diagnostic characterisation of rare diseases

Specific Challenge: Rare diseases are diseases which affect not more than 5 per 10 000 persons in the European Union. It is estimated that rare diseases encompass between 6 000 and 8 000 different entities which affect altogether more than 30 million people in the EU. However, patient populations for individual rare diseases are small and dispersed, which makes international collaboration crucial. Despite the recent advances in understanding the molecular pathogenesis of these diseases, today many rare diseases still lack means of molecular diagnosis. An accurate molecular diagnosis is an essential starting point for the understanding of mechanisms leading to diseases as well as for adequate patient management and family counselling and it paves the way for therapy development.

Scope: The aim of this research should be to apply genomics and/or other –omics and/or other high-throughput approaches for the molecular characterisation of rare diseases in view of developing molecular diagnoses for a large number of undiagnosed rare diseases. Undiagnosed rare diseases may range from a group of unnamed disorders with common characteristics to a phenotypically well described disease or group of diseases with an unknown molecular basis. Genetic variability due to geographical distribution and/or different ethnicity should be taken into account as well as genotype-phenotype correlation whenever

applicable. In addition, age, sex and gender aspects should be included where appropriate. This large-scale proposal should promote common standards and terminologies for rare disease classification and support appropriate bioinformatics tools and incentives to facilitate data sharing. Existing resources should be used for depositing data generated by this proposal. Molecular and/or functional characterisation may be part of the proposal to confirm diagnosis. The proposal should enable and foster scientific exchange between stakeholders from countries and regions with different practices and strategies of rare disease diagnostics.

The selected proposal shall contribute to the objectives of, and follow the guidelines and policies of the International Rare Diseases Research Consortium IRDiRC (www.irdirc.org).

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

Expected Impact: Providing better and faster means of high quality and clinical utility for the correct diagnosis of undiagnosed rare diseases for which there is no or unsatisfactory diagnosis available.

• Contribute towards the IRDiRC objectives.

• Foster dissemination of scientific results and knowledge exchange between stakeholders.

• Develop knowledge management strategies, with the view of facilitating models of care and access to the data gathered.

• Providing better knowledge for improved family counselling as well as to improve follow-up for patients and research initiatives.

• Gather a big number of patients with similar phenotypes to facilitate match making, to avoid duplication and to unravel a considerable number of diagnoses.

• Pave the way to the development of new therapies and for a better treatment outcome in rare disease patients.

Type of Action: Research and Innovation action

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

SC1-PM-04–2016: Networking and optimising the use of population and patient cohorts at EU level

Specific Challenge: Population cohorts are invaluable resources to obtain detailed description of individual biological variations in connection with a variety of environmental, pathogenic, occupational, societal, and lifestyle determinants that influence the onset and evolution of diseases. Europe currently has some of the most valuable population and patient cohorts, including well annotated clinical trial cohorts. However, the lack of integration of these

cohorts hampers the optimal exploitation of these resources, essential to underpin and facilitate the development of stratified and personalised medicine[9].

.

Scope: Proposals should aim at maximizing the exploitation of cohorts by bringing together national and/or European cohorts with common scientific interests (e.g. across diseases, children, mothers, elderly, birth, gender, etc.), and by taking advantage of new technologies (e.g. ICT, social platforms, etc.) and new type of data (e.g. geographical, genetic, eHealth records, etc.). Based on those cohorts using a comprehensive integration strategy to facilitate hypothesis-driven research, data sharing, harmonisation and analysis, proposals should provide expanded resources and knowledge on health and disease determinants, onset and course of diseases (including aspects of co-morbidity and/or co-infections), clinical, public health and socio-economic research. Synergies with relevant existing European infrastructures and additional collaborations with relevant international initiatives are encouraged. Proposals should also engage with relevant international/national/regional authorities to ensure that findings are implemented and translated into health policy.

The Commission considers that proposals requesting a contribution from the EU of between EUR 8 and 10 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: Expected impacts include one of or a combination of the following point(s):

- Make major conceptual, methodological and analytical contributions towards integrative cohorts and their efficient exploitation.
- Contribute to providing novel information on health maintenance, onset and course of diseases, or population stratification, with a view to tailor diagnosis or to optimise prevention and treatment.
- Provide the evidence base for the development of policy strategies for prevention, early diagnosis, therapies, health economics as well as addressing health inequalities. Wherever relevant, evidence for economic evaluation of interventions should also be included.
- Optimise the use of population cohorts in defining/improving clinical practice and public health policy.

Type of Action: Research and Innovation action

[9] Personalised medicine refers to a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) 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 term "personalised medicine" is used throughout this Work Programme with this definition in mind.

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

1.2. PREVENTING DISEASE

Proposals are invited against the following topic(s):

SC1-PM-05–2016: The European Human Biomonitoring Initiative

Specific Challenge: A major hurdle in reliable risk assessment and management of chemicals is the lack of harmonised information about the exposure of citizens, including workers, to chemicals and their interplay with other concurrent environmental exposures and impact on health. Each individual is today exposed to a large number of chemicals in their environment, including the workplace, through the air, food, water and consumer products. For many of the chemicals, the health impact, including long-term, is still unknown. Innovative approaches are needed to enable us to decipher the potential causal associations between exposures and health effects over a lifetime and, where such links are identified, to understand the underlying mechanisms.

A first step to better assess and understand this potential impact on heath is to gather harmonised and comparable information on population exposure to chemicals in Europe through human biomonitoring (HBM), to link this information to data on exposure sources and epidemiological surveys and to promote research on the exposure-response relationships in humans.

Scope: The objective is to create a European joint programme for monitoring and scientific assessment of human exposures to chemicals and potential health impacts in Europe, building on previous activities undertaken at EU and national levels. This European Human Biomonitoring Initiative (EHBMI) should:

- be achieved through coordination of HBM initiatives at national and EU level, with a special focus on linking research to evidence-based policy making.
- build on European excellence in the field and promote capacity building and the spread of best practice.
- provide a platform through which harmonised and validated information and data collected at national level can be accessed and compared.
- support research and innovation in various ways, e.g., by improving underlying methods and procedures (e.g., for sampling, sample analysis, data analysis, and data management), by improving the understanding of the impact of the exposure on human health (e.g., development of validated exposure and effect biomarkers and establishing

correlation between biomarker levels and health risks) and by improving the use of HBM data in risk assessment of chemicals and their mixtures.

The acquired knowledge should support informed decision taking and policy making in a wide variety of sectors, one of the most important being the EU chemicals legislation under REACH[10].

The governance structure of the EHBMI should allow for review of the priority setting with regards to chemicals to be investigated by the initiative, taking into account the scientific advances at national and EU level.

The proposal should include a five-year roadmap describing the key priorities and governance processes as well as the first annual work plan.

The joint programme should be structured along three main components:

- a platform providing support for field sampling and analytical work by competent national laboratories and a data infrastructure;
- a research programme to assess the impact of chemical exposure on human health; and
- an activity focused on translation of programme results into policy.

The three components must operate in close coordination, in order to address the overall priorities of the initiative.

The platform on field sampling and analytical work should include joint activities aiming at advancing, harmonising and quality assurance in field work practices and analytical methods and contribute to the development of EU reference values. Potential research aspects to be addressed are, inter alia, related to developing innovative analytical methods, new biological matrices, non-invasive technologies, new biomarkers, and reference materials. A network of reference laboratories and field survey entities of high quality must be established, engaged in capacity building across Europe and facilitating access to special equipment. Best practices for management of data resulting from linking analytical results and field surveys must be established, facilitating the data inclusion into the Information Platform for Chemical Monitoring Data (IPChem platform[11]) currently under development by the EU Joint Research Centre.

The EHBMI should ensure the inclusion of new HBM data and whenever possible existing HBM data to IPChem and address outstanding issues related to HBM data policy and data quality assurance. Furthermore, the consortium should ensure that the new data, relevant for policy making, produced in this initiative, will be made available to regulators at the national and EU level. For this purpose the proposal should include a draft Data Management Plan,

[10] http://echa.europa.eu/regulations/reach

[11] IPChem aims to support a coordinated approach to collecting, storing and accessing monitoring data on chemicals and chemical mixtures in humans and in the environment: http://ipchem.jrc.ec.europa.eu/#home-page

renewed annually, detailing what data the project will generate, how it will be used and/or made accessible for regulatory purposes.

The research programme to understand the impact of exposures on human health should include joint research on correlation, integration and analysis of data from different sources, e.g., HBM data, environmental, occupational, health examination and epidemiological surveys; research on exposure mechanisms and modes of actions and research for innovative approaches to risk assessment.

The work undertaken under the science-policy interface component should aim at informing existing policy making processes (from chemicals to health) at EU and national level about the outcome of the EHBMI, exploring the possibilities and requirements for an increased use of HBM data in evidence-based policy processes and mobilising existing committees and expert/advisory groups to contribute to setting priorities.

Research activities may be supported by open calls for proposals organised by the consortium, if deemed necessary, aiming at bringing in additional expertise and engaging with the wider research community.

Dissemination, communication and training activities should be included in the initiative, in particular efforts to increase public awareness and understanding of the obtained results and their implications for policy making and self-responsible lifestyle management. A public engagement component should be included whereby citizen science approaches to human biomonitoring are explored and sought.

The minimum number of participants is five independent legal entities from different Member States or associated countries owning or managing national research and innovation programmes. In addition to the minimum conditions, other legal entities may participate if justified by the nature of the action.

Horizon 2020 contribution will be limited to a maximum of 70% of the total eligible costs of the action with a maximum of EUR 50 million of EU contribution for the expected five years duration of the action.

The Commission will only fund one proposal under this topic.

Expected Impact:

- Coordinating HBM initiatives in Europe at national and EU level and spreading of best practice and capacity building.
- Advancing the understanding of the nature and level of chemical exposure of EU citizens at all ages, including workers, and the potential health risks leading to better protection of the health of EU citizens. Gender aspects should be taken into account where relevant.

- Establishing a strong EU-wide evidence base of comparable and validated exposure and health data for sound policy-making at EU and national level, based on evidence-based regulation, risk assessment and management, whilst striking an appropriate balance with industrial competitiveness.

- Preparation for a possible public-public partnership under Article 185 of the Treaty.

Type of Action: COFUND (European Joint Programme)

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

SC1-PM-06–2016: Vaccine development for malaria and/or neglected infectious diseases

Specific Challenge: Vaccines offer a safe and cost-effective way to protect large populations against infectious diseases. Yet, many poverty-related and neglected infectious diseases continue to escape attempts to develop effective vaccines.

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 pipeline.

Scope: Proposals will have to address bottlenecks in the discovery, preclinical and early clinical development of new vaccine candidates (antigens/adjuvants) for malaria and/or neglected infectious diseases[12]. Filoviral diseases are specifically excluded from this topic.

Depending on the maturity of the research landscape for each disease, proposals may range from large research platforms developing multiple vaccine candidates and/or vaccines for multiple diseases, to proposals specifically focused on one disease.

a) The larger platforms proposals should among others:

1. Take advantage of recent advances in vaccinology (e.g. *in silico* analysis and novel *in vitro* and *in vivo* immunoscreens) or establish completely new approaches for the discovery and selection of novel, appropriately immunogenic antigens, and/or novel formulations/combinations for the generation of new vaccine candidates.

2. Include a systematic approach and define key gate-criteria for selection across each step of the research and development pipeline they address. Based on these criteria the most promising new vaccine candidates, should be able to be compared as early as possible in an

[12] Neglected Infectious Diseases for the scope of this call: In addition to the 17 Neglected Tropical Diseases prioritized by WHO, also eligible are childhood diarrhoeal diseases and neglected viral emerging epidemic diseases.

objective and transparent process according to their merit in line with effective vaccine portfolio management.

b) Smaller proposals specifically focused on a single disease and/or a single vaccine candidate should adopt similarly innovative and comprehensive approaches to tackle one or more of the major bottlenecks in vaccine development for the specific disease.

For all antigen/vaccine candidates and for all diseases, it is necessary to ensure that a protective immune response (in the specific target population of the vaccine candidate) is adequately understood and that the candidate can elicit such a response.

Depending on the development stage, the downstream constraints of vaccine candidates for effective deployment and utilisation in resource-poor settings should be taken into account. This might include (as early clinical pipeline gate-criteria) considerations of the optimal route and immunization regime, field-deployment logistics (e.g. storing temperatures), as well as an evaluation of the predicted cost and affordability of final vaccine products. If relevant, an assessment of the target population risk-perception attitudes and immunization behaviours should be made and sex- and gender differences should be taken into account.

Both types of proposals should take into account existing mapping exercises on vaccine candidates, as well as the current vaccine development roadmaps and target product profiles for each disease (e.g. Malaria Vaccine Technology Roadmap).

The Commission considers that proposals requesting a contribution from the EU of between EUR 3 and 5 million for smaller specifically focused proposals, and between EUR 15 and 20 million for the larger platform proposals, 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 deliver new vaccine candidates or move existing ones along the vaccine candidate pipeline in support of the sustainable development goal No. 3.3, i.e. to end by 2030 the epidemics of malaria and neglected tropical disease
- This should provide 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.
- Increase the number and quality of vaccine candidates for malaria and neglected infectious diseases available to proceed into further development and clinical testing, if appropriate within the context of the European and Developing Countries Clinical Trials Partnership (EDCTP2).

Type of Action: Research and Innovation action

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

SC1-PM-07–2017: Promoting mental health and well-being in the young

Specific Challenge: Mental well-being[13] is integral to population health and well-being and contributes to the functioning of individuals, families, communities and the social and economic prosperity of society. Mental and behavioural disorders including addictive behaviour place immense burdens on individuals, families and society; they also increase the risk of co-morbidities and social exclusion. Childhood and adolescence are crucial periods for laying the foundations for healthy development and mental well-being. There is compelling evidence that promotion of mental well-being and prevention interventions, when implemented effectively, can reduce risk factors for mental disorders, enhance protective factors for good mental and physical health and lead to lasting positive effects on a range of educational, social and economic outcomes for young people[14]. Medical and psychological factors, family and social factors (including working conditions) as well as digital environments are some of the different determinants impacting the health and well-being of the young. Resilience to adversity will enhance their ability to cope. There is a need for more robust evidence on resilience factors and on effective interventions promoting mental well-being. Developing these in the young offers the possibility of a positive influence on child development in critical/sensitive periods (childhood, adolescence, transition to young adulthood), thanks to early neuroplasticity.

Scope: Proposals should develop population-oriented primary prevention[15] interventions to promote mental well-being of young people and assess them for their effectiveness. The interventions should build on but may go beyond existing state-of-the art knowledge on biological, psychological and social determinants of mental well-being such as societal, cultural, work life, lifestyle, epidemiological, economic and environmental perspectives. The proposals should aim at increasing resilience and mitigating the impact of biological, psychosocial and environmental risk factors. The target group should include young up to 25 years (or a subgroup there of), which is an age limit often used as many severe disorders start in this period.

[13] The term mental well-being is often used in both policy and academic literature, interchangeably with positive mental health. The WHO has declared mental health to be the 'foundation for well-being and effective functioning for both the individual and the community' and defined it as a state 'which allows individuals to realise their abilities, cope with the normal stresses of life, work productively and fruitfully, and make a contribution to their community. World Health Organisation: *Promoting Mental Health; Concepts emerging evidence and practice. Summary report*, Geneva; World Health Organisation; 2004.

[14] Clarke, A.M., Morreale, S., Field, C.A., Hussein, Y., & Barry, M.M. (2015). What works in enhancing social and emotional skills development during childhood and adolescence? A review of the evidence on the effectiveness of school-based and out-of-school programmes in the UK. A report produced by the World Health Organization Collaborating Centre for Health Promotion Research, National University of Ireland Galway

[15] Primary prevention is directed towards preventing the initial occurrence of a disorder (WHO Health Promotion Glossary 1998)

The research design should be developed by means of a multidisciplinary approach and involve the young themselves and other relevant stakeholders. Innovative approaches in involving the young and gathering their inputs for the design of the intervention should be considered. The interventions should use a holistic approach, taking gender and health inequality aspects into account, in increasing resilience and empowering the young. The interventions to be developed should reflect the diversity of the different countries and regions in Europe and beyond. The research should pay particular attention to ethical issues. The interventions should be assessed for mental well-being outcomes as well as the economic and social benefits and impact on reducing inequalities. These analyses of impact and effectiveness should be presented in quantitative as well as qualitative terms, in a gender disaggregated way where relevant. The results should be disseminated throughout Europe and beyond in order that the evidence generated is fully exploited.

The Commission considers that proposals requesting a contribution from the EU of between EUR 2 and 4 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: Short or medium term impact, likely during the lifetime of the project:

- Improved mental well-being in the targeted group of young people.
- The innovative interventions will create a strong evidence base for mental well-being promotion programmes in Europe, contributing to greater health equity and improved societal benefits.

Longer term impact, likely beyond the lifetime of the project:

- Improved mental well-being in youth should contribute to reducing school and college/university dropout in the short term, strengthening personal confidence and cognitive function, improving educational efforts and enhancing employability.
- Preventative strategies are established which have a real effect of reducing the occurrence of mental disorders and co-morbidities associated with mental disorders later in life.

Type of Action: Research and Innovation action

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

1.3 TREATING AND MANAGING DISEASES

Proposals are invited against the following topic(s):

SC1-PM-08–2017: New therapies for rare diseases

Specific Challenge: Rare diseases are diseases which affect not more than 5 per 10 000 persons in the European Union, as defined in the context of the EU legislation. A considerable amount of knowledge has been generated by biomedical research in recent years, yet most of the 6 000 to 8 000 rare diseases are lacking therapies despite many of these 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. Amongst other challenges, this leads to the requirement for seeking early advice of regulatory authorities during development. In addition, despite the special incentives for the development of orphan medicinal products, and the often high prices of some of the developed therapies, the limited market for such therapies lead to a low commercial return, and/or limited access.

Scope: Support will be provided to clinical trials on substances where orphan designation has been given by the European Commission, 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. Clinical trials may focus on a range of interventions with an orphan designation, from small molecule to gene or cell therapy, may include novel interventions and/or repurposing of existing and known interventions. The intervention must have been granted the EU orphan designation at the latest on the date of the full proposal call closure. A concise feasibility assessment justified by available published and preliminary preclinical or clinical results and supporting data shall also be provided. Appropriate plans to engage with patient organisations, Member States health authorities and considerations of efficacy/potential clinical benefit as well as early indication on health economics should be integrated in the application. In addition to the clinical trial, proposals may also include limited elements of late stage preclinical research and/or experimental evaluation of potential risks which must be complementary/contribute to the clinical trial(s) carried out within the proposal. The centre of gravity must clearly be the clinical trial(s). The participation of SMEs is highly welcomed.

Selected proposals shall contribute to the objectives of, and follow the guidelines and policies of the International Rare Diseases Research Consortium, IRDiRC (www.irdirc.org).

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 line with the objectives of the Union pharmaceutical legislation on orphan medicinal products, proposals shall contribute to advance the development of new therapeutic options with concrete benefits for patients living with rare diseases.

• Rapid progress in orphan drug development due to well-prepared clinical trials and a multinational multicentre clinical trial with an appropriate number of patients.

• Develop a preliminary assessment of the potential economic and public health aspects of the new therapeutic option.

• Contribute to growth of SMEs involved in drug development.

• In line with the Union's strategy for international cooperation in research and innovation, proposals shall contribute towards IRDiRC objectives.

Type of Action: Research and Innovation action

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

SC1-PM-09–2016: New therapies for chronic diseases

Specific Challenge: Chronic diseases represent a significant burden on individuals and healthcare systems in the European Union and beyond. Innovative and effective therapeutic approaches are required to provide the best quality of care when prevention strategies fail. While considerable basic knowledge has been generated by biomedical research in recent years, the development of new therapies is stagnating, in part due to a lack of clinical validation.

Scope: Proposals should focus on clinical trial(s), supporting proof of concept of clinical safety and efficacy in humans [16] of novel therapies (pharmacological as well as non-pharmacological) or the optimisation of available therapies (e.g. repurposing) for chronic non-communicable or chronic infectious diseases. Preclinical research should be completed before the start of the project. Proposals should provide a sound feasibility assessment, justified by available publications or provided preliminary results. Gender and age must be considered whenever relevant. Due consideration should also be paid to involve patients and take their views into account wherever relevant. Rare diseases and regenerative medicine are not within the scope of this topic[17,18].

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:

[16] Phase 3 and phase 4 clinical trials are excluded.

[17] See topic SC1-PM-08-2017 addressing new therapies for rare diseases.

[18] See topic SC1-PM-11-2016-2017 addressing clinical research on regenerative medicine.

- New or optimised therapeutic strategies, adapted where relevant to the different needs of men, women, children and the elderly, with the highest potential to generate advances in clinical practice and care for chronic non-communicable or chronic infectious diseases.

- Improve the therapeutic outcome of major chronic health issues with significant impact on disease burden of individual patients and health care systems.

Type of Action: Research and Innovation action

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

SC1-PM-10–2017: Comparing the effectiveness of existing healthcare interventions in the adult population

Specific Challenge: Effective health care and prevention may be improved by additional evidence as to the most effective health interventions. Growing numbers of patients affected by chronic diseases also call for efficiently managing co-morbidities.

Scope: Proposals should compare the use of currently available preventative or therapeutic (pharmacological as well as non-pharmacological) healthcare interventions in adults[19]. 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 and socio-economic impact, i.e. interventions addressing conditions that are particularly frequent, may lead to co-morbidities, 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. A cost effectiveness analysis must be included. Given the focus on existing interventions, proposals will aim to contribute to improve interventions, take decisions about the discontinuation of interventions that are less effective or less cost-effective than others, and make recommendations on the most effective and cost-effective approaches. 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 systems) for chosen populations should be assessed. Agreed core outcome sets (COS) 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. Where relevant the study population should address gender as well as socio-economic differentials in health and/or any other factors that affect health equity.

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.

[19] Screening and / or the involvement of elderly populations are not excluded.

Expected Impact: This topic is to provide the required evidence base for:

- more effective and safer interventions at individual and population level;
- enhanced compliance with healthcare interventions in the adult population;
- 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 prevention or treatment of diseases and the management of comorbidities.
- Provision of more accurate information to patients, caregivers and prescribers.

Type of Action: Research and Innovation action

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

SC1-PM-11–2016-2017: Clinical research on regenerative medicine

Specific Challenge: Translating basic knowledge on regenerative medicine into the clinic is often delayed by the difficulty of undertaking "first in man" studies and carrying out the specific research needed for proving safety and efficacy of new treatments as well as reproducibility of their therapeutic effect. Moreover, financing for these steps in the new therapeutic field of regenerative medicine is particularly scarce, due to lack of established business and regulatory models. The challenge is to overcome these hurdles to in-patient research and to determine the potential of new regenerative therapies.

Scope: Proposals should target regenerative medicine therapies which are ready for clinical (in-patient) research and should focus on one specific clinical phase of work. Any stage of clinical work (e.g., first in man, late stage trial, observational study) may be proposed though later stages are preferred; clinical work should represent the core of the proposal. To justify the clinical work proposed, phase I proposals must present appropriate preclinical and toxicology data, and later phase proposals must present appropriate preliminary results.

Proposals should include authorization to conduct clinical trials and ethical approvals or provide evidence of regulatory engagement and that such approval is close. Preference will be given to proposals which 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. Proposers should also justify why the therapy proposed is regenerative and how it represents a new approach compared to any existing treatment. Sex and gender differences should be investigated, where relevant. To

allow an adequate coverage in the field of regenerative medicine, proposals should take into account the projects previously funded under this topic in Horizon 2020[20].

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:

- Obtain results by means of in-patient regenerative medicine research that allows new therapies to safely reach the next level of testing or medical practice.
- 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 for development of new therapeutic options.
- Lever existing investments in fundamental research into regenerative medicine.
- Develop new approaches to currently untreatable diseases.

Type of Action: Research and Innovation action

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

1.4 ACTIVE AGEING AND SELF-MANAGEMENT OF HEALTH

Proposals are invited against the following topic(s):

SC1-PM-12–2016: PCP - eHealth innovation in empowering the patient

Specific Challenge: Empowering the hospitalised patients, outpatients and their families/carers to support a continuum of care across a range of services can relieve the pressure on governments to provide more cost-effective healthcare systems by improving utilisation of healthcare and health outcomes. The support for patients should be understood broadly covering a continuum of care in hospital, in outpatient care, and integration back to working life. For example rare diseases are particularly difficult to manage far from specialised centres. The eHealth action plan 2012-2020[21] and the outcome of the mHealth Green paper[22]pave the way towards empowerment of the patient with the assistance of ICT.

[20] Project abstracts will be provided on the call page on the Participant Portal.

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

Scope: : Actions that focus on enabling the transition to new services or better integration of existing services through appropriate ICT based technologies using relevant elements e.g., proof of concept, user acceptance, use of the service, training of the professionals including online courses/forums that bring professionals and patients together, trust and security and consent of the patient. These strategies should allow communication to happen by increasing the level of interactions between the patient and the health professionals or informal carers, sharing of data and enabling the users to stay in control of their health condition and to adhere to prescribed medical plans and contribute to increasing the effectiveness of interventions. Examples of services could contain but not limited to:

i) telemedicine services to follow patients e.g., with chronic or rare diseases after hospital discharge, and to interact with patients, carers and health professionals;

ii) e-mental health for patient empowerment with self-management tools and blended care; and

iii) domestic rehabilitation (both physical and cognitive) procedures under remote professional supervision.

Proposals should aim to develop a common language between patient and health care professionals, increase patient health and IT literacy, and foster individual patient empowerment giving the patient tools to take major life decisions and actively participate on the treatment and recovery from the disease. ICT solution should address relevant ethics and gender aspects and should also address related regulatory questions such as ownership of data, data protection/privacy and consumer protection. Open innovation with patients or/and informal carers could be included as an integral part of the concept.

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

- Improve the quality and cost-effectiveness of healthcare systems by challenging industry from the demand side to develop innovative solutions that: increase the role and the responsibility of the patient, support self-management; reduce the number of severe episodes and complications; enhance the ICT skills and increase adherence of patients and care givers; strengthen the evidence base on health outcomes and management of comorbidities; increase the information about disease progression with advanced diagnostic techniques; provide early and predictive data about patient disease; reduce the number of unproductive visits to the hospital; and implement intensive rehabilitation programs at home when appropriate

[22] http://ec.europa.eu/digital-agenda/en/public-consultation-green-paper-mobile-health

- Reduced fragmentation of demand for innovative solutions to facilitate PCPs of expected minimum value of EUR 3 million by leveraging resources, encouraging among others also synergies with Structural Funds

- Increase the opportunities for solution uptake across wider international procurement markets by aiming at interoperable solutions that are validated through field testing by participating procurers in multiple countries across Europe and contribution to standardisation where relevant

- Equal access rights to the results generated by the PCP for all procurers jointly undertaken a PCP aiming for a fair and transparent level playing field for modernizing public services

Type of Action: Pre-Commercial Procurement

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

SC1-PM-13–2016: PPI for deployment and scaling up of ICT solutions for active and healthy ageing

Specific Challenge: The fast growing ageing population in Europe is bringing new demand-side pressures on public health and care providers. These pressures undermine the long-term sustainability of existing models of delivering care services to the ageing population.

The challenge is to scale up innovative solutions, which have been tested and have demonstrated success in smaller scale settings and that have not yet been deployed on a large scale, by contributing to collaborative efforts in public purchasing of innovative ICT-based solutions for active and healthy ageing. These include inter alia integrated care and active ageing solutions, independent living solutions and telecare, support for self-care and person-centred care. Moreover, take-up of these ICT-based solutions by both public care providers as well as people in need for care is a crucial factor in successfully alleviating the demand-side pressures on public health and care provision.

Scope: This topic will contribute to the Scaling Up Strategy[23] of the European Innovation Partnership on Active and Healthy Ageing and to boosting the Silver Economy and Digital Single Market in Europe. The actions supported will target deployment of active and healthy ageing solutions at large scale across different regions in Europe.

In line with the priority actions of the Scaling-up Strategy, the scope of the PPI pilot(s) is to specify, purchase and deploy ICT based solutions for active and healthy ageing which can deliver sustainable, new or improved services in which public procurement approaches for innovative solutions are successfully applied.

[23] European Scaling-up Strategy in Active and Healthy Ageing: https://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/scaling_up_strategy.pdf

Proposals should:

- Be driven by clearly identified procurement needs of the participating organisations and building on a complete understanding of the needs of the ageing population, as well as the needs of the relevant health and care providers;
- Support sustainable deployment of new or improved services by providers involved in the procurement of solutions for active and healthy ageing;
- Contribute to the creation of scalable markets across Europe in innovative solutions for active and healthy ageing;
- Specify measures that will ensure the sustainability of solutions beyond the lifespan of the proposed project;
- 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;
- Be based on a complete set of common specifications for end to end services;
- Demonstrate that the implementation phase will reach "large scale" (i.e. sufficient scale to achieve statistical significance) through region-wide deployment across multiple regions of Europe;
- Contribute to the use of interoperable solutions based on open platforms and take into account existing best practices and standardisation initiatives;
- Provide robust safeguards to ensure compliance with ethical standards and privacy protections and take account of the gender dimension;
- Contribute good practices to be made available for replication across other regions (e.g. "detailed plans" for larger scale sustainable uptake of innovative solutions for active and healthy ageing, reference material and guidelines, manuals and education materials).

The European Commission considers that proposals requesting a contribution from the EU of between EUR 2 and 5 million would allow this specific challenge to be addressed appropriately through PPI. This does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Growing awareness and successful use of public procurement to boost ICT innovation applied to active and healthy ageing, ultimately benefiting the growing ageing population across Europe;

- Contribution with data and experiences to regulatory and legislative process development addressing potential barriers to procurement of innovative solutions for active and healthy ageing;

- Contribution of an open and comprehensive socio-economic evidence base for ICT investments in the field that can support the development of sustainable business models (e.g. cost-benefit analysis, increased efficiency of health and care systems, impact assessments, return on investments, quality of life improvements for users, ethics, safety gain and user satisfaction);

- Support initiatives on interoperability and standardisation that can contribute to defragmentation of the market for ICT based active and healthy ageing solutions;

- Creation of economic boundary conditions that can support long-term sustainability of health and care systems and emergence of new business models to develop ICT innovation for active and healthy ageing in Europe;

- Support forward-looking, concerted public-sector investment strategies that benefit from joint approaches across different regions;

- Create new opportunities for market uptake and economies of scale for the supply side for ICT based solutions and services for active and healthy ageing in a Digital Single Market for Europe.

- Contribute to inform policy measures that foster the take-up of ICT solutions for active and healthy ageing.

Type of Action: Public Procurement of Innovative solutions

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

SC1-PM-14–2016: EU-Japan cooperation on Novel ICT Robotics based solutions for active and healthy ageing at home or in care facilities

Specific Challenge: Citizens in ageing European and Japanese populations wish to stay in their homes for as long as possible. They are however at risk of age related impairments such as poor health, 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.

Scope: The call will address joint research and innovation proposals for developing and demonstrating advanced ICT Robotics based solutions for extending active and healthy ageing in daily life.

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. Gender and ethical issues should be paid due attention.

1. In order to support older people in ordinary daily life at home and in care facilities, proposed solutions should be driven by the needs, interests and lifestyles of older people through personalised and self-adaptable human-robot interaction. The proposed solutions should also provide a sense of stability and comfort, and reduce the burden on caregivers in time and labour costs.

2. The proposed solutions should further develop and build upon open platforms[24] and Internet of Things approaches. There should be a system integration approach between robotics devices, intelligent living environments, which can support novel service delivery models, including the integration of robots, home (indoor) sensor networks, and handling of big data and IoT data in the cloud.

3. The proposed work should develop novel service models for facilitating prolonged independent living and support prevention of care/efficient delivery of care in accordance with the proposed applications and services (such as maintenance of cognitive function or well-being etc.) and improvements in social situation (living assistance and reduction of isolation and loneliness etc.) and empowering older people to make the most of their remaining faculties (engaging in housework and hobbies etc.) and reducing the burden on caregivers.

4. The proposed application fields should demonstrate how solutions can be designed to allow for adaptation towards different histories and cultures across the EU and Japan and a variety of individual perception and preferences and cognitive capabilities.

5. There should be realistic test sites in both the EU and Japan with sufficient users involved to validate the expected benefits and impact.

6. In order for the ICT robotics service to be accepted in real life, it is necessary to ensure Ethical, Legal, and Social Issues (ELSI). Appropriate consideration on ELSI is required in both the EU and Japan.

7. In order to spread services, extensive use of generalized infrastructures such as a cloud system and open sources are required.

[24] An open platform describes a software system which is based on open standards, such as published and fully documented external application programming interfaces (API) that allow using the software to function in other ways than the original programmer intended, without requiring modification of the source code. Using these interfaces, a third party could integrate with the platform to add functionality. The opposite is a closed platform. An open platform does not mean it is open source, however most open platforms have multiple implementations of APIs. Proposers are encouraged to work with open platforms like FIWARE and UniversAAL where relevant.

Without limitations of specific application or hardware system, platform developments are required to ensure interoperability under appropriate standardization and ongoing (expected) one.

The European 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:

- To extend the independence and autonomy of older persons in need of care for example through reduction of admissions and days spent in care institutions, and prolongation of time spent living in own home when ageing with emerging functional and/or mental impairments.
- To provide high quality service corresponding to the needs in daily lives of older persons.
- To improve quality of life of older persons and their carers.
- To reduce caregivers burden due to work sharing with robots and supplement/complement human resources in care service provision allowing consecutive services such as 24-hour ones.
- Improvement of efficiency in care provision.
- Global leadership in advanced solutions supporting active and healthy ageing

Type of Action: Research and Innovation action

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

SC1-PM-15-2017: Personalised coaching for well-being and care of people as they age

Specific Challenge: The activity aims at developing and validating radically new ICT based concepts and approaches for empowering and motivating people in need of guidance and care due to age related conditions, in cooperation with their carers where relevant, and to help them improve and maintain their independence, functional capacity, health status as well as preserving their physical, cognitive, mental and social well-being.

Scope: Proposals should develop a proof of concept of radically new solutions for a personalised "virtual coach", building upon intelligent ICT environments, access to relevant physiological and behavioural data, new forms of accessible interaction based on tangible user

interaction concepts, open platforms[25] and emotional computing. Usability and ease of user interaction should be essential design elements of the "coach".

The "coach" should provide personalised advice, guidance and follow-up for key age related issues in daily life which impact the person's ability to remain active and independent, for example diet, physical activity, risk avoidance, preventive measures, lifestyle and activity management, leisure, social participation and overall wellness. The goal should be to preserve physical, cognitive, mental and social well-being for as long as possible and to facilitate interaction with carers (where relevant).

Solutions should build on and apply multi-disciplinary research and include intelligent algorithms beyond state-of-the-art capable of reasoning, autonomous learning and adaptation to personal needs, emotional and behavioural patterns, conditions and preferences as well as the users' living environment and their social connections. Solutions should be integrated seamlessly in existing every-day activities and provide desired information in fast and efficient manner. Attention theft by ICT (consuming too much of the user's time) should be avoided.

Proposals should address relevant ethics and gender aspects and should also assess related legal and regulatory questions such as ownership of data, data protection/privacy, liability and consumer protection. It is crucial that users are involved and drive the innovation at all stages of design and development, including user acceptability, satisfaction and impact in realistic settings.

The Commission considers that proposals requesting a contribution from the EU of between EUR 3 and 4 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 proposal should present methodologies and metrics as appropriate for measuring its progress towards the expected impact in:

- Usefulness and effectiveness of personalized recommendations and follow-up in terms of the goals of preserving physical, cognitive, mental and social well-being for as long as possible;
- Validation of non-obtrusive technology for physical, cognitive, social and mental well-being;
- Evidence of user-centred design and innovation, new intuitive ways of human-computer interaction, and user acceptance;
- Potential cost-effectiveness due to enhanced self-care, life-style and care management.

Type of Action: Research and Innovation action

[25] Proposers are encouraged to work with open platforms like FIWARE and UniversAAL where relevant.

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

1.5 METHODS AND DATA

Proposals are invited against the following topic(s):

SC1-PM-16–2017: In-silico trials for developing and assessing biomedical products

Specific Challenge: In biomedical, pharmaceutical and toxicology research, the safety and efficacy of biomedical products are ultimately tested on humans via clinical trials after prior laboratory testing in vitro and/or in vivo on animal models. The complete development chain of a new biomedical product and its introduction to the market is very long and expensive. Alternative methodologies to reduce the animal and human testing are needed in order to answer both the ethical issues and the imperfection of predictions issued from laboratory and animals when applied to humans. Computer modelling and simulation is currently used to a certain degree in pharmacokinetics, pharmacodynamics or mechanical simulations (e.g. fluid dynamics simulations). A research and technological roadmap for "in-silico clinical trials" is currently being developed. Preliminary results show the strong interest/potential benefit to expand the computer-modelling in drugs and other biomedical products including bioactives, medical foods research by developing new ways for in-silico testing.

Scope: Proposals will develop innovative in-silico trials for designing, developing and assessing drugs, radiation and other biomedical and bioactive products. They will build on comprehensive biological and biomedical knowledge management and advanced modelling paradigms in order to be able to simulate the individual human physiology and physiopathology at the biological levels relevant for the biomedical product under study (at the cell level, tissue level or organism level) and the interaction with the product, thus taking into account the variability among individuals (for example, molecular pathways, cellular microenvironments, microbiota, genetics, gender characteristics, behaviours, comorbidities, development, diet). Virtual populations of individual patients will be built for simple or composite diseases, for example, from the patient-specific models by variations of different parameters and will allow simulating the action of the products and predicting the treatments outcomes in order to develop a personalised medicine approach. The proposed in-silico trials will be the result of a multidisciplinary effort (e.g. within the fields of computational modelling, systems biology, tissue mechanics, biology, pharmaceutics, medicine) and will also explore and inform of the reasons of fails and suggest improvements. To help establishing such computer simulated trials, measures for validation (human trials, animal studies, validation in cell cultures) of the in-silico models shall also be included in the proposed projects. The benefit for human health, environment and animal welfare should be analysed and quantified. Contact with regulators and consideration of the regulatory framework issues are highly recommended.

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:

- Reducing the size and the duration of the human clinical trials
- A more effective human clinical trials design
- Leading to a significant reduction of animal testing
- Innovative medical products on the market with lower development costs and/or shorter time-to-market
- Improving prediction of human risks for new biomedical products including medical foods
- Improving drug repositioning
- Potential of re-use of the developed in-silico models in the chemical testing.
- Setting standards for in-silico trials.
- Providing libraries of virtual patients that can be re-used in pre- and post-competitive testing of biomedical products

Type of Action: Research and Innovation action

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

SC1-PM-17–2017: Personalised computer models and in-silico systems for well-being

Specific Challenge: There is continuous progress in systems medicine, multi-scale modelling and patient-specific modelling aspects. But these opportunities have been inconstantly explored for the entire chain of health and disease. Thus, there are very few in well-being, prevention or rehabilitation while these areas are crucial for reducing healthcare needs, building sustainable healthcare and for assuring a healthy and motivated workforce. More, innovative methods are needed for better understanding and analysing brain, neurobiological and the gut-brain axis and the stress-related disorders or whole body data (e.g. where the development of multiscale and high spatiotemporal resolution imaging methods are critical) and their interactions with social, environmental, lifestyle, occupational, economic etc. factors that promote well-being and health. Well-being is a consequence of resilience to challenges and illness and of better prevention adapted to predispositions and behaviours (including

gender), of better consideration given to the functional troubles, of better recovery and rehabilitation after illness.

Scope: Proposals should aim at the development of new integrative dynamic computer-models and simulation systems of acceptable validity, with the potential to being reused, build on open service platforms and with application in well-being, health and disease. The projects have to support computer modelling and simulations able to aggregate various information sets e.g. molecular, biochemical, medical imaging, social, lifestyle, economic, occupational, microbiome, environmental, developmental, psychological, gender etc. into robust predictors for resilience in coping with and overcoming challenges and stresses and for recovery after challenges and illness. They will process and apply individual/patient-specific information in a multi-scale approach required for integrating information at a certain biological level within a wider context (at least one biological level from molecule to entire body). Proposals will focus on multi-disciplinary research in medicine, SSH and ICT and should take advantage when relevant of existing large databases in clinical medicine, biomedical or occupational research, environmental sciences, Social Sciences and Humanities (SSH), so enabling and facilitating the accumulation and relinking of complex and heterogeneous data collections. The models integrated in these multi-scale and multi-disciplinary approaches will have their predictive capability validated by state-of-the-art clinical and/or laboratorial studies and/or against large health registries. Whenever relevant, proposals will integrate data collected over time in order to inform on individual trajectories with periods of well-being and periods of illness and on the heterogeneity of resilience and recovery that can be different during the individual lifetime.

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:

- Benefit for health and well-being: new personalised interventions for increasing resilience and recovery.
- Advancements in medical computer-modelling and simulation that takes into account time and spatial scales.
- Supporting predictive and preventive approaches in medicine, neurosciences and life sciences.
- Improving knowledge about well-being and association with life circumstances.

Type of Action: Research and Innovation action

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

SC1-PM-18–2016: Big Data supporting Public Health policies

Specific Challenge: A defining characteristic of today's data-rich society is the collection, storage, processing and analysis of immense amounts of data. This characteristic is cross-sectorial and applies also to healthcare. Big Data is generated from an increasing plurality of sources and offers possibilities for new insights, for understanding human systems at the systemic level to develop personalised medicine, prevent diseases and support healthy life. Primary sources are new eHealth personal solutions, but can be extended also to more generic and commercial instruments, like mobile apps for health and well-being. In addition, social networks can be considered for integrating the social dimension in the analysis of health and well-being scenarios. It is important to assure ethical aspects of data, confidentiality, anonymity of data transfer and engagement of those who collect/ code such data in its analysis and interpretation, in order to avoid misinterpretation and inappropriate conclusions. Greater involvement of those who work within healthcare systems, patients and the public is needed.

Scope: Rather than improving existing isolated systems, proposals should focus on how to better acquire, manage, share, model, process and exploit the huge amount of data to develop integrated solutions that support public health authorities of Member States and associated countries in particular in healthcare system management, long-term policy making and increase the ability to provide actionable insights at the point of care. Relevant solutions include, for example, systems for determining and monitoring the combined effects of environment, lifestyle and genetics on public health, enabling early identification of effects, both on women and men, that can have large impacts on health including lifestyle and provision of healthcare – both short term and long term as well as when interaction with other public sectors is required (e.g. physical planning). Focus should also be on the governance of Big Data in order to use it proficiently across organisations and at policy levels. Integrated solutions should include suitable approaches towards securing security and privacy issues.

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

Expected Impact:

- Mapping comprehensive big data in a reachable and manageable way by applying principles for sharing and reusability, creating a network of knowledge by linking heterogeneous data sources for public health strategy;
- Emerging data driven analytics and advanced simulation methods to study causal mechanisms and improve forecasts of spatial and temporal development of ill-health and disease;
- Develop innovative approaches to improve current risk stratification methodologies;

- Turning large amounts of data into actionable information to authorities for planning public health activities and implementation of an approach "health in all policies";
- Placing prevention strategies on evidence base, evaluation of the efficiency and effectiveness of implemented strategies, feedback of results into the development of methods;
- Analysing the efficiency of patient pathway management both at primary care level (prevention and early detection) and *en route* encompassing;
- Aligning big data and advanced simulation methods in order to provide high-leverage policy analysis for public health officials, across a range of epidemiology challenges;
- Cross-border and networking coordination and technology integration facilitates interoperability among the components of Big Data value chain.

Type of Action: Research and Innovation action

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

SC1-PM-19–2017: PPI for uptake of standards for the exchange of digitalised healthcare records

Specific Challenge: The use of interoperability standards is essential to the wider deployment of an EU eHealth single market. Despite previous Framework Programmes investments, there is still a profound lack of deployed interoperability between healthcare systems and services delivering healthcare and a need to stimulate the public procurement of eHealth solutions and integrated care services addressing complex organisational structures and interactions among people (recipients of care, care-givers, and others).

Scope: Proposals should address as primary aim public procurement of innovative solutions (PPI) to facilitate the deployment of an eHealth infrastructure taking into consideration the European eHealth Interoperability Framework and EU guidelines adopted by the eHealth Network. The PPI(s), and any accompanying innovation activities in particular by participating procurers themselves to facilitate the uptake of newly developed solutions, should focus on clear target outcomes such as allowing the sharing of health information, the use of semantically interoperable Electronic Health Records (EHRs) for safety alerts, decision support, care pathways or care coordination. The scope of the PPI(s) is to specify, purchase and deploy innovative ICT based solutions which can deliver sustainable, new or improved healthcare services across organisational boundaries while implementing eHealth interoperability standards and/or specifications (e.g. EN13606, HL7, Continua Alliance, IHE...).

The Commission considers that proposals requesting a contribution from the EU of between EUR 3 and 4 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:

- Wider uptake of eHealth interoperability standards
- Increased suppliers opportunities from wider market uptake of innovative solutions and services by forming a critical mass on the public demand side
- Better solutions specifications designed from a demand side perspective
- More forward-looking, concerted, public sector approach to eHealth interoperability
- Achieve the wider deployment of eHealth services
- Create a European role model in the eHealth interoperability field
- Increasing jobs in health and ICT and contributing to economic growth in the EU in the long-term
- Support forward looking, concerted public-sector investment strategies that benefit from jointly implementing PPIs across different countries around Europe

Type of Action: Public Procurement of Innovative solutions

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

SC1-PM-20-2017: Development of new methods and measures for improved economic evaluation and efficiency measures in the health sector

Specific Challenge: This topic will be developed during the course of 2016.

Type of Action: Research and Innovation action

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

1.6 HEALTH CARE PROVISION AND INTEGRATED CARE

Proposals are invited against the following topic(s):

SC1-PM-21-2016: Implementation research for scaling-up of evidence based innovations and good practice in Europe and low- and middle-income countries

Specific Challenge: Research evidence and technological and process improvements during the past decades present a large opportunity for improving the functioning and sustainability of health systems[26]. However, the uptake of well-researched and proven interventions addressing current challenges is still slow. Implementation research on scaling up evidence-based innovations and good practices intervention should facilitate the transferability of these practices across the borders of Europe and beyond.

Scope: Based on the concept of implementation research[27], proposals should seek to replicate and scale up a comprehensive intervention in the field of health systems that is innovative and well-researched, supported by sufficient documented evidence. This scaling up can take place within Europe as well as outside it, notably in low- and middle-income countries (LMIC). The topic does not cover micro-level interventions, e.g. to promote a specific therapeutic regimen for a single disease.

The selected intervention to be scaled up should be one that has proven to make health systems and health services more responsive, person-centred, safe, effective, and efficient. Its stated impact should be broad, addressing economic and social benefits and its effect on reducing inequalities. The research should identify the facilitators of and barriers to scaling-up, including context-specific factors and differing social and health systems environments in Europe or in LMIC.

Proposals should be multidisciplinary and relevant gender aspects should be taken into account. They also should reflect and take advantage of the regional diversity across Europe and/or the diversity of LMIC settings. Relevant stakeholders and end-users of research should be identified and involved throughout the project lifetime. Innovative approaches towards gathering their inputs for the scaling up process should be considered, notably of patients when relevant.

The organisational and resource requirements (data, personnel and financing) necessary for the implementation of the intervention must be tracked and evaluated in detail. The research and system-wide scientific monitoring should allow future users (researchers, healthcare providers, policy makers, and the public) to review the step-by-step, partial outcomes of the intervention, thus facilitating a wider adoption of these practices. The appropriate contextual, financial and political-economy[28] analysis should be provided.

---

[26] A health system consists of all organizations, people and actions whose primary intent is to promote, restore or maintain health (WHO)

[27] The scientific study of methods to promote the uptake of research findings (Walker AE, 2003). Process modelling in implementation research. doi:10.1186/1472-6963-3-22)

[28] "Political economy analysis is concerned with the interaction of political and economic processes in a society; including the distribution of power and wealth between groups and individuals, and the processes that create, sustain and transform these relationships over time" (OECD –DAC)

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:

- A larger group of citizens benefits from the studied health system intervention. The intervention should lead to improving the functioning and sustainability of health systems, and greater health equity and additional societal benefits.
- A validated framework and strategy for a large-scale implementation of an effective and safe evidence-based health systems intervention will be available to healthcare providers and policy makers that will facilitate the transferability of these practices.
- In the medium and long-term, the health systems will be more effective, efficient and equitable; health services are more responsive to the needs of users.

Type of Action: Research and Innovation action

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

COORDINATION ACTIVITIES

Proposals are invited against the following topic(s):

SC1-HCO-01-2016: Valorisation of FP7 Health and H2020 SC1 research results

Specific Challenge: Over 1,000 projects have been funded under the Health theme of the Seventh Framework Programme (FP7, 2007-2013) and close to 100 projects are already supported under the Societal Challenge 1 of Horizon 2020. These projects have and will lead to breakthrough discoveries and innovations with a potential for further valorisation and exploitation. The translation of research and innovation outcomes into new diagnostics or medicines and improved health outcomes for patients is however hampered by the scattering of knowledge generated across public and private research organisations in Europe. Although Technology Transfer Offices (TTOs) have developed tools to promote their organisations' innovations, there is potential for increased critical mass and visibility of these EU FP7 Health and Horizon 2020 SC1 projects' outcomes.

Scope: The objective of this coordination and support action is to develop a European web marketplace referencing all types of innovations such as patents, licensing opportunities, prototypes, products, technologies or services with a potential for future exploitation and/or commercialisation, primarily generated by FP7 Health and Horizon 2020 SC1 programmes.

The marketplace should become a one-stop-shop between innovation providers (mainly academic research organisations) and innovation developers (such as SMEs, midcaps and larger companies, EU research infrastructures). The further assessment and/or validation of any high-value discovery shall not be performed within the framework of the proposal.

Further exploitation should be widely promoted to innovation developers; therefore the proposal should detail how it intends to incentivise academia, TTOs, SMEs and the healthcare sector at large to ensure a broad use, exploitation and feeding of the marketplace in Europe. The proposal should include a solid monetization strategy to ensure sustainability of the marketplace after the end of the project.

TTOs with proven track records in exploitation of research results as well as business development departments from healthcare companies should be involved in the consortium to ensure a coherent and consistent approach between innovation providers and innovation developers. Special attention should be given to project outcomes in low performing Member States and Associated Countries[29]. Benchmarking of existing initiatives at European, Member States or international level (such as Enterprise Europe Network or the United States National Institutes of Health (NIH) Office of Technology Transfer) is a prerequisite. This benchmarking should contribute to identifying best practices, rightly positioning contents and services of the marketplace, as well as defining Key Performance Indicators that will be monitored throughout the deployment of the marketplace.

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:

- Development of a sustainable one-stop-shop innovation marketplace promoting primarily EU FP7 Health and Horizon 2020 SC1 project outcomes
- Demonstrate clear impact of the marketplace in stimulating in- and out-licensing activity from TTOs, SMEs, and large pharmaceutical companies (ADD)
- Identify innovative, sustainable business models increasing the attractiveness of the marketplace, especially towards SMEs

[29] As defined by Widening Participation and Spreading Excellence: Member States below 70% of the EU average of the Composite Indicator of Research Excellence. The Composite indicator of Research Excellence (with a corrective threshold of 70% of the EU average) has been selected to distinguish those countries identified as "low R&I performing" or "widening" countries. These are:
− Member States: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia and Slovenia.
− Associated Countries (subject to valid association agreements of third countries with Horizon 2020): Albania, Bosnia and Herzegovina, Faroe Islands, Former Yugoslav Republic of Macedonia, Moldova, Montenegro, Serbia, Turkey and Ukraine.

- Identification and promotion of scientific discoveries as well as advice on possible value-adding strategies

Type of Action: Coordination and support action

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

SC1-HCO-02-2016: Standardisation of pre-analytical and analytical procedures for in vitro diagnostics in personalised medicine[30]

Specific Challenge: Standards are part of the knowledge economy that facilitate innovation and the adoption of new technologies. They are key elements of the competitiveness of European industry. They can improve safety and performance of products and services. Patients would benefit from the standardisation of in vitro diagnostic practice.

Progress in medical diagnostics is limited by insufficient guidelines for pre-analytical procedures and diagnostic services. The accuracy of measured values may be hampered by deficiencies of pre-analytical steps (sample collection, handling, etc.) and poor harmonisation and quality assurance of diagnostic practice (not all diagnostic laboratories are even accredited ISO15189).

Scope: Provide pan-European quality assurance schemes and guidelines for pre-analytical procedures - such as sample collection, handling, transportation, processing and storing of clinical samples - and/or harmonisation and quality assurance of diagnostic practice.

The proposal should contribute to accreditation and certification, and participate in standardization activities at European level. Interaction with the European Metrology Programme for Innovation and Research (EMPIR) should be considered as appropriate. Outcomes could be coordination of validation studies, assessment of the results of method validations, training, counselling, quality procedures and guidelines.

Involvement of industry, including SMEs, and organizations for standardisation is expected.

The Commission considers that a proposal requesting a contribution from the EU of around EUR 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:

[30] Personalised medicine refers to a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) 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 term "personalised medicine" is used throughout this Work Programme with this definition in mind.

- Harmonisation and quality assurance of in vitro "diagnostic" procedures for disease diagnosis, patient stratification and/or prognosis of disease outcome leading to improved clinical decisions and health outcomes for the benefits of patients.

- Contribution to the sustainability of health care systems by reducing the number of diagnostic mistakes.

- Growth and benefit to the European diagnostics industry, in particular SMEs.

Type of Action: Coordination and support action

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

SC1-HCO-03–2017: Implementing the Strategic Research Agenda on Personalised Medicine

Specific Challenge: By providing the right intervention to the right person at the right time, personalised medicine[31] can improve quality of life and contribute to more sustainable healthcare at Member State level. It may drive new and faster development processes and products, providing European life sciences industries with a competitive edge that can secure growth and jobs. Today, development is uneven across and within sectors, regions and Member States due to fragmented activities, insufficient communication and lack of commonly accepted solutions and standards.

The FP7 funded coordination and support action "Personalised Medicine 2020 and beyond – Preparing Europe for leading the global way (PerMed)[32]" was launched in 2013 with the objective to develop a Strategic Research Agenda to progress personalised medicine in Europe. PerMed partners have strived to focus their strategy on concrete research actions, many of which should be addressed through transnational collaborative health research.

An ERA-NET Cofund action is therefore a suitable and timely tool to implement relevant parts of PerMed's Strategic Research and Innovation Agenda[33], which will be published in 2015.

Scope: Proposals should pool the necessary financial resources from the participating national (or regional) research programmes with a view to implementing a joint call for proposals resulting in grants to third parties with co-funding in this area.

---

31 Personalised medicine refers to a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) 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 term "personalised medicine" is used throughout this Work Programme with this definition in mind.

32 www.permed2020.eu

33 Available at http://www.permed2020.eu/1428.php

This call should aim at implementing a key area of the PerMed Strategic Research Agenda and be complementary with other funding programmes and activities at European and international level. Proposers are encouraged to include other joint activities including additional joint calls without EU co-funding. This work should be informed by the output of the coordination and support action envisaged in topic SC1-HCO-05-2016 - Coordinating personalised medicine research, without duplicating any of its work.

The proposed ERA-NET 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. Participation of international partners is highly welcome.

The Commission considers that a proposal requesting a contribution from the EU 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:

- Deepened and extended coordination of national and transnational research in the field of personalised medicine.
- 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 such as ESFRI infrastructures

Type of Action: ERA-NET Cofund

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

SC1-HCO-04–2016: Towards globalisation of the Joint Programming Initiative on Antimicrobial resistance

Specific Challenge: The Joint Programming Initiative on antimicrobial resistance (JPIAMR) was established in 2011 to enable the participating EU Member States and other countries supporting this initiative to work together to address the rise in antibiotic resistance that threatens human and animal health. Throughout the past four years, the JPIAMR has proven to be an important tool for the establishment of a European Research Area in this field. The JPIAMR launched its strategic research agenda (SRA) in 2014. The JPIAMR is currently implementing this SRA via alignment of national activities and launching transnational research calls.

An immediate challenge for the JPIAMR is to move towards a global initiative. In this context, the JPIAMR should capitalize on the current momentum to take the necessary steps for securing its sustainability by Member States, to extend globally and mobilize the EU Members States which are not yet participating in the JPIAMR. A sustainable structure should allow the JPIAMR to progressively move from coordination to integration of national research activities, to further develop its visibility at global level, and to facilitate greater innovation to address AMR.

Scope: Proposals should support the development and extension of the JPIAMR capacities. In particular, resources should be used to:

- Explore possible scenarios for long-term sustainability by Member States, implement the most appropriate scenarios to ensure full self-sustainability at the end of this project, and create political awareness for implementation. The proposal should also dedicate resources to develop and implement a dedicated structure responsible for the long-term JPIAMR management and implementation;

- Extend the capacities of the JPIAMR to the Members States which are not yet participating in the initiative. For this purpose, the proposal should dedicate resources to develop a strategy to attract and raise awareness of the missing EU Member States. This should include identification of available national research and innovation resources in the area of antimicrobial resistance;

- Attract global capacities towards JPIAMR and dedicate resources to implement its global strategy. This should include awareness raising and the development of a strategy to attract non-EU countries to join the initiative including low and middle income countries. In addition to this, the JPIAMR should play a key role in supporting the implementation of the WHO global action plan on antimicrobial resistance and the development of a global SRA.

- Develop and implement current and new strategies for further coordination of national AMR action plans, research agendas and activities, and in particular for the take-up of JPIAMR strategies and policies at national level. This should clearly demonstrate the leverage effect of the JPIAMR. In this context, the proposal should dedicate resources to develop and implement initiatives for knowledge management, brokerage and transfer, as well as establishing collaborations with other initiatives or partners at European and global level;

- Provide innovative strategies for the creation of infrastructures and tools to facilitate more rapid uptake of data and methodologies for research on antimicrobial resistance in the EU and beyond;

- Facilitate building networks of industrial and academic experts to boost industrial innovation in the field of antimicrobial research in Europe in collaboration with IMI.

The proposal should not duplicate work already covered under the ERA-NET (HCO 11 – 2015). 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:

- Reinforcing the JPI scheme as a major tool for the achievement of the European Research Area;
- Implementing a stronger global dimension of the JPIAMR, aligned with the WHO global action plan on antimicrobial resistance;
- Increased multiannual commitment of JPIAMR members, long-term sustainability of the JPIAMR research and innovation strategy, and long-term structuring effect and critical mass mobilization;
- Achieving coordination and integration of national research and innovation programmes with the JPIAMR research strategy in coherence with Horizon 2020 objectives;
- Faster international progress for research and innovation on antimicrobial resistance through the development of novel research tools and infrastructures;
- Increasing efficiency of research and innovation investments by European Member States by avoiding duplication of research and infrastructure investment at national level;
- Awareness and potential extension of the JPIAMR to missing EU Member States, as well as non-EU Member States;
- Further establishing the JPIAMR as a reference for European and global knowledge and innovation platform in the area of antimicrobial resistance.

Type of Action: Coordination and support action

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

SC1-HCO-05–2016: Coordinating personalised medicine research

Specific Challenge: By providing the right intervention to the right person at the right time, personalised medicine[34] can improve quality of life and contribute to more sustainable healthcare at Member State level. It may drive new and faster development processes and

[34] Personalised medicine refers to a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) 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.

products, providing European life sciences industries with a competitive edge that can secure growth and jobs. Today, development is uneven across and within sectors, regions and Member States due to fragmented activities, insufficient communication and lack of commonly accepted solutions and standards.

Scope: Support the development and operations of a European platform for collaboration between funders of personalised medicine research, possibly based on the International Consortium model[35]. The platform should coordinate research and innovation efforts across borders, regions and countries. It should foster an interdisciplinary approach to personalised medicine by actively involving relevant interested parties. It should develop policies, guidelines, etc. aiming to speed up the development and implementation of personalised medicine (addressing policy-related, economic, and socio-cultural factors). The platform should aim to create synergies with ongoing activities at European and national level (e.g. research infrastructures[36], ERA-NETs, personalised medicine pilot projects, EIT Health KIC[37]). It should moreover explore the best use of funds in the implementation of personalised medicine. It should actively disseminate information and best-practice examples and contribute to awareness raising in the medical professions (accelerating the reshaping of academic curricula) and among the general public. The proposal should explore scenarios for long-term sustainability.

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

- Improved coordination across and within regional, national and pan-European research funding programmes and initiatives.
- Faster development of personalised medicine approaches through the development of frameworks for research priorities, policies and guidelines aimed at accelerating research and implementation efforts.
- Development of a framework for linking established research efforts, platforms, infrastructures such as biobanks or databases, building synergies between ongoing activities.
- Increased information exchange between sectors and scientific disciplines.
- Increased public awareness and understanding of personalised medicine approaches among the public and the medical professions.

35 See for example the International Rare Diseases Research Consortium (IRDiRC -www.irdirc.org) or the International Human Epigenome Consortium (IHEC – www.ihec.org).

36 http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=esfri

37 http://eit.europa.eu/eit-community/eit-health

- Improved use of funds in the implementation of personalised medicine.

Type of Action: Coordination and support action

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

SC1-HCO-06–2016: Towards an ERA-NET for building sustainable and resilient health system models

Specific Challenge: Currently, public health-related research, whether population health or health services research, is fragmented, not coordinated and not aligned across the European Union. There is a need to render investments in public health research more efficient, learn from each other and better capitalise on the on-going so called 'natural experiments' in Europe. While some public health problems are specific to countries, and health care systems are different. Member States still face many similar challenges. There are many public health problems common to most countries, such as the burden posed by chronic diseases, multi-morbidity or obesity, and mental health issues. Many countries are considering innovative solutions in order to achieve a better design of services and interventions throughout the entire chain of care, including public health and prevention. It implies, among others, strategies for strengthening community care and primary care in relation to social care and prevention, redesigning hospital care and de-institutionalising long term care with more care provided closer to home. This implies placing more emphasis on self-management of patients and new ways of linking health and social care. There are many opportunities to learn from one another on what works best under what conditions, agreeing on what issues could be best researched jointly, and where the problems are more localized. This is an opportunity of capitalizing on existing know-how and to draw on comparative advantages in European research, thus enhancing innovation.

Scope: To pave the way to an ERA-NET co-fund action for building sustainable and resilient health systems models, this coordination and support action (CSA) will develop a structured system of exchange of information between public health research funders and other relevant bodies, as well as academia, in order to establish synergies and avoid duplication. It will further facilitate the development of a strategic research agenda taking into account the diversity which exists within Europe. This agenda will identify at least a number of measurable, performance enhancing, scientific-technological or socio-economic objectives, supported by an appropriate analysis.

This action implies the preparation and organisation of meetings as well as support to information exchange with relevant stakeholders groups and with the public at large.

The proposed action should ensure a broad geographical representation of European countries.

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:

- Build on the communalities of existing knowledge gathering in past EU and national level studies, thus ensure a better use of limited resources.
- Identification of common research priorities and research needs, also taking into account developments at the international level where relevant.
- Development and alignment of national and regional plans.
- Sharing of data, metadata, knowledge and best practice.

Type of Action: Coordination and support action

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

SC1-HCO-07–2017: Global Alliance for Chronic Diseases (GACD)

Specific Challenge: Topic details will be developed in line with the timetable of the GACD priority setting process and will be provided during the course of 2016.

Type of Action: Research and Innovation action

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

SC1-HCO-08–2017: Actions to bridge the divide in European health research and innovation

Specific Challenge: Despite serious efforts deployed at national and European level, the European Union sees significant internal disparities in terms of research and innovation performance as also identified in the Innovation Union Scoreboard. The disparities are equally present in health research and innovation and this call seeks solutions specifically adapted to this domain.

The European Commission has been funding projects to analyse the roots of the divide in European health research and innovation (HCO-14 2014) and wishes to continue efforts in closing the gap.

Scope: Any type of activities that can help less performing countries and regions to build capacities and exploit opportunities to eventually increase their participation in EU funded collaborative projects can be supported.

Beneficiaries of the activities should be low performing[38] Member States/regions that have identified health R&I as a priority in their Research and Innovation Strategies for Smart Specialisation (RIS3). Applicants shall seek synergies with European Structural and Investment Funds, the operational programmes and support from managing authorities.

The proposals will propose concrete measures for tackling structural barriers to health research and innovation, including those related to capacity, skills, policy, regulatory environment, and economic and socio-cultural factors including gender equality issues and gender dimension in research content.

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 action should demonstrate good practice on how synergies between Structural Funds and Horizon 2020 can be exploited in the health R&I domain. This shall contribute to increased Horizon 2020 participation of low performing regions.

Type of Action: Coordination and support action

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

SC1-HCO-09–2016: EU m-Health hub including evidence for the integration of mHealth in the healthcare systems

Specific Challenge: Exchange of best practices and innovation monitoring are essential to support wider deployment of mHealth solutions on non-communicable diseases (NCDs) within Member States or countries associated to Horizon 2020.

Evidence on mHealth effectiveness to help support the management of non-communicable disease still remains fragmented in Europe, as illustrated by the results to the Green Paper consultation on mobile Health.

An EU innovation hub would enable wider collaboration among EU researchers and private stakeholders in mHealth. This could become the "right arm" of EU action in mHealth by streamlining efforts in research and innovation, passing the difficult stage from research to large scale deployment.

Scope: The core activities of the 'innovation hub for mHealth' should focus on fostering research and innovation in mHealth and bolster policy making efforts in implementing mHealth strategies tailored to the need of the European countries and regions involved.

[38] As defined by Widening Participation and Spreading Excellence: Member States below 70% of the EU average of the Composite Indicator of Research Excellence.

The hub should act as a convening platform to bring together experts and innovators for institutionalising best practices in mHealth whilst avoiding the creation of silos and fragmentation in mHealth knowledge across the EU.

Emphasis should be put on the development of a multi-stakeholder ecosystem targeted at increasing collaboration between various stakeholders such as researchers, national, regional, local authorities, and mHealth manufacturers, supported by a central resource that tracks innovation and best practices and identifies gaps in policy while fostering cross-border knowledge sharing among Member States or countries associated to Horizon 2020.

The hub should gather evidence on health outcomes, quality of life, care efficiency gains of mHealth solutions to support treatment and prevention of NCD through the creation of a central database, and/or integration of existing databases, that will constitute a repository of all evidence on mHealth effectiveness and benefits, including common criteria and methodology for comparing mHealth solutions, best practices and innovative solutions, business models/reimbursements, governance and oversight of apps with specific solutions targeting identified groups: vulnerable populations and with chronic diseases.

The action may involve financial support to third parties in line with the conditions set out in Part K of the General Annexes. The selection process open to relevant health authorities and innovation institutes in the EU Member States or countries associated to Horizon 2020 should be defined. Transparency and a good geographical balance should be ensured. The hub will help to fully implement mHealth programmes or strategy of selected third parties, for which financial support will be granted.

Comparison of solutions and situations in the database between different countries and regions should be made in order to identify specific contextual links as well as to identify opportunities for exchange of knowledge and experience on mHealth best practices and solutions.

In the longer term, the hub should aim to become self-sustaining and therefore develop measures of sustainability, while seeking at covering the whole territory of the European Union.

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

Expected Impact:

- Creating evidence on health outcomes, quality of life and care efficiency gains in the NCD management by using mHealth solutions.
- Enabling mHealth to be deployed in national and regional level health services and to deliver large scale benefits, first of the selected entities and later in the rest of Europe.

- Becoming the focal point for expertise on mHealth in the EU and identifying and highlighting trends and gaps in policies, standards, regulations, etc. and best practices and barriers to the creation of consistent mHealth infrastructure and strategy.

- Unique platform to support innovation in and up-scaling of mHealth by convening cross sector stakeholders (young entrepreneurs, start-ups, governments, technical officers etc.).

- Creating synergies with the existing EU platforms of stakeholders such as eHealth network of Member States and also the EU EIP on Active and Healthy Ageing. (requirement, scope, impact)

Type of Action: Coordination and support action

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

SC1-HCO-10–2016: Support for Europe's leading Health ICT SMEs

Specific Challenge: The business environment and sustainable business models for eHealth SMEs have been a major challenge when introducing innovations in new healthcare delivery. Helpful findings are already available in similar support measures, e.g., Get eHealth[39], iLink[40] and existing private support activities for SMEs.

Scope: The scope is co-ordinating post R&D and offering support for developing business models, improving the maturity of the new products emerging from Europe's leading Health ICT SMEs, developing a pro-innovation approach to address legal conditions in Europe and globally on a case-by-case basis. The selected project will build up and maintain a support structure for the SMEs including but not limited to the following elements:

a) Support for networked opportunities in collaboration with high calibre third parties

b) eHealth specific networking events organised by the project

c) Support for training of the staff of the SMEs

d) Professional assistance improving the maturity of the business for further investment purposes

e) Support addressing legal challenges

f) Support addressing issues related to registration and certification.

Synergies between the Enterprise Europe Network and the relevant sector groups are encouraged.

[39] Delivering Growth to eHealth business,http://www.get-ehealth.eu/

[40] European Network of ICT Law Incubators,http://lincup.eu/

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

Expected Impact:

- Evidence of positive business outcome based on e.g., networking activities and ecosystems including various types of business opportunities (e.g., venture and crowd funding, European Investment Fund).
- Demonstration of success with the investors.
- Reduction of market failures.
- Successful business models including sustainable co-operation with the demand side in the value chain.
- Increased useful options for patients and citizens to manage their health.
- Optimisation of the efficiency and effectiveness of healthcare provision, personalised medicine/personalised health and consumer health across Europe.
- Successful legal outcome fostering the innovation in eHealth sector.
- Self-sustaining support structures for eHealth SMEs.

Type of Action: Coordination and support action

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

SC1-HCO-11–2016: Coordinated action to support the recognition of Silver Economy opportunities arising from demographic change

Specific Challenge: The ageing of European populations coincides with the increasing digitalisation of both, the economy and the society. The emerging European Silver Economy offers numerous opportunities for digital solutions to help address the ageing challenge and to create new socio-economic opportunities.

Despite becoming an increasingly large section of Europe's population very often older adults remain an "overlooked demographic", underserved by products and services that do not meet their particular needs.

Developing products, services and solutions for the older population is not naturally perceived as an attractive proposition by some of the most talented innovators and (social) entrepreneurs. Very often the negative connotation of "old-age" reduces the talent-pool of entrepreneurs that could be engaged in developing ICT solutions for active and healthy

ageing. It also hampers the attractiveness of capital investment channelled into active and healthy ageing solutions already developed and finally reduces significantly the market up-take of innovative solutions for active and healthy ageing.

The challenge is to reward excellence in innovative products and services for the ageing population, and highlight the opportunities that a growing ageing population can generate for entrepreneurs, investors, public authorities and civil society interested in developing new products, services and solutions.

Scope: This shall be achieved by establishing a widely recognised European annual award scheme for innovative solutions which can demonstrate a significant impact improving the quality of life of the ageing population, for both women and men, and sustaining a viable and promising business model.

This Annual award will bring together all relevant societal actors and economic sectors to create a pan-European movement that acknowledges and exploits the opportunities brought about by demographic change and innovation.

The proposal should develop and implement an integrated communication and innovation concept, built upon this annual European award scheme promoting the best examples of ICT innovation for active and healthy ageing, addressing key stakeholders and sectors of the Silver Economy, such as advertising, innovative consumer products and services, age-friendly workplaces, age friendly living environments etc.

Specific issues to be addressed include:

- Identification of the most relevant categories of awards (products, services and solutions, supporting uptake of ICT innovation for active and healthy ageing);
- Establishment of a high-level selection jury which can ensure widespread recognition of the movement and award scheme;
- Implementation of an annual European award scheme with high visibility;
- Identification of award sponsors and securing commitment including funding;
- Achieving a considerable number of high-quality applications for the awards;
- Effective engagement of key stakeholders and dissemination of awarded projects across Europe on the basis of a positive narrative for demographic change and ICT innovation;
- Effective engagement of and networking with similar initiatives within Member States;
- Establishment and implementation of a methodology for tracking the outreach and impact of the award scheme;

- Mobilisation of (social) entrepreneurs, social partners, citizens, grass-roots initiatives, designers, brands, retailers, industrial operators, researchers, innovators, investors and other societal actors.

The proposal should present ways to promote and reward innovative and creative ideas that tap into the potential that lies in an ever growing number of active, healthy, mobile and solvent older citizens. Ideas may be found in enterprises, social innovation initiatives, local and regional governments.

The proposal can cover partly or fully the funding dedicated to the award itself during the first year of the project with the aim of attracting other sponsors for a long-term establishment of the award scheme. Until alternative long-term funding sources are defined and secured, proposals may use a share of the action budget during the project for the provision of financial support to third parties in the form of an award in line with the conditions set out in Part K of the General Annexes.

It must be clearly demonstrated how this action promotes the opportunities arising from demographic change and how it will build on existing EU and national networks and fora in the area (e.g. Horizon 2020, EIP-AHA, AAL JP, JPI MYBL, EIT Health, national strategies on demographic change, research networks…).

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 proposal should present quantitative and qualitative metrics for measuring its progress towards the expected impact in:

- Sustainable establishment and widespread recognition of a European Silver Economy Innovation Award scheme.
- Encouraging further innovation and entrepreneurship to improve the quality of life of the ageing population
- Increased interest by social entrepreneurs, investors, retailers, brands, designers, and public authorities in supporting the development of innovation for active and healthy ageing.
- Increased public awareness about the opportunities and potential of demographic change and innovation across Europe.

Type of Action: Coordination and support action

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

SC1-HCO-12–2016: Digital health literacy

Specific Challenge: Citizens' digital health literacy is an essential element for successful eHealth deployment. However, citizens often do not have the necessary skills to understand and appraise online health information and apply their knowledge to make health decisions. Digitally health literate citizens are empowered to play a more active role in their health management (improved self-management) and will be better informed about health issues. Digital health literacy can also help improve prevention and adherence to a healthy lifestyle, improve the use of pharmaceutical products enhance the safe and proper use of medicines, strengthen the patient involvement and empowerment, and finally improve health outcomes.

Scope: Proposals should provide support for the improvement of digital health literacy of citizens. In particular, proposals should design open access online courses ("MOOCs") for different population cohorts including children and the elderly and other high-risk patient groups, supporting an interactive learning environment. These courses should ensure user-friendliness and involve citizens to co-design, test and implement learning modules that would help them improve their digital health literacy skills. The courses should be designed tailored to users' needs based on a strong understanding and projections of key factors, drivers, barriers and trends of the future that affect digital health literacy, be targeted specifically to citizens with low levels of digital health literacy and take into account and quantifying demographic, social, cultural and gender differences and address critical and/or interactive skills and competencies, as well as support peer learning. The work should also articulate a roadmap roll-out, simulate system level changes and detail the most appropriate policy actions for ongoing enablement.

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

Expected Impact:

- Increased awareness of the opportunities of eHealth tools and enhanced skills on how to use ICT for health-related purposes in order to obtain better health outcomes and safer care;
- A better understanding for citizens of online information on health-related topics and a better understanding of health, disease and their own capacity of intervention, including how to decrease the risks of self-medication and self-treatment;
- Positive impact at the personal level (knowledge, motivation, self-confidence, stronger feelings of control), involvement and empowerment;
- Strengthened evidence base on health outcomes, quality of life, safety of care, care efficiency gains from a more digitally health literate population;

- Improved adherence to a healthy lifestyle, to a preventive approach and to more empowered lifestyle choices.

Type of Action: Coordination and support action

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

SC1-HCO-13-2016: Healthcare Workforce IT skills

Specific Challenge: Healthcare systems require a robust supply of both highly proficient eHealth/IT professionals as well as an overall workforce that has a sufficient level of IT skills to make the optimum use of eHealth information technology. There is a shortage in the EU of eHealth workers across the full spectrum of job roles, spanning clinical, social care, informatics, and administration. There is a dearth of structured education and training opportunities to address this shortage.

Scope: Proposals should focus on mapping, quantifying and projecting the need, supply and demand of workforce skills and competencies to develop IT skills and training programmes for the healthcare workforce taking into account the EU-US collaboration underway in this area under the EU-US MoU eHealth Roadmap[41] and other international cooperation in this area. The work should identify how key factors and trends will be investigated, the different scenarios the system and eHealth workforce face, quantify and model these futures as well as describe how the most robust policies to deliver the desired impacts and outcomes will be investigated. They should also demonstrate knowledge of systematic workforce investigations including skills and competences existing curricula and training, identify gaps and propose solutions to bridge them. A series of case studies in some of the areas where IT already has an impact on the provision of health services, will support the proposed solutions in the most critical areas for example in primary health care, monitoring of chronic diseases, high risk patient care and geriatry. A familiarity with the ICT Skills' European eCompetence Framework for healthcare is also important.

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

Expected Impact:

- Mapping of the current knowledge structure, identification and quantification of the main trends and gaps, catalysts and barriers in IT skills and training needs of the healthcare workforce for optimum use of eHealth solutions;

[41] http://ec.europa.eu/digital-agenda/en/news/transatlantic-ehealthhealth-it-cooperation-roadmap

- Improved access to training programmes, including continuous professional development, and upgrading of skills for all types of actors in healthcare workforces;
- Assessment of the effectiveness of training strategies and requirements for provision of programmes in different scenarios;
- Strengthened international collaboration in the area of healthcare professionals IT skills including contributions to the actions of the EU-US MoU eHealth Roadmap and better informed policy decisions.

Type of Action: Coordination and support action

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

SC1-HCO-14–2016: EU-US interoperability roadmap

Specific Challenge: In order to implement the EU-US interoperability roadmap, activities including inter-alia piloting and standardisation activities need to be put in place. Further actions would be needed to implement recommended measures, taking into account the importance to have a convergent EU-US approach.

Scope: The main objective remains to achieve one single international standard for the patient summary and the possibility to establish pilots that will validate the principles established within the roadmap. The proposal should focus on the need to develop an interoperability framework taking into account the EU-US collaboration underway in this area under the EU-US MoU eHealth Roadmap[42] and other international cooperation in this area. Consortium partners should demonstrate familiarity with transatlantic cooperation, standardisation process and ability to implement the activities outlined in the EU-US roadmap.

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 below the indicative budget.

Expected Impact:

- Improved international interoperability of eHealth Systems in the US and in Europe.
- Accelerated establishment of interoperability standards in eHealth and of secure, seamless communication of health related data.

Type of Action: Coordination and support action

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

[42] http://ec.europa.eu/digital-agenda/en/news/transatlantic-ehealthhealth-it-cooperation-roadmap

SC1-HCO-15-2016: EU eHealth Interoperability conformity assessment

Specific Challenge: This coordination and support action (CSA) aims at maintaining and developing the adoption and take-up of testing of eHealth standards and specifications as defined in the eHealth European Interoperability Framework (eEIF).

Scope: The proposal should aim at the establishment of a sustainable European Conformance Assessment Scheme associated with the maintenance of the eEIF, fostering a wider eHealth interoperability uptake for the entire European market.

The CSA relies on some of the recommendations of the EU funded ANTILOPE project. In particular, the proposal is expected to put in place a conformity scheme which should allow entities to test the capabilities of its healthcare products and related services in any accredited testing laboratory against the requirements of a set of standards and profiles that are recognized and listed in the eHealth EIF. This conformity scheme should ensure consistent testing results across testing laboratories and a suitable corresponding trusted label/certificate should be considered. It is expected that the proposal will bring together a wide range of relevant stakeholders with expertise in the development, implementation, assessment, maintenance and dissemination of such a conformity scheme.

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 below the indicative budget.

Expected Impact:

- Develop a core eHealth interoperability conformity scheme for the European market based on the eHealth EIF
- Enable healthcare systems suppliers to assess their conformance to the eHealth EIF and advertise such compliance to procurers
- Help procurers in their solution specifications and evaluation
- Facilitate the development and testing of cross-border, national, and regional eHealth projects
- Setting common criteria for effective benchmarking of different European eHealth implementations

Type of Action: Coordination and support action

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

SC1-HCO-16-2016: Standardisation needs in the field of ICT for Active and Healthy Ageing

Specific Challenge: The area of ICT for active and healthy ageing (AHA) is a new cross-sectorial domain in which standards play a key role. Standardisation efforts in the area tend to be taken by the different domains' actors individually, often lacking a coordinated and targeted approach. Different national/regional initiatives, labels and standards are emerging in some of the related fields, which could potentially make interoperability difficult and impede or reduce scalable growth opportunities. Therefore, an action needs to be established that links together the standardisation needs from the different domains and addresses them in a coordinated way.

This action will support progress within the Silver Economy overall, since it will be directly contributing to its different sectors such as age-friendly environments, smart houses and integrated care. It will thus provide support to the other Active and Healthy Ageing topics published in this Work Programme.

Scope: The proposal is expected to foster user-centred ICT innovation on AHA by engaging, supporting and coaching stakeholders to develop and implement their actions in the area of standardisation. They should cover standardisation within the area of AHA, in particular in the domains of ICT infrastructures for the implementation and delivery of services for independent living in age-friendly buildings, scaling-up of innovative care services and interoperability profiles for independent living[43].

Relevant activities at national and EU level, as well as by industry should be taken into account.

In order to comprehensively support relevant stakeholders in implementing their actions in the field of standardisation, proposals should clearly address the following:

- Mapping of the relevant harmonisation activities in the area and relevant on-going developments, focusing on standardisation efforts;
- Fostering cooperation between standard development organisations active in the field of AHA;
- Establishing a platform to facilitate discussion and decision-making among relevant stakeholders on the actions to be taken in the field of standardisation in ICT for AHA;
- A clear approach for how to engage relevant stakeholders throughout the action;

[43] Interoperability profiles describe specific solutions to interoperability in a specific use case scenario. A profile documents how standards will be used in order to achieve interoperability. Profiles ensure implementers and users are talking about the same solution without having to restate all the technical details that establish actual interoperability.

- Identifying harmonisation and standardisation needs in the field of ICT for AHA and the best ways to address them through the various existing mechanisms such as standards, specifications, requirements, procurement, legislation, etc.;
- Providing guidance on best practise in co-developing standards and certificates within the covered areas, such as age-friendly environments;
- Providing guidance on procurement and coaching on how to best exploit the opportunities to foster innovation in the field of AHA;
- Identifying the relevant major standardisation actors and their potential contribution on the needs identified;
- Coordinating relevant contributions to AHA standardisation from EU (and national) funded R&I projects.

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:

- Engagement of required stakeholders to ensure lasting impact;
- Identification of standardisation and other types of harmonisation needs and creation of a clear roadmap with actions needed to address them;
- Accelerated progress in the establishment of favourable framework conditions for introducing user-friendly ICT solutions for AHA into the European market and a metrics for measuring the progress;
- Elaboration of a first draft for smart / age-friendly home guidelines and roadmap for the development of a certification or label;
- Networking and match-making among stakeholders, including R&I projects and relevant standardisation bodies.

Type of Action: Coordination and support action

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

Conditions for the Call - Personalised Medicine

Opening date(s), deadline(s), indicative budget(s):[44]

Topics (Type of Action)	Budgets (EUR million)		Deadlines
	2016	2017	
Opening: 20 Oct 2015			
SC1-PM-14–2016 (RIA)	5.00		19 Jan 2016
SC1-HCO-09–2016 (CSA)	3.00		16 Feb 2016
SC1-HCO-10–2016 (CSA)	3.00		
SC1-HCO-11–2016 (CSA)	1.00		
SC1-HCO-12–2016 (CSA)	2.00		
SC1-HCO-13-2016 (CSA)	0.50		
SC1-HCO-14–2016 (CSA)	1.00		
SC1-HCO-15-2016 (CSA)	1.00		
SC1-HCO-16-2016 (CSA)	1.00		
SC1-PM-12–2016 (PCP)	18.00		
SC1-PM-13–2016 (PPI)	10.50		

[44] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
All deadlines are at 17.00.00 Brussels local time.
The Director-General responsible may delay the deadline(s) by up to two months.
The deadline(s) in 2017 are indicative and subject to a separate financing decision for 2017.
The budget amounts for the 2016 budget are subject to the availability of the appropriations provided for in the draft budget for 2016 after the adoption of the budget 2016 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.
The budget amounts for the 2017 budget are indicative and will be subject to a separate financing decision to cover the amounts to be allocated for 2017.

SC1-PM-18–2016 (RIA)	10.00		
SC1-HCO-01-2016 (CSA)	2.00		13 Apr 2016
SC1-HCO-02-2016 (CSA)	2.00		
SC1-HCO-04–2016 (CSA)	2.00		
SC1-HCO-05–2016 (CSA)	2.00		
SC1-HCO-06–2016 (CSA)	2.00		
SC1-PM-01-2016 (RIA)	30.00		
SC1-PM-04–2016 (RIA)	30.00		
SC1-PM-05–2016 (COFUND-EJP)	50.00		
SC1-PM-06–2016 (RIA)	40.00		
SC1-PM-09–2016 (RIA)	60.00		
SC1-PM-11–2016-2017 (RIA)	30.00	30.00	
SC1-PM-21-2016 (RIA)	40.00		
Opening: 29 Jul 2016			
SC1-PM-02-2017 (RIA)		40.00	04 Oct 2016 (First stage) 11 Apr 2017 (Second stage)
SC1-PM-07–2017 (RIA)		20.00	
SC1-PM-08–2017 (RIA)		60.00	
SC1-PM-10–2017 (RIA)		40.00	
SC1-HCO-03–2017 (ERA-NET-Cofund)		5.00	11 Apr 2017
SC1-HCO-07–2017 (RIA)		24.00	

SC1-HCO-08–2017 (CSA)		1.00	
SC1-PM-03–2017 (RIA)		15.00	
SC1-PM-20-2017 (RIA)		9.00	
Opening: 20 Sep 2016			
SC1-PM-15-2017 (RIA)		25.00	31 Jan 2017
Opening: 08 Nov 2016			
SC1-PM-16–2017 (RIA)		19.00	14 Mar 2017
SC1-PM-17–2017 (RIA)		19.00	
SC1-PM-19–2017 (PPI)		8.26	
Overall indicative budget	346.00	315.26	

Beneficiaries will be allowed to charge the cost of clinical trials on the basis of unit costs established in line with a methodology set up in the Commission Decision (C2014) 1393, which is available on the Participant Portal. This applies to topics SC1-PM-01-2016, SC1-PM-02-2017, SC1-PM-03–2017, SC1-PM-04–2016, SC1-PM-06–2016, SC1-PM-07–2017, SC1-PM-08–2017, SC1-PM-09–2016, SC1-PM-10–2017, SC1-PM-11–2016-2017, SC1-HCO-01-2016, SC1-HCO-02-2016, SC1-HCO-03–2017, SC1-HCO-04–2016, SC1-HCO-06–2016, SC1-HCO-07–2017, SC1-HCO-08–2017, SC1-PM-13–2016, SC1-PM-14–2016, SC1-PM-15-2017, SC1-PM-20-2017, SC1-PM-21-2016, , SC1-HCO-11–2016 and SC1-HCO-16-2016.

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission.

For two stage procedure:

- Information on the outcome of the evaluation: Maximum 3 months from the final date for submission for the first stage and maximum 5 months from the final date for submission for the second stage; and

- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission of the second stage.

Exceptional funding rates:

SC1-PM-13–2016, SC1-PM-19–2017	The funding rate for PPI actions is limited to 35% of the total eligible costs to leverage co-financing from the procurers in this specific case.
SC1-PM-12–2016	The funding rate for PCP actions is limited to 90% of the total eligible costs to leverage co-financing from the procurers in this specific case.

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

SC1-HCO-01-2016, SC1-HCO-02-2016, SC1-HCO-03–2017, SC1-HCO-04–2016, SC1-HCO-06–2016, SC1-HCO-07–2017, SC1-HCO-08–2017, SC1-HCO-10–2016, SC1-HCO-11–2016, SC1-HCO-12–2016, SC1-HCO-13-2016, SC1-HCO-14–2016, SC1-HCO-15-2016, SC1-HCO-16-2016, SC1-PM-01-2016, SC1-PM-02-2017, SC1-PM-03–2017, SC1-PM-04–2016, SC1-PM-06–2016, SC1-PM-07–2017, SC1-PM-08–2017, SC1-PM-09–2016, SC1-PM-10–2017, SC1-PM-11–2016-	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 these topics.

2017, SC1-HCO-02-2016, SC1-HCO-03–2017, SC1-PM-14–2016, SC1-PM-15-2017, , SC1-PM-16–2017, SC1-PM-17–2017, SC1-PM-18–2016, SC1-PM-20-2017, SC1-PM-21-2016,	
SC1-PM-14–2016	Additional admissibility criterion: • Participants in the EU collaborative projects are required to conclude a coordination agreement with the participants in the coordinated project funded by MIC (Ministry of Internal Affairs and Communications) or NICT (National Institute of Information and Communications Technology). A final draft of this agreement has to be provided with the proposal. Additional eligibility criteria: • Proposals submitted to this call which do not include coordination with a Japanese proposal will be considered ineligible. • The proposed project duration shall not exceed 36 months. • The Japanese authorities can consider non-eligible proposals with participation of partners from third countries (countries other than Japan, EU and Associated states). Consultation to MIC or NICT representatives is highly advisable before submitting proposals involving third country organisations. • Proposals will only be selected on the condition that their corresponding coordinated Japanese project will be funded by MIC or NICT.

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

SC1-PM-14–2016	Criterion 3 "Quality and efficiency of the implementation": additional evaluation sub-criterion: Balanced effort between the two coordinated projects and a research plan properly involving coordinated research activities between Europe and Japan, that ensure a more genuine EU-Japan cooperation and represent an

	added value to the activities.
SC1-PM-01-2016, SC1-PM-02-2017, SC1-PM-03–2017, SC1-PM-04–2016, SC1-PM-06–2016, SC1-PM-07–2017, SC1-PM-08–2017, SC1-PM-09–2016, SC1-PM-10–2017, SC1-PM-11–2016-2017, SC1-PM-14–2016, SC1-PM-15-2017, SC1-PM-16–2017, SC1-PM-17–2017, SC1-PM-18–2016, SC1-PM-20-2017, SC1-PM-21-2016	The thresholds for each criterion in a single stage process will be 4, 4 and 3. The cumulative threshold will be 12. The same applies to the second stage of the Two-stage call for topics SC1-PM-02-2017, SC1-PM-07–2017, SC1-PM-08–2017, and SC1-PM-10–2017,

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

SC1-PM-05–2016	The page limit for sections 1-3 of the proposal is 70 pages.

The full evaluation procedure is described in the relevant guide published on the Participant Portal.

Consortium agreement: Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.

FAST TRACK TO INNOVATION PILOT

Full details on this pilot are provided in the separate call for proposals under the Horizon 2020 Work Programme Part – Fast Track to Innovation Pilot (Part 18 of this Work Programme).

SME INSTRUMENT

Full details on the continuously open SME instrument call (*H2020-SMEInst-2016-2017*) are provided under the Horizon 2020 Work Programme Part – Innovation in SMEs (Part 7 of this Work Programme).

This Work Programme part contributes the following two challenges of the SME instrument call:

SMEInst-05-2016-2017 - Supporting innovative SMEs in the healthcare biotechnology sector

Specific Challenge: The healthcare biotechnology sector offers huge business and commercial opportunities; however it also requires heavy and risky investments which are often lacking in Europe, hampering the development of the industry.

The challenge includes either:

a) Cell technologies in medical applications (all phase 1 and phase 2 deadlines in 2016 and 2017)

Cell technologies include cell manufacturing (culture, multiplication, scale-up and automation), preservation, banking and transport; identification, cell sorting and delivery, imaging, tracking, process and quality control; genetic engineering and gene editing; production of therapeutic biomolecules. The medical applications of cell technologies include diagnostics and biosensors; cell and gene therapy, tissue engineering, bio-artificial organs, haematology, immunotherapy, and vaccine and antibody production; predictive toxicology, synthetic biology, and modelling development and disease processes.

However, the diversity, complexity and variability of living cells pose challenges for bringing safe, reliable, regulatory-compliant and cost-effective products to the market and to the patient. SMEs developing cell-based products and processes have limited financial resources to take the critical steps to move from proof of concept to practical application while at the same time addressing considerations such as scale-up/scale-out, automation, logistics, regulatory pathways and business models.

Particular attention should be given to dialogue with regulators and compliance with safety and regulatory requirements, such as those pertaining to cell procurement, GMP, ethics, clinical trials, ATMPs and medical devices.

The challenge addresses cells from any eukaryotic source though their eventual application must be to human medicine.

Or:

b) Clinical research for the validation of biomarkers and/or diagnostic medical devices (only in 2017 and for phase 2 applications - phasing out of the topic PHC-12-2014/2015 introduced in the Work Programme 2014-2015)

Biomarkers are used in clinical practice to indicate both normal and pathological conditions. They are also used for predictive or prognostic purposes. They are being used increasingly in medicine and many potential new biomarkers are proposed every year. However, only a few of these have been validated for clinical use. To achieve validation a robust analytical method is required and a link to a pertinent clinical process or endpoint needs to be demonstrated.

This validation process should provide evidence for high analytical value, appropriate sensitivity and specificity, and clinical validity. Particular attention should be given to validation of biomarkers with potential for rapid uptake into clinical practice. Both in vivo and in vitro potential biomarkers are eligible. Priority is given to the validation of disease-related biomarkers (i.e. diagnostic, susceptibility/risk, monitoring and prognostic biomarkers). Validation of the clinical performance of new diagnostic devices can also be supported, either in combination with the biomarker validation or against existing standards.

Scope: The SME instrument consists of three phases, including a coaching and mentoring service for beneficiaries. Participants can apply to phase 1 or directly to phase 2.

In phase 1, a feasibility study shall be developed in order to verify the technological/practical as well as economic viability of an innovation idea/concept with considerable novelty to the industry sector in which it is presented (new products, processes, design, services and technologies or new market applications of existing technologies). The activities could, for example, comprise risk assessment, market study, user involvement, Intellectual Property (IP) 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. The proposal should contain an initial business plan based on the proposed idea/concept. It should outline the specifications of a more elaborate business plan, which is to be the outcome of the project, and the criteria for success.

Funding will be provided in the form of a lump sum of EUR 50.000. Projects should last around 6 months.

In phase 2, innovation projects[45] will be supported that address the specific challenges identified 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,

[45] In the case of SMEInst-05-2016-2017, research type activities in medical application and clinical validation, including support for clinical studies and trials, will be predominant and will necessitate reimbursement at 100%.

service etc.) to industrial readiness and maturity for market introduction, but may also include some research. For technological innovation, Technology Readiness Levels of 6 or above (or similar for non-technological innovations) are envisaged[46]; please see part G of the General Annexes.

Proposals shall be based on an elaborate business plan. Particular attention must be paid to IP protection and ownership; applicants will have to present convincing measures to ensure the possibility of commercial exploitation ('freedom to operate').

Proposals shall contain a specification for the outcome of the project and criteria for success. They will include an explanation of how the results of the supported project are to be commercialised and of what kind of impact on the company is expected.

The Commission considers that proposals requesting a contribution from the EU of between EUR 0.5 and 2.5 million[47] would allow phase 2 to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts (higher or lower). Projects should last between 12 and 24 months.

Phase 3 of the SME Instrument aims to increase the economic impact of the funding provided by the SME Instrument phase 1 and 2 grants and by the business innovation coaching and mentoring support. Phase 3 is not subsequent to phase 1 and/or 2, but provides specific support to SME instrument beneficiaries during and after phase 1 or 2.

All support under phase 3 of the SME instrument will be accessible through a single, dedicated entry point, which will serve as an information portal and a networking space.

This platform will offer access to two main strands of services:

- Access to markets
- Access to finance

In addition, phase 3 will create opportunities for partnering, networking and training, which are set out in the Other Actions of the Work Programme.

SME instrument beneficiaries are also offered dedicated business innovation coaching and mentoring support. This service is facilitated by the Enterprise Europe Network (EEN) and delivered by a dedicated coach through consultation and signposting to the beneficiaries. The coaches are recruited from a central database managed by the 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

[46] Since TRLs are not commonly used in the health research and development sector, TRLs do not need to be referred to in proposals to the Health Challenge (SMEInst-05-2016-2017)

[47] In the case of SMEInst-05-2016-2017, phase 2 proposals can request a contribution from the EU of between EUR 1 and 5 million.

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.

Expected Impact:

- 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[48].
- Market uptake and distribution of innovations tackling the specific challenges in a sustainable way.
- Increase of private investment in innovation, notably leverage of private co-investor and/or follow-up investments.
- The expected impacts should be clearly described in qualitative and quantitative terms (e.g. on turnover, employment, market seize, IP management, sales, return on investment and profit).

Type of Action: SME Instrument

SMEInst-06-2016-2017 - Accelerating market introduction of ICT solutions for Health, Well-Being and Ageing Well

Specific Challenge: The challenge is to help overcome the current gaps in exploitation of promising research results in ICT for Health, Well-being and Ageing well and to stimulate increased availability and market uptake of relevant ICT products and services. This concerns both interoperable and secure eHealth[49] solutions for consumers and institutional healthcare delivery building on standards and new ICT solutions and innovation ecosystems for ageing well building on open software platforms[50], in order to deliver new and more efficient care to European citizens and respond to new market opportunities for SMEs.

[48] In the case of SMEInst-05-2016-2017, the development of innovative solutions should lead to value creation through the increased use of cell-based products/processes, biomarkers and/or diagnostic medical devices in industrial or clinical settings, and should contribute to technical and regulatory progress in these domains.

[49] eHealth in Digital Agenda, see http://ec.europa.eu/digital-agenda/ehealth;
eHealth projects - Research and Innovation in the field of ICT for Health and Wellbeing: an overview, see https://ec.europa.eu/digital-agenda/en/news/ehealth-projects-research-and-innovation-field-ict-health-and-wellbeing-overview

[50] An open platform describes a software system which is based on open standards, such as published and fully documented external application programming interfaces (API) that allow using the software to function in other ways than the original programmer intended, without requiring modification of the source code. Using these interfaces, a third party could integrate with the platform to add functionality. The opposite is a closed platform. An open platform does not mean it is open source, however most open platforms have multiple implementations of APIs.

Particular attention should be given to potential for disruptive innovation and fast market uptake in ICT for health, wellbeing and ageing well. In particular it will be interesting for SMEs and young companies that are looking for swift support to their innovative ideas.

Scope: The SME instrument consists of three phases, including a coaching and mentoring service for beneficiaries. Participants can apply to phase 1 or directly to phase 2.

In phase 1, a feasibility study shall be developed in order to verify the technological/practical as well as economic viability of an innovation idea/concept with considerable novelty to the industry sector in which it is presented (new products, processes, design, services and technologies or new market applications of existing technologies). The activities could, for example, comprise risk assessment, market study, user involvement, Intellectual Property (IP) 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. The proposal should contain an initial business plan based on the proposed idea/concept. It should outline the specifications of a more elaborate business plan, which is to be the outcome of the project, and the criteria for success.

Funding will be provided in the form of a lump sum of EUR 50.000. Projects should last around 6 months.

In phase 2, innovation projects will be supported that address the specific challenges identified 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.) to industrial readiness and maturity for 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; please see part G of the General Annexes.

Proposals shall be based on an elaborate business plan. Particular attention must be paid to IP protection and ownership; applicants will have to present convincing measures to ensure the possibility of commercial exploitation ('freedom to operate').

Proposals shall contain a specification for the outcome of the project and criteria for success. They will include an explanation of how the results of the supported project are to be commercialised and of what kind of impact on the company is expected.

The Commission considers that proposals requesting a contribution from the EU of between EUR 0.5 and 2.5 million would allow phase 2 to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts (higher or lower). Projects should last between 12 and 24 months.

Phase 3 of the SME Instrument aims to increase the economic impact of the funding provided by the SME Instrument phase 1&2 grants and by the business innovation coaching and mentoring support. Phase 3 is not subsequent to phase 1 and/or 2, but provides specific support to SME instrument beneficiaries during and after phase 1 or 2.

All support under phase 3 of the SME instrument will be accessible through a single, dedicated entry point, which will serve as an information portal and a networking space.

This platform will offer access to two main strands of services:

- Access to markets
- Access to finance

In addition, phase 3 will create opportunities for partnering, networking and training, which are set out in the Other Actions of the Work Programme.

SME instrument beneficiaries are also offered dedicated business innovation coaching and mentoring support. This service is facilitated by the Enterprise Europe Network (EEN) and delivered by a dedicated coach through consultation and signposting to the beneficiaries. The coaches are recruited from a central database managed by the 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.

Expected Impact:

- 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.
- Market uptake and distribution of innovations tackling the specific challenges in a sustainable way.
- Increase of private investment in innovation, notably leverage of private co-investor and/or follow-up investments.
- The expected impacts should be clearly described in qualitative and quantitative terms (e.g. on turnover, employment, market seize, IP management, sales, return on investment and profit).

Type of Action: SME Instrument

Other actions[51]

1. Subscription fee: Human Frontier Science Programme Organisation

An annual subscription to the international Human Frontier Science Programme Organisation (HFSPO)[52] will allow EU non-G8 Member States to fully benefit from the Human Frontier Science Programme (HFSP) and provide increased visibility for European research, as well as contributing to the implementation of the Union's strategy for international cooperation[53] in research and innovation.

Type of Action: Subscription

Indicative timetable: 2016 and 2017

Indicative budget: EUR 4.96 million from the 2016 budget (precise amount 4.958.000 €) and EUR 5.00 million from the 2017 budget

2. InnovFin Infectious Diseases (InnovFin ID) Pilot[54]

Infectious diseases (ID) are a major global threat to health. ID R&D is hampered by a funding gap and a lack of investment by industry. In addition, many existing ID treatments and vaccines are jeopardised by the emergence of antimicrobial resistance, which threatens the effective prevention and treatment of an ever-increasing range of infections. Combating ID is a public health priority for the EU.

InnovFin Infectious Diseases aims to finance pre-commercial stage investments in the field of ID, i.e. the project produces innovative vaccines, drugs, medical and diagnostic devices or novel research infrastructures for combatting infectious diseases. Projects developing innovative vaccines, drugs, medical and diagnostic devices must have gone successfully through the preclinical stage and preferably through early stage clinical development and now require clinical validation or be ready for later stage clinical trials in order to be eligible for InnovFin ID. Projects on research infrastructures must refer to facilities, resources and related services to be used by the scientific community to conduct top-level research and must be novel e.g. not replicate what already exists, in order to be eligible for InnovFin ID. The InnovFin ID Operation must have proven public health impact and potentially have market

51 The budget amounts for the 2016 budget are subject to the availability of the appropriations provided for in the draft budget for 2016 after the adoption of the budget 2016 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.
The budget amounts for the 2017 budget are indicative and will be subject to a separate financing decision to cover the amounts to be allocated for 2017.

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

53 COM(2012)497

54 The indicative budget complements the allocation in 2015 of EUR 100 million to this pilot facility from revenues and repayments generated by the FP7 RSFF.

prospects. It will make loans of between EUR 7.5 million and EUR 75 million to SMEs, midcaps, special project vehicles, research institutions and other legal entities for the purposes of corporate or project finance, and to large pharmaceutical companies for financing the development of pre-identified medical products on a risk-sharing basis. Other forms of finance may also be possible. Projects and/or the IP development (such as clinical trials) can be undertaken outside the EU or Associated Countries.[55]

Expected impact: **InnovFin Infectious Diseases** will help in:

- increasing EU investments in ID research;
- de-risking investments and hence encouraging industry, in particular, to invest more heavily in this area;
- preparing for further roll-out to the market of new drugs, vaccines, diagnostics and medical technologies to combat ID;
- fostering the healthcare sector and hence creating jobs and growth in the EU.

Type of Action: Financial Instrument

Indicative timetable: First quarter of 2016 and first quarter of 2017

Selection procedure: EIB checks the financial viability of each potential financing operation, while DG Research & Innovation, assisted by other Commission DGs, approves each operation against eligibility criteria[56] set for the pilot. Eligible projects will be financed on a first-come, first served basis.

Indicative budget: EUR 50.00 million from the 2016 budget and EUR 50.00 million from the 2017 budget (this budget may be revised on the basis of the level of demand, and may be complemented by other sources of funding)

3. First interim evaluation of the EDCTP2 programme

A first interim evaluation of the second European and Developing Countries Clinical Trials Partnership programme (EDCTP2) is required by decision No 556/2014/EU of the European Parliament and of the Council. This decision requires the Commission to carry out an interim evaluation of the EDCTP2 Programme by 30 June 2017 with the assistance of independent experts, and deliver by 31 December 2017 a report on that evaluation to the European Parliament and to the Council, including the Commission's conclusions of the evaluation and observations. Furthermore, the decision requires that the result of the interim evaluation of EDCTP2 Programme shall be taken into account in the interim evaluation of Horizon 2020. The interim evaluation will assess the progress of the EDCTP2 programme towards the

[55] Please see part A of the General Annexes.

[56] See p.2 of http://www.eib.org/attachments/documents/innovfin_infectious_diseases_flysheet_en.pdf

objectives set out in decision No 556/2014/EU, and in particular in its Annex 1, taking into account observations and recommendations made in evaluations of the first EDCTP programme, and on whether the level of financial contribution of the participating states is appropriate. A special allowance of EUR 450/day will be paid to the experts appointed in their personal capacity and acting independently and in the public interest.

Type of Action: Expert Contracts

Indicative timetable: Fourth Quarter of 2016 to Second Quarter of 2017

Indicative budget: EUR 0.15 million from the 2016 budget

4. First interim evaluation of the IMI2 programme

A first interim evaluation of the second Innovative Medicines Initiative programme (IMI2) is required by decision No 557/2014/EU of the European Parliament and of the Council. This decision requires the Commission to carry out an interim evaluation of the IMI2 Programme by 30 June 2017 with the assistance of independent experts, and deliver by 31 December 2017 a report on that evaluation to the European Parliament and to the Council, including the Commission's conclusions of the evaluation and observations. Furthermore, the decision requires that the result of the interim evaluation of IMI2 Programme shall be taken into account in the interim evaluation of Horizon 2020. The interim evaluation will assess the progress of the IMI2 programme towards the objectives set out in decision No 557/2014/EU, taking into account observations and recommendations made in evaluations of the first IMI programme. A special allowance of EUR 450/day will be paid to the experts appointed in their personal capacity and acting independently and in the public interest.

Type of Action: Expert Contracts

Indicative timetable: Fourth Quarter of 2016 to Second Quarter of 2017

Indicative budget: EUR 0.15 million from the 2016 budget

5. European registry for human embryonic stem cell lines

A contribution for 4 years will be made to ensure the continued registration of human Pluripotent Stem Cell (hPSC) lines in a European registry maintained by Charité Universitätsmedizin Berlin. The aim is to gather and make available detailed information on the different hPSC lines derived in Europe and beyond, thereby also avoiding needless creation of new cell lines. This registry operates through an internet website that will continue to provide high quality data about the lines (e.g. cell characteristics), details regarding their source and contact information regarding their location.

Legal entities:
Berlin- Brandenburg Centre for Regenerative Therapies – BCRT Charité, Universitätsmedizin Berlin, Augustenburger Platz 1, D-13353 Berlin, Germany

Type of Action: Grant to identified beneficiary - Coordination and support actions

The standard evaluation criteria, thresholds, weighting for award criteria and the maximum rate of co-financing for this type of action are provided in parts D and H of the General Annexes.

Indicative budget: EUR 1.00 million from the 2016 budget

6. Studies, activities of the Scientific Panel for Health, conferences, events and outreach activities

A number of specific contracts will be signed under existing framework contracts in order to support operations of the independent secretariat of the Scientific Panel for Health; dissemination and exploitation of project results; in order to contribute to the definition of future challenge priorities; and to organise conferences (the subjects of which may include but are not limited to the annual Conference of the Scientific Panel for Health[57]), events and outreach activities. Should existing framework contracts prove unsuitable or insufficient to support the abovementioned activities, one or more calls for tender may be launched as appropriate.

Type of Action: Public Procurement - eight specific contracts and two direct service contracts (indicative numbers)

Indicative timetable: Second semester 2016 and for 2017

Indicative budget: EUR 2.40 million from the 2016 budget and EUR 2.61 million from the 2017 budget

7. External expertise

This action will support the use of appointed independent experts for the monitoring of running projects, where appropriate, as well as for the evaluation of entries submitted to prize contests and for the evaluation of the EDCTP2 annual work plans.

Type of Action: Expert Contracts

Indicative budget: EUR 2.72 million from the 2016 budget and EUR 2.90 million from the 2017 budget

8. Horizon Prize on reducing maternal and new-born morbidity and mortality - the Birth Day Prize[58]

The UN summit of September 2015 adopted the new Sustainable Development Goals (SDGs) as part of the post-2015 development agenda. The third proposed goal aims to "Ensure healthy lives and promote well-being for all at all ages". More specifically it aims to reduce

[57] The Scientific Panel for Health is mandated by Regulation (EU) No 1291/2013 establishing Horizon 2020

[58] A possible co-funding is under discussion with other funders such as Bill and Melinda Gates Foundation.

by 2030 the global maternal mortality ratio to less than 70 per 100,000 live births (and less than 140 per 100,000 for countries with maternal mortality ratio above 400 per 100,000) as well as reduce child and neonatal deaths. As a result of coordinated and targeted global efforts since 1990, maternal deaths worldwide have dropped by 45% as per 2013 data. The child mortality rate has also dropped by 51%, from 90 deaths per 1,000 live births in 1990, to 46 in 2013. However the rate of these reductions is still insufficient, and according to the World Health Organization in 2013 approximately 300,000 women died from preventable causes related to pregnancy and childbirth. Overall, maternal and perinatal conditions contributed the seventh highest burden of disease globally[59], and 6.3 million children died under the age of five. These deaths are disproportionately concentrated in the developing world[60], where 99% of maternal deaths occur, three-quarters due to preventable or treatable conditions such as haemorrhage, hypertensive disorders of pregnancy, and sepsis. In addition, for every woman who dies of pregnancy-related causes, 20 or 30 others experience acute or chronic morbidity, often with permanent sequelae that undermine their normal functioning[61]. This represents, according to some, 10-20 million women worldwide each year[62], with the highest number in low- and middle-income countries, especially among the poorest women. The Birth Day Prize will reward solutions to reduce the burden of maternal and/or new-born morbidity and mortality and/or stillbirth during facility-based deliveries.

The specific rules of the contest will be published in late 2015 or early 2016 by the European Commission[63], which will directly launch and manage the contest and award the prize based on the judgement of independent experts.

Expected results: A novel solution is expected to improve the outcome of facility-based deliveries, which might be of a clinical, technological or managerial nature, or a combination of these. Any solution must take full account of relevant social factors and have the potential of scaling up rapidly.

Eligibility criteria: The contest is open to all legal entities (including natural persons) or groups of legal entities regardless of their place of establishment. Contestants that have already received an EU or Euratom prize cannot receive a second prize for the same activities. Exclusion criteria foreseen in the provisions of articles 106(1), 107, 108 and 109 of the Financial Regulation (regulation 966/2012) will apply.

Essential award criteria: The prize will be awarded, after closure of the contest, to the contestants who in the opinion of the jury demonstrate a solution (which is at least a system

---

59 Lozano, R, Naghavi, M, Foreman, K et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010.Lancet. 2012;380: 2095–2128

60 Lale Say, Doris Chou, Alison Gemmill, Özge Tunçalp, Ann-Beth Moller, ,Jane Daniels, A Metin Gülmezoglu, Marleen Temmerman, Leontine Alkema, Global causes of maternal death: a WHO systematic analysis, The Lancet Global Health, Volume 2, Issue 6, June 2014, Pages e323–e333

61 http://www.who.int/bulletin/volumes/91/10/13-117564/en/

62 http://www.ossyr.org.ar/pdf/bibliografia/2.5.pdf

63 On the Participant Portal but also actively publicised elsewhere to maximise participation.

pilot demonstrated in an operational environment) that best addresses following cumulative criteria[64]:

- Demonstrated (through scientifically sound and well-established methods) reduction of maternal and/or new-born morbidity and mortality and/or number of stillbirths in facility-based deliveries
- Absence of clear safety concerns (also with respect to the potential effect in the longer term – no adverse effects)
- Potential for rapid scalability

Details on the evaluation criteria, thresholds, weighting for award criteria will be specified in the rules for this contest published at the launch of the contest.

Indicative timetable of contest(s):

Stages	Date and time or indicative period
Opening of the contest	Last quarter 2015/First quarter of 2016
Deadline for submission of application	Second quarter of 2017
Evaluation and solutions demonstration (if applicable)	Third quarter of 2017
Award of the prize	Fourth quarter of 2017

Type of Action: Inducement prize

The common Rules of Contest for Prizes are provided in part F of the General Annexes.

Indicative budget: EUR 0.99 million from the 2016 budget (the launch of the contest is subject to the availability of the appropriations following the vote of the budget for the year concerned)

9. Grant to the Global Alliance for Chronic Diseases

The European Commission will make a contribution towards activities of the Global Alliance for Chronic Diseases (GACD). This will enable the European Commission to take part in GACD, which brings together leading health research funding agencies of key countries (currently Australia, UK, Canada, China, India, Mexico, USA, and South Africa) to

[64] Further clarification of these criteria might be published in the Rules of Contest

coordinate research activities addressing on a global scale the prevention and treatment of chronic, non-communicable diseases such as cardiovascular diseases, diabetes, mental health and cancer. Recommendations of GACD are expected to have a fundamental value for future orientation of public health research policy. This will also contribute to the implementation of the Union's strategy for international cooperation[65] in research and innovation.

Legal entities:
Funding will be provided through an action grant to the secretariat of the GACD, hosted by University College London, Gower Street 1, WC1E 6BT, London, UK

Type of Action: Grant to identified beneficiary - Coordination and support actions

The standard evaluation criteria, thresholds, weighting for award criteria and the maximum rate of co-financing for this type of action are provided in parts D and H of the General Annexes.

Indicative timetable: Second quarter 2017

Indicative budget: EUR 0.24 million from the 2017 budget

10. Expert group for alternatives to animal testing

An expert group will be established to examine the development, validation and implementation of alternative methods to animal use for scientific, regulatory and safety activities, identify potential gaps and assess trends and further requirements. The experts should make a comprehensive analysis of relevant research projects and initiatives supported at European and Member State levels, identify future interdisciplinary research opportunities in this area taking into consideration the optimal synergies with promising international endeavours, assess the socio-economic impact as well as the innovation and business potential, and provide recommendations to address the bottlenecks to the validation and rapid implementation of alternative tests in the various sectors. The experts should also explore the challenges of a European observatory on alternative methods and propose options for its set up. The group of experts will deliver the results to the Health Directorate of DG Research and Innovation as a series of reports, of which the first interim one should be ready for the stakeholders' conference foreseen around the end of 2016 as action 4 of the reply from the European Commission to the STOP VIVISECTION citizen's initiative[66]. The overall output of this expert group should translate into clear and implementable strategies for research, validation and implementation into alternatives for animal testing.

A special allowance of EUR 450/day will be paid to the experts appointed in their personal capacity who act independently and in the public interest.

Type of Action: Expert Contracts

[65] COM(2012)497

[66] http://ec.europa.eu/environment/chemicals/lab_animals/pdf/vivisection/en.pdf

Indicative timetable: 2016

Indicative budget: EUR 0.20 million from the 2016 budget

11. Presidency events - eHealth

A maximum of EUR 300,000 will be allocated to one Presidency in each year, for the organisation of a conference focusing on eHealth.

Legal entities:
1 - 2016: The Dutch Presidency of the Council of the European Union / Ministerie van Volksgezondheid, Welzijn en Sport, Parnassusplein 5, 2511 VX Den Haag, The Netherlands
2 - 2017: The Maltese Presidency of the Council of the European Union / Ministry for Energy and Health, Auberge de Castille, Valletta VLT 1061, Malta

Type of Action: Grant to identified beneficiary - Coordination and support actions

The standard evaluation criteria, thresholds, weighting for award criteria and the maximum rate of co-financing for this type of action are provided in parts D and H of the General Annexes.

Indicative timetable: First semester 2016; First semester 2017

Indicative budget: EUR 0.30 million from the 2016 budget and EUR 0.30 million from the 2017 budget

Budget[67]

	Budget line(s)	2016 Budget (EUR million)	2017 Budget (EUR million)
Calls			
H2020-SC1-2016-2017		346.00	315.26
	from 08.020301	*290.00*	*244.00*
	from 09.040301	*56.00*	*71.26*
Contribution from this part to call H2020-DS-2016-2017 under Part 14 of the work programme		11.00	
	from 09.040301	*11.00*	
Contribution from this part to call H2020-FTIPilot-2016 under Part 18 of the work programme		17.30	
	from 08.020301	*14.70*	
	from 09.040301	*2.60*	
Contribution from this part to call H2020-IOT-2016-2017 under Part 17 of the work programme		10.00	
	from 09.040301	*10.00*	
Contribution from this part to call H2020-SMEInst-2016-2017 under Part 7 of the work programme		53.00	57.50
	from 08.020301	*35.00*	*45.00*
	from 09.040301	*18.00*	*12.50*

[67] The budget figures given in this table are rounded to two decimal places.
The budget amounts for the 2016 budget are subject to the availability of the appropriations provided for in the draft budget for 2016 after the adoption of the budget 2016 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.
The budget amounts for the 2017 budget are indicative and will be subject to a separate financing decision to cover the amounts to be allocated for 2017.

Other actions			
Prize		0.99	
	from 08.020301	*0.99*	
Expert Contracts		3.22	2.90
	from 08.020301	*2.50*	*2.00*
	from 09.040301	*0.72*	*0.90*
Public Procurement		2.40	2.61
	from 08.020301	*0.50*	*0.50*
	from 09.040301	*1.90*	*2.11*
Grant to Identified beneficiary		1.30	0.54
	from 08.020301	*1.00*	*0.24*
	from 09.040301	*0.30*	*0.30*
Financial Instrument		50.00	50.00
	from 08.020301	*50.00*	*50.00*
Subscription		4.96	5.00
	from 08.020301	*4.96*	*5.00*
Estimated total budget		**500.17**	**433.81**

Call - Digital Security Focus Area

H2020-DS-2016-2017

DS-03-2016: Increasing digital security of health related data on a systemic level

Specific Challenge: Full implication of different private and public actors, as well as empowered citizens, is needed in order to unlock eHealth potential in Europe. To achieve the trust of users, measures of safety have to be taken into consideration in accordance with the "privacy by design" approach. This requires secure storage of information including personal data but also guaranteeing safe exchange of these data over a number of architectures of differing security levels preventing unauthorised access, loss of data and cyber-attacks. A systemic approach to security will increase patients' empowerment, help protect their health also while abroad, and possibly encourage a larger number of Member States to apply it and adapt national legislations.

Scope: Proposals would provide a holistic approach to address challenges of secure storage and exchange (including cross-border) of data, protection and control over personal data, and security of health related data gathered by mobile devices combined with the usability of the eHealth solutions. Proposals should build on existing solutions or developments (openNCP, projects DECIPHER, EPSOS, STORK and others) where possible. Proposals would also analyse the legal applicable frameworks and societal aspects in the context of deployment of the solution. Existing European and national law including data protection rules, right to be forgotten, giving consent as well as recognized standards have to be respected. The operational solution should be piloted in three different Member States or associated countries. Technologically, it should be easily adaptable in other countries wishing to use it.

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

The outcomes of the proposals are expected to lead to development up to Technology Readiness Level (TRL) 3 to 5; please see part G of the General Annexes.

Expected Impact:

- Better acceptance of eHealth solutions among patients
- Encouraging Member States to widen the use of eHealth
- Ensuring the right of patients to cross-border healthcare
- Supporting the development of European legal and operational standards for cross-border data exchange and patient privacy protection

- Better protection against unauthorised use of personal data, breach of confidentiality and cybercrime
- Increasing the awareness of stakeholders, private and public ones, on the current level of data security.
- Definition of clear architectures that will promote interoperability between eHealth solutions

Type of Action: Research and Innovation action

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

Call - Internet of Things

H2020-IOT-2016/2017

IoT-01-2016: Large Scale Pilots

Specific Challenge: The challenge is to foster the deployment of IoT solutions in Europe through integration of advanced IoT technologies across the value chain, demonstration of multiple IoT applications at scale and in a usage context, and as close as possible to operational conditions. Compared to existing solutions, the roadblocks to overcome include i) the integration and further research and development where needed of the most advanced technologies across the value chain (components, devices, networks, middleware, service platforms, application functions) and their operation at large scale to respond to real needs of end-users (public authorities, citizens and business), based on underlying open technologies and architectures that may be reused across multiple use cases and enable interoperability across those; ii) the validation of user acceptability by addressing, in particular, issues of trust, attention, security and privacy through pre-defined privacy and security impact assessments, liability, coverage of user needs in the specific real-life scenarios of the pilot, iii) the validation of the related business models to guarantee the sustainability of the approach beyond the project.

Scope: Pilots are targeted, goal driven initiatives that will propose IoT approaches to specific real-life industrial/societal challenges. Pilots are autonomous entities that involve stakeholders from supply side to demand side, and contain all the technological and innovation elements, the tasks related to the use, application and deployment as well as the development, testing and integration activities. Large scale validation is characterised by the fact that it will be possible to operate the functional entities implemented in the pilot under load and constraints conditions close to operational load one's, either with real traffic/request/processing loads, or with emulated loads where full implementation is not possible. Demonstration to operate the system across multiple sites, scalability to large amount of heterogeneous devices and systems, as well as with large amount of real users are expected. Pilot work plans should include feedback mechanisms to allow adaptation and optimisation of the technological and business approach to the particular use case.

Use of experimental testbeds, such as FIRE[68], and real-world demonstrations may support IoT technologies validation before they are deployed in field trials. Given the considerable amount of work carried out on M2M/IoT and Cyber Physical Systems architectures (e.g. IoT-A) open platforms (e.g. FIWARE, CRYSTAL, UniversAAL) and standards (e.g. oneM2M) over the last few years, pilots are encouraged to exploit this previous work where applicable with the objective of further demonstrating the generic applicability and interoperability of these and/or other architectures, platforms and standards, and to identify where standards are missing or should evolve, as well as needed pre-normative activities.

[68] Future Internet Research and Experimentation

IoT finds applicability in a broad range of industry, business and public services scenarios. On the basis of European relevance, technology readiness and socio-economic interest the following areas have been identified to be addressed with Large Scale IoT Pilots.

Pilot 1: Smart living environments for ageing well

The objective is to deploy innovative and user-led pilot projects capable of supporting and extending independent living at home for older adults based on Internet of Things (IoT) technologies. The smart living environments should be based upon an integrated system of a range of IoT-based technologies and services with user-friendly configuration and management of connected technologies for homes and outside.

They should provide seamless services and handle flexible connectivity while users are switching contexts and moving in their living environments. The proposed pilots should also demonstrate feasibility of integration with other relevant application domains such as energy, transport, or smart cities. The solutions shall build upon advanced IoT technologies, using and extending available open service platforms, standardised ontologies and open standardised APIs. Proposals shall address integration, standardisation and interoperability work on required ICT platforms, services and data sources, as well as on innovation in organisational and business models for service delivery.

Proposed solutions should take into account the specific requirements for accessibility, usability, cost efficiency, personalisation and adaptation arising from this application sector. They should be based on active user engagement from the outset and should involve a multi-disciplinary approach in order to ensure the understanding of user needs and their evolution, safeguarding ethics and privacy and the assessment of impact. This should include quality of life for older adults and their carers, care system efficiency gains, business and financing models and organisational changes required for service delivery.

A clear methodology for socio-economic impact assessment should be included. Large scale pilots should demonstrate the benefits of smart living environments based on IoT in terms of prolonged independent and safe living of older adults at home with good quality of life. The number of users involved and duration of pilot services should be sufficient to ensure statistical significance in impact analysis, with a minimum of 4 pilot sites in 4 countries.

[For information: the other IoT pilots are Pilot 2: Smart Farming and Food Security, Pilot 3: Wearables for smart ecosystems, Pilot 4: Reference zones in EU cities, Pilot 5: Autonomous vehicles in a connected environment.]

Specific Pilot considerations:

- Mapping of pilot architecture approaches with validated IoT reference architectures such as IoT-A enabling interoperability across use cases;
- Common or interoperable object connectivity/functionality/intelligence approaches on various levels – protocols, data formats

- Common or interoperable set of IoT related enablers and services. Pilots are requested to address the elements that provide the basis for interoperability with related fields outside the pilot especially for key aspects such as object identification/naming, service publication characteristics, search, semantic properties.

- For the incorporation of users of the pilots, developers of additional applications, replication of the pilot through new sites or new connected devices, and complementary assessment of the acceptability of the use case where appropriate, the actions may involve financial support to third parties in line with the conditions set out in Part K of the General Annexes. Each consortium will define the selection process of the third parties for which financial support will be granted (typically in the order of EUR 100 000 to 300 000[69] per party). Up to 20% of the EU funding requested by the proposal may be allocated to the purpose of financial support to third parties[70].

- Exchange on requirements for legal accompanying measures.

- Involvement of social scientists and representative user groups, in order to design systems that are useful and acceptable for people/citizens and optimise testing and experimentation.

- Integration of objects, devices and systems in an IoT environment adapted to the expressed needs of the users.

Pilots Implementation:

Pilots in the selected areas will clearly identify the supply and demand sides. The effort devoted to supply and demand should be balanced for each pilot.

The supply side represents the technological part of the pilot and addresses all the ICT elements that constitute the proposed approach. This includes:

- definition of the IoT architecture;

- IoT platform choice, technologies , necessary adaptations, trade-offs required for the application requirements, and their management,

- Retained platform deployment conditions, of non-technological nature

- development and operation of the distributed IoT nodes;

- management and adaptation of involved sensing, actuating, processing, energy supply, storage technologies at node level (setting, programming, conditioning);

[69] In line with Article 23 (7) of the Rules for Participation the amounts referred to in Article 137 of the Financial Regulation may be exceeded, and if this is the case proposals should explain why this is necessary to achieve the objectives of the action.

[70] It is recommended to also use established networks reaching out to SMEs like the Enterprise Europe Network and the NCP network for calls publications and awareness raising towards SME's.

- integration of devices, objects and systems in an IoT environment;
- approaches to interoperability and openness;
- security and privacy approaches;
- contribution and compliance to relevant IoT standards;

The demand/user side of the pilot covers all the application and usage related elements. This includes:

- definition, design, implementation and testing of multiple use-case scenarios;
- setting up application(s) requirements in terms of performance, scale, reliability, cost, usability, maintenance;
- interoperability needs and testing;
- security and privacy needs;
- feed-back to IoT supplier for technology optimisation;
- users/citizen awareness, involvement and acceptance;
- pro-active uptake of societal (RRI-SSH) issues;
- impact, added value and affordability assessment;
- mechanisms for replication;
- business and sustainability models;
- pilot conclusions and validation from the user side;
- dissemination of results in relevant communities;
- contribution and compliance to relevant IoT standards.

Pilot projects are expected to contribute to the consolidation and coherence work that will be implemented by the CSA supporting the activities defined under "Horizontal Activities" below. This requires that they contribute to clustering their results of horizontal nature (interoperability approach, standards, security and privacy approaches, business validation and sustainability, methodologies, metrics, etc.).

The Commission considers that proposals requesting a contribution from the EU up to EUR 30 million (pilot 2), up to EUR 20 million (pilot 1), up to EUR 15 million (pilots 3, 4) and up to EUR 20 million (pilot 5) would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. It is expected that at least one large pilot is supported for each area.

Expected Impact: Pilots are expected to have a high impact on citizens, both in the public and private spheres, industry, businesses and public services. Key performance indicators should be identified to measure progress on citizen benefits, economic growth, jobs creation, environment protection, productivity gains, etc.

Pilots' impact should go beyond involved partners and will aim at influencing external communities by putting in place appropriate mechanisms.

- Validation of technological choices, sustainability and replicability, of architectures, standards, interoperability properties, of key characteristics such as security and privacy;
- Exploration and validation of new industry and business processes and innovative business models validated in the context of the pilots.
- User acceptance validation addressing privacy, security, vulnerability, liability, identification of user needs, concerns and expectations of the IoT solutions
- Significant and measureable contribution to standards or pre-normative activities in the pilots' areas of action via the implementation of open platforms
- Improvement of citizens' quality of life, in the public and private spheres, in terms of autonomy, convenience and comfort, participatory approaches, health and lifestyle, and access to services.
- Creation of opportunities for entrepreneurs by promoting new market openings, providing access to valuable datasets and direct interactions with users, expanding local businesses to European scale, etc.
- Development of secure and sustainable European IoT ecosystems and contribution to IoT infrastructures viable beyond the duration of the Pilot.

For Pilot 1:

- Proposals should show clear evidence of the benefits of the proposed solutions for active and independent living and quality of life of older persons compared to current state of the art based on appropriate methodologies and metrics.

Type of Action: Innovation action

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