DRAFT SC1 WORK PROGRAMME 2016-2017

Placeholder for INTRODUCTION

Personalised Medicine

H2020-PM-2016/2017

1.1 Understanding health, well-being and disease

PM 01A – 2016 – Multi omics for personalised therapies [RTD]

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. There is increasing evidence that interactions with the environment, as reflected in genome-epigenome-metabolome-microbiome crosstalk, play an important role in disease development and progression. International initiatives such as International Cancer Genome Consortium, International Human Epigenome Consortium and International Human Microbiome Consortium have generated high quality comprehensive large scale data catalogues and maps. The challenge is to use the existing high quality data deposited in relevant data bases (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-metabolome-microbiome data produced in the above mentioned 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 complex diseases. Proposals should address relevant ethical implications and include a section on research data management.* International cooperation is requested.

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.
- Identify and select new biomarkers for clinical validation.
- Develop new targeted therapies for complex diseases.
- 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: RIA

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

PM 01B – 2017- New paradigms in patient stratification [RTD]

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:

The 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.. Proposals should focus on diseases having high economic impact. Proposals on rare diseases are excluded from this topic.

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 & innovation opportunities in this innovative industries-driven field, particularly small or medium enterprises (SMEs).

Type of action: RIA

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

PM 02 – 2016 – 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 is 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. Proposals should enable and foster scientific exchange between stakeholders from countries and regions with different practices and strategies of rare disease diagnostics.

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 between EUR 10 and 12 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: RIA

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

PM 03 – 2016 - Networking and optimising the use of population cohorts at EU level [RTD]

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. 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.

Scope:

The 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, elderly, birth, etc.), and by taking advantage of new technologies (e.g. ICT, social platforms, etc.) and new type of data (e.g. geographical, eHealth records, etc.). Based on those cohorts integration, 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):

- 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 treatment.
- Provide the evidence for the development of policy strategies for prevention, early diagnosis, therapies, health economics as well as addressing health inequalities.
- Optimise the use of population cohorts in defining/improving clinical practice and public health policy.
- Make major conceptual, methodological and analytical contributions towards integrative cohorts and their efficient exploitation including novel path towards sustainability.

Type of action: RIA

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

1.2. Preventing disease

PM 04 – 2016 - The European Human Biomonitoring Initiative [RTD]

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. 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. The EHBMI should build on European excellence in the field and promote capacity building and the spread of best practice. The EHMBI should provide a platform through which harmonised and validated information and data collected at national level can be accessed and compared. It should 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. 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.

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 European Environment Agency will facilitate knowledge gathering, internal and external information sharing and will assist the coordinator for secretariat-related activities.

The proposal should include a 5-year roadmap describing the key priorities and governance processes as well as the 1st annual work programme.

The joint programme should be structured along four main work packages: support for field sampling and analytical work by competent national laboratories; data infrastructure; a research programme to assess the impact of chemical exposure on human health; and, translation of programme results into policy. The four work packages must operate in close coordination, in order to address the overall priorities of the initiative.

The work package on field sampling and analytical work should carry out 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. Best practices for management of data resulting from linking analytical results and field surveys should be established, facilitating the data inclusion into the Information Platform for Chemical Monitoring Data (IPChem platform[1]). A

[1] 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

network of reference laboratories and field survey entities of high quality should be established, engaged in capacity building across Europe and facilitating access to special equipment.

The data infrastructure will be provided by the IPChem, currently under development by the EU Joint Research Centre. The EHBMI should promote the inclusion of existing and new HBM data to IPChem and address outstanding issues related to HBM data policy and data quality assurance.

The work package on research to understand the impact on human health should carry out 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 science-policy interface work-package would be in charge of informing existing policy making processes at EU and national level about the outcome of the EHBMI, explore 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 should be supported by open calls for proposals organised by the Consortium, aiming at bringing in additional expertise and engaging with the wider research community. Dissemination, communication and training activities should also 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.

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.

- 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: Programme co-fund action (European Joint Programme). General details on the form of funding are provided in Annex XX.

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. The exact co-fund rate is under discussion with the EHBMI Steering Group and will depend on the agreed co-fund rate per area of activity. Member States' contribution can be in-kind or cash.

Indicative budget: max. EUR 50 million committed in annual instalments over the 5 years, 2016-2020.

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

PM 05 – 2016 - Vaccine development for malaria and/or neglected infectious diseases [RTD]

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:

The proposals will have to address bottlenecks in the discovery, preclinical and early clinical development of new vaccine candidates for malaria and/or neglected infectious diseases[2]. 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

[2] 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. Filoviral diseases are specifically excluded from this topic.

vaccine candidates, should be able to be compared as early as possible in an 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 poor resource 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.

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 million and EUR 20 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Proposals should deliver new vaccine candidates or move existing ones along the vaccine candidate pipeline.

- 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.

- Vaccine candidates selected towards clinical development would be anticipated to move into further development and clinical testing in the context of the Art.185 initiative on European and Developing Countries Clinical Trials Partnership (EDCTP-2).

Type of action: RIA

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

PM 06 – 2017 - Promoting mental health and well-being in the young [RTD]

Specific challenge:

Mental disorders place immense burdens on individuals, families and society; they also increase the risk of co-morbidities. Despite the advances in the effectiveness of current treatment modalities for mental and behavioural disorders, an important method for reducing the burden caused by these disorders are prevention[3], early detection and appropriate management. Mental health is one of the contributing factors to well-being but it is not the only aspect. Psychological factors, social and 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 health and wellbeing. 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 interventions to promote mental health and 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 medical (including psychological) and social determinants of mental health such as societal, cultural, lifestyle, epidemiological, economic and environmental perspectives. 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.

The research design should be developed by means of a multidisciplinary approach and involve the young themselves and relevant stakeholders. The interventions should use a holistic approach, taking gender and health inequality aspects into account, and strengthen and empower 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 health and 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. 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:

- Improved mental health and well-being in the targeted group of young people.

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

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

- Improved mental health and 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.

- A longer-term impact would be that 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: RIA

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

PM 07 – 2017 - New therapies for rare diseases [RTD]

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 6000-8000 rare diseases are lacking therapies despite the fact that 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 the 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, the 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 encouraged.

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: RIA

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

PM 08 – 2016 - New therapies for chronic diseases [RTD]

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[4] of novel therapies (pharmacological as well as non-pharmacological) or the optimisation of available therapies (e.g. repurposing) for chronic non-communicable or 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[5,6].

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

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

PM 09 – 2017 - Comparing the effectiveness of existing healthcare interventions in the adult population [RTD]

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:

4 Phase 3 and phase 4 clinical trials are excluded.
5 See topic PM7 addressing new therapies for rare diseases.
6 See topic PM10 addressing clinical research on regenerative medicine.

Proposals should compare the use of currently available preventative or therapeutic (pharmacological as well as non-pharmacological) healthcare interventions in adults. 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, 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 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. The study population should address gender as well as socio-economic differentials in health where relevant.

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

Expected impact:

This topic is to provide the required evidence base for:

- more effective and safer interventions at individual and population level;
- enhanced compliance 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 and prescribers.

Type of action: RIA

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

PM 10 – 2016+2017 - Clinical research on regenerative medicine [RTD]

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 the necessary ethical and regulatory authorisations to carry out the work or provide evidence of regulatory engagement and that such approval is close. Preference will be given to proposals which 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 existing treatment.

Assessment of the extent to which a proposal is beyond state of the art will take into account projects supported following previous calls for proposals on this topic.

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: RIA

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

PM 11 – 2016+2017 - Cell technology in medical applications [RTD - SME Instrument] [phase 1 and 2]

Specific challenge:

Cell-based products and processes are showing increasing potential in medical research, diagnosis and therapy. 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.

The challenge overall is to support European SMEs developing products and processes from cell technologies in their efforts to overcome these barriers and to strengthen their business and commercial potential.

Scope:

Cell technologies have as their objective the development of cell-based products and cell-based processes.

Cell technologies have a broad scope, including cell manufacturing (culturing, multiplication, scale-up and automation), preservation, banking and transport; identification, cell sorting and delivery, imaging, tracking and process 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. Some cell technologies will have multiple areas of application and this will increase their commercial potential.

Proposals should include analysis of the safety and regulatory requirements of the technology under development and should carry out the measures needed to ensure compliance. Regulations that might need to be considered would include cell procurement, GMP, ethics, clinical trials and devices. Early dialogue with regulators, and obtaining scientific advice and protocol assistance as appropriate is required.

Proposals may focus on cells from any eukaryotic source though their eventual application must be to human medicine.

Proposals should demonstrate a clear business potential and set out an exploitation strategy for commercialising promising cell technologies in business-to-business (B2B) or business-to-customer (B2C) contexts.

Expected impact:

- Increased value of the SME by, for example, attracting investment partners, making progress in safety or regulatory compliance, licensing technology to others, or commercialising an innovative product or process.
- Increased range of cell technologies available for use in commercial or clinical settings.
- Support innovation and competitiveness by strengthening European SME product pipeline.
- Hasten development of innovative therapies and processes with commercial or clinical potential.
- Stimulate growth and competitiveness of European cell technology based medical applications.

Type of action: SME Instrument (up to 100% funding)

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

PM 12 – 2016: Clinical research for the validation of biomarkers and/or diagnostic medical devices [RTD – SME Instrument] [phase 2 only]

Specific challenge:

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

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

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

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

Scope:

The SME instrument consists of three separate phases and a coaching and mentoring service for beneficiaries, while this topic is open for phase 2 only.

In phase 2 proposals should address the specific challenge described, elaborated in the scope section above, and demonstrate high potential in terms of applicant's competitiveness and growth underpinned by a strategic business plan.

Proposals shall be based on a business plan developed either through phase 1 or another means. Particular attention must be paid to IP protection and ownership; applicants should provide evidence of the possibility of commercial exploitation (‘freedom to operate’).

The clinical validation of existing potential biomarkers (not the identification of new ones) is sought. This validation should provide evidence for: high analytical validity; appropriate sensitivity and specificity; clinical validity/ utility. Preference will be given to validation of biomarkers with high potential for short term uptake into clinical practice.

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

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

Proposals shall contain a specification for the outcome of the project, including a first commercialisation plan, and criteria for success.

The Commission considers that phase 2 proposals requesting a contribution from the EU of between EUR 1 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. Phase two proposals should duly justify their duration making reference to obtaining patient samples, ensuring patient follow up, etc.

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

Successful beneficiaries will be offered coaching and mentoring support during phase 2. This service will be accessible via the Enterprise Europe Network (EEN) and provided by a dedicated coach through consultation to the beneficiaries. The coaches will be recruited from a database managed by the Commission and on the basis of their business experience and competencies. Throughout the three phases of the instrument, the EEN will complement coaching support by providing access to its innovation and internationalisation services. This may include, for example, depending on the needs 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:

This should provide:

- Increased clinical availability and exploitation of biomarkers for the benefit of the patient.
- New diagnostic devices.
- Facilitation of entry of improved diagnostics in the clinic and the market.

- Support for the implementation of the Commission proposal for a revised in vitro diagnostic devices regulation[7].
- Enhancing profitability and growth performance of SMEs by combining and transferring new and existing knowledge into innovative, disruptive and competitive solutions seizing European and global business opportunities.
- Contribution to the sustainability of health care systems.
- Increased likelihood of market uptake and distribution of resulting innovations tackling the abovementioned specific challenge(s) in a sustainable way.
- Leveraging of private investment in clinical validation as described above, notably leverage of private co-investor and/or follow-up investments.

Type of action: SME instrument (up to 100% funding)

While all other instances of the use of the SME instrument in Horizon 2020 provide for reimbursement at 70%, the predominance of research type activities in clinical validation necessitate reimbursement at 100% in this case.

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

(PM 13 – 2016 + 2017 - Support for European eHealth SMEs [CNECT- SME Instrument])

(This topic will be referenced in the SME instrument part of the WP.)

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 challenge of the SME instrument call:

SMEinst xx – 2016 + 2017 - Support for European eHealth SMEs [CNECT- SME Instrument]

Specific challenge

The challenge is delivering new and more effective interventions and healthcare strategies by mobilising various stakeholders including SMEs that are often interlinked with large industry and regulators, patients and national/regional/local authorities. Additionally, Europe is falling behind many regions of the world with regards to eHealth and Health informatics. This topic will provide

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

support for Europe to catch up in consumer health and institutional health markets. The Commission has supported a large spectrum of activities in eHealth including policies, research and innovation in FP7 and Horizon 2020[8]. There has been a challenge to increase the capability of eHealth SMEs to engage in the work programmes.

The European Commission supported under FP7 the Virtual Physiological Model (VPH)[9] area that funded research on multi-scale computer modelling and disease simulations with clinical applications coupled with developing a set of infrastructures, networking and road-mapping projects. This funding successfully resulted in numerous prototypes that proved the concept. Users trust and commercial exploitation are highly dependent on the clinical assessment of proposed prototypes. Performing extensive clinical validation will allow gathering the evidence for VPH solutions, accelerating the re-use of validated models and obtaining both clinical and European industrial/IT benefits.

Scope

The scope is to support high growth, highly innovative eHealth SMEs with global ambitions, industry focused, allow single entity involvement when relevant and clear commercial appropriateness to the company's strategy. The proposal should promote a disruptive solution or service and include privacy by design.

i) A broad spectrum of bottom up eHealth approaches including combination of existing technologies, for a) medical applications related to person-centred monitoring or health-care delivery, b) innovative managerial and organisational tools, in particular in the case of reference networks providing crossborder healthcare, c) preventive and well-being solutions and benefits for healthy citizens, and d) rehabilitation devices for home-use. The target market should be clearly indicated in the proposal.

ii) Proposals should focus on validating existing computer multi-scale computer models and prototypes that are technically highly prepared for starting a clinical validation on real patients as a necessary step before translation into clinical practice. The proposals should demonstrate sensibility, sensitivity, specificity and clinical benefits of models for health promotion and relevant clinical applications in diagnosis and treatment. The work may include research-type activities needed for refining and adapting the models so they can be implemented in specific clinical contexts.

Depending on the context of the proposal it is important to verify how ICT should deal with ethics committee for validation in clinical settings, to verify the regulatory compliance, and address the standards and interoperability to be truly scalable. User centred and/or participatory design approaches are requested to ensure that user needs and perspectives are incorporated from the outset

[8] http://ec.europa.eu/digital-agenda/ehealth
https://ec.europa.eu/digital-agenda/en/news/ehealth-projects-research-and-innovation-field-ict-health-and-wellbeing-overview

[9] http://ec.europa.eu/digital-agenda/en/virtual-physiological-human

and all stages of development and /or validation. For both subtopics see also an interrelated topic HCO 10 supporting the development of sustainable business in eHealth.

TRL: 6 or higher

Expected impact

- Financial sustainability and stimulation of innovation, investments and growth in SMEs
- Promotion of healthy ageing and personalised healthcare through new and faster development processes and products
- Providing European health-related SME industries with a competitive edge that can secure growth and jobs
- Generated evidence-based results for prevention measures, promotion of mental well-being and social inclusion, and more efficient health and care systems.
- Validated models, prototypes and decision support systems that will be available and ready for use in clinical practice
- Increased trust and attractiveness for investors
- Increased commercial exploitation and support to the European industry development
- Growing the sector of European SMEs and creating interesting jobs
- Benefit for the diagnosis and the treatment of the studied disease and potential of re-use for other diseases
- Participation to building a sustainable healthcare
- Benefit for the EU citizens by facilitating access to high quality healthcare through European Reference Networks

Type of action:

SME instrument (70% funding); Phase 1 and Phase 2 in 2016 8 M EUR; Phase 2 in 2017 8 MEUR.

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 challenge of the SME instrument call:

PM 14 – 2016 - SMEInst-xx-2016-2017- ICT solutions for Active and Healthy Ageing based on open platforms /CNECT- SME Instrument]

Specific Challenge
For the ageing society ICT based solutions can offer important support for older citizens to remain autonomous, active and healthy as long as possible. A key design goal is to achieve easy integration of a range of required services, high user acceptance through service independent, accessible and customisable user interfaces, and flexible adaptation of specific services as individual needs change during the life course.

In order to reach this goal, new approaches for application design and delivery are required, which build on open platforms[10] that have the features needed to support the requirements set out in this topic.

The challenge is to support rapid development and market validation of ICT innovative solutions (products, applications and services) addressing the key needs and desires of an ageing population. Focus will be on SMEs which have innovative business models with high potential for market entry, where the use of suitable open platforms is key to success and competiveness.

Scope
Proposed projects will be supported through the Horizon 2020 SME instrument and should have a potential for disruptive innovation based on open platforms and fast market up-take in ICT for ageing well. In particular it will be interesting for SMEs and young innovative companies that are looking for swift support to their innovative ideas.

Proposals should clearly address the following:
- The choice and potential of the proposed application area in view of the needs of an ageing population;
- The selection of the suitable open platform to address this specific challenge and the rationale behind;
- How they will contribute to and benefit from the innovation ecosystem related to the chosen open platform.

Expected Impact
The proposal should present quantitative and qualitative metrics (e.g. about innovation advances in processes, products, services and business models, socio-economic return in terms of quality of life, return on investment, savings, etc.) as appropriate for measuring its progress towards the expected impact in:
- Creation of ICT scalable solutions and innovation ecosystems building on relevant open platforms suitable for addressing the needs and desires of an ageing population;

[10] 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.

- Enhancing profitability and growth performance of SMEs by building on open platforms as an efficient means for rapid product and service development;
- Increased availability and market uptake of ICT innovations for ageing well;
- Increase of private investment in ICT based innovation for ageing well, notably through leveraging public and private co-investments and/or follow-up investments in successfully supported SMEs;
- Solutions should enable cross-sectorial development and support interoperable products and services for the aging society.

Type of Action
SME Instrument (70% funding): Phase 1 and Phase 2 in 2016 10 M EUR; Phase 2 in 2017 4.5 MEUR.

PM 15 – 2016 – PCP - eHealth innovation in empowering the hospitalised patient [CNECT]

Specific challenge

Empowering the hospitalised patients, outpatients and their families/carers to support a continuum of care across a range of services is expected to result in 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. Furthermore rare diseases are particularly difficult to manage far from specialised centres. The eHealth action plan 2012-2020[11] and the outcome of the mHealth Green paper[12] pave the way towards empowerment of the patient with the assistance of ICT. Innovation Procurement including PCP has been selected giving an explicit and complementary opportunity for the health procurers to address the legitimate research and innovation challenges supported in many cases by the national/local legislation as well.

Scope

Proposals should focus on the research and development of new services or better integration of existing services through the use of appropriate technology with 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 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. 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.

Expected impact

- Increasing the role and the responsibility of the patient, supporting self-management
- Reducing the number of severe episodes and complications
- Enhance ICT skills and increase adherence of patients and care givers
- Strengthened evidence base on health outcomes and management of comorbidities
- Increase the information about disease progression with advanced diagnostic techniques

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

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

- Provide early and predictive data about patient disease
- Reduce the number of visits to the hospital

Type of action:

PCP co-fund Actions

Indicative budget: EUR 18 million 2016

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

PM 16 - 2016- PPI for deployment and scaling up of ICT solutions for active and healthy ageing [CNECT]

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 in smaller contexts, by contributing to collaborative efforts in public purchasing of innovative ICT-based solutions for active and healthy ageing. Particularly in areas that have demonstrated success in smaller-scale settings and that have not yet been deployed on a large scale. 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.

This topic will contribute to the scaling up strategy of the European Innovation Partnership on Active and Healthy Ageing and to boosting the Silver Economy in Europe. The actions supported will target deployment of active and healthy ageing solutions at large scale across different regions in Europe.

Scope

In line with the priority areas of the Scaling Up Roadmap of the European Innovation Partnership on Active and Healthy Ageing, the scope of the PPI pilot(s) is to specify, purchase and deploy ICT based solutions for active and healthy ageing. Solutions which can deliver sustainable, new or improved services in which public procurement approaches for innovative solutions are successfully applied.

The 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 proposal;

- 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;

- Contribute comprehensive impact assessments of deployment based on 3 criteria "Increase in the quality of Life of users", "Economic growth and job-creation" and "Contribution to the Sustainability of the health and care systems".

- Contribution of 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, 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 co-fund actions.

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

PM 17 – 2016 - EUJ X – 2016: Novel ICT Robotics based solutions for active and healthy ageing at home or in care facilities such as ambient assisted living facilities, nursing homes, etc. [CNECT]

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[13] 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 wellbeing 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.

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

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[13] 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.

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

It is considered that proposals requesting a funding contribution of between EUR 2 and 3 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Additional eligibility criteria apply for the EU-Japan WP part as set out in the Annex xx.

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

PM 18 - 2017- Personalised coaching for well-being of older persons [CNECT]

Specific Challenge

The activity aims at developing and validating radically new ICT based concepts and approaches for empowering and motivating people in need of care, 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 "virtual", personalised "360^0 coach", building upon intelligent ICT environments, new forms of accessible interaction based on tangible user interaction concepts, open platforms and emotional computing. Usability and ease of user interaction should be essential design elements of the "coach".

The "coach" should provide personalised advice 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.

Solutions should 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. They should be integrated seamlessly in existing every-day activities and provide desired information in fast and efficient manner. The 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 address related regulatory questions such as ownership of data, data protection/privacy and consumer protection will be approached. Users must be involved at all stages of design and development, including validation of user satisfaction and impact in realistic settings.

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, 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

RIA

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

1.5 Methods and data

PM 19 – 2017- In-silico trials for developing and assessing biomedical products [CNECT]

Specific challenge

In the 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 medical foods research by developing new ways for in-silico testing.

Scope

The proposals will develop innovative in-silico trials for designing, developing and assessing drugs, radiation and other biomedical 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 e.g. molecular pathways, cellular microenvironments, genetics, behaviours, comorbidities, development, diet). Virtual populations of individual patients will be built for simple or composite diseases for e.g. from the patient-specific models by variations of different parameters and will allow simulating the action of the products and predicting the treatments outcomes. The proposed ISCT will be the result of a multidisciplinary effort (e.g. within the fields of computational modelling, systems biology, tissue mechanics, biology, pharmaceutics, medicine) and it 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.

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 assessment.
- 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

Instrument

RIA

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

PM 20 – 2016 - Increasing digital security of health related data on a systemic level [CNECT]

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. But to do so, trust of the users involved, requires that the security of eHealth solutions, is guaranteed, 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. Security issues should be addressed within the usability of the eHealth solutions, which is an important factor to motivate the participation of patients.

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

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

Action:
RIA

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

PM 21 – 2017 - Personalised computer models and in-silico systems for well-being [CNECT]

Specific challenge

There is continuous progress in systems medicine, multi-scale modeling and patient-specific modeling 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 analyzing brain 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, 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, of better consideration given to the functional troubles, of better recovery and rehabilitation after illness.

Scope

The 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 not harmful well-being, health and disease. The projects have to support computer modelling and simulations able to aggregate various information sets e.g. molecular, biochemical, imaging, social, economic, occupational, environmental, developmental, psychological etc. into robust predictors for resilience in coping with and overcoming challenges 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). The proposal will focus 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 and SSH, so enabling and facilitating the accumulation and relinking of complex and heterogeneous data collections.

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 the predictive and preventive approaches in medicine, neurosciences and life sciences
- Improving knowledge about well-being and association with the life circumstances: medical, occupational, social and environmental.

Instrument

RIA

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

PM 22 – 2016 - Big Data supporting Public Health policies [CNECT]

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 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 in particular in long-term policy making and increase the ability to provide actionable insights at the point of care. Relevant solutions include for e.g. systems for determining and monitoring the combined effects of environment, lifestyle and genetics on public health, enabling early identification of effects that can have large impacts on health – both short term and long term as well as when interaction with other public sectors is required (e.g. physical planning). Focus should be also on the governance of Big Data in order to use it proficiently across organisations and policy levels would be an asset. Integrated solutions should include suitable approaches towards securing security and privacy issues.

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";
- 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.

Instrument RIA

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

PM 23 – 2017 - PPI for uptake of standards for the exchange of digitalised healthcare records [CNECT]

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

This action aims at facilitating the purchasing of an eHealth infrastructure using the European eHealth Interoperability Framework and EU guidelines adopted by the eHealth Network. Examples of target outcomes may include the procurement of solutions allowing the sharing of health information, the use of semantically interoperable EHRs for safety alerts, decision support, care pathways or care coordination. The scope of the PPI is to specify, purchase and deploy 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…).

Expected impact

- Increased opportunities for wider market uptake for the supply side based solutions and services by forming a critical mass on the public demand side
- Wider uptake of interoperability standards
- 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

Instrument

PPI

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

PM 24 - Development of new methods for improved economic evaluation and efficiency measures in the health sector [RTD]

Placeholder for an action to be developed in a further workshop

Type of instrument: RIA

***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

PM 25 - 2016- Implementation research for scaling-up of evidence based innovations and good practice [RTD]

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[14]. However, the uptake of well-researched and proven interventions addressing current challenges is 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[15], the proposal should seek to scale up a comprehensive intervention in the field of health systems that is innovative and well-researched, supported by sufficient documented evidence. 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 scale-up implementation facilitators and barriers, including context-specific, at the different levels of the health system and across the borders.

The gender dimension and the multidisciplinary nature of the research should be adequately addressed. The proposal should reflect and take advantage of the regional diversity across Europe and beyond. Relevant stakeholders and end-users of research should be identified and involved throughout the project lifetime.

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[16] analysis should be provided.

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

[15] 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)

[16] analysis that situates development interventions within an understanding of the prevailing political and economic processes in society; specifically, the incentives, relationships, and distribution and contestation of power between different groups and individuals (GSDRC.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:

- 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 evidence-based health systems intervention is available to healthcare providers and policy makers, and facilitates the transferability of these practices across the borders of Europe and beyond.

In the medium and long term, the health systems are more effective, efficient and equitable; health services are more responsive to the needs of users.

Type of action: RIA

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

CONDITIONS FOR THIS CALL

Publication date: XX/XX/2015

Deadline (2016)[17, 18]: XX/XX/2016 (single stage call); SME instrument PM 11 – 2016 (as below) and PM 12 – 2016/2017 (as below)

	Single stage – XX month 2016 at 17.00.00 Brussels time	Budget EUR million	Single stage
PM 01a - 2016		30	The thresholds for each criterion in a single stage process will be 4, 4 and 3. The cumulative threshold will be 12.
PM 02 - 2016		15	
PM 03 - 2016		30	
PM 04 - 2016		50	
PM 05 - 2016		40	
PM 08 - 2016		60	
PM 10 - 2016		30	
PM 11 - 2016		35	SME instrument
PM 12 - 2016		10	SME instrument
PM 25 - 2016		40	Single stage, see above
	Single stage – XX month 2017 at 17.00.00 Brussels time		Single stage
PM 01b - 2017		40	The thresholds for each criterion in a single stage process will be 4, 4 and 3. The cumulative threshold will be 12.
PM 06 - 2017		20	
PM 07 - 2017		60	
PM 09 - 2017		40	
PM 10 - 2017		30	
PM 11 - 2017		35	SME instrument
PM-24 - 2017		9	Single stage, see above

Indicative budget: EUR XX million from the 2016 budget[19], EUR XX million from the 2017 budget[20]

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:

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

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 a Commission Decision which is expected to be adopted and made available on the Participant Portal.

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

[18] Any deadlines provided in brackets are indicative and are subject to a separate financing decision for 2017.

[19] Subject to the availability of the appropriations provided for in the draft budget for 2016 after the adoption of the budget for 2016 by the budgetary authority or if the budget is not adopted as provided for in the system of provisional twelfths.

[20] The budget amounts are indicative and will be subject to a separate financing decision to cover the amounts to be allocated for 2017.

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

Except for the SME instrument, the thresholds for each criterion in a single stage process will be 4, 4 and 3. The cumulative threshold will be 12.

Evaluation procedure: The procedure for setting a priority order for proposals with the same score is given in part H of the General Annexes.
The full evaluation procedure is described in the relevant guide associated with this call.

DG CNECT Topics

Publication date: XX/XX/2015
Deadline (2016)[21, 22]: XX/XX/2016 (single stage call); SME instrument PM 11 – 2016 (as below) and PM 12 – 2016/2017 (as below)

PM 16 – 2016 (PM 17) EUJ xx – 2016 (PM 14) SMEinst xx- 2016 Focus Area: IoT xx - 2016: Large Scale Pilots	Single stage – [draft date] 16 February 2016 at 17.00.00 Brussels time	Budget EUR million 6 5 10 10	Single stage The thresholds for each criterion in a single stage process will be 4, 4 and 3. The cumulative threshold will be 12. SME instrument
PM 18 – 2017 (PM 14) SMEinst xx- 2017	Single stage – XX February 2017 at 17.00.00 Brussels time	Budget EUR million 24 4.5	Single stage The thresholds for each criterion in a single stage process will be 4, 4 and 3. The cumulative threshold will be 12. SME instrument
(PM 13) SMEinst xx-2016		8	SME instrument

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

[22] Any deadlines provided in brackets are indicative and are subject to a separate financing decision for 2017.

PM 15 - 2016 PM 20 - 2016 PM 22 - 2016	Single stage – 1st March 2016 at 17.00.00 Brussels time	18 11 10	The thresholds for each criterion will be 4, 4 and 3. The cumulative threshold will be 12.
(PM 13) SMEinst xx - 2017 PM 19 - 2017 PM 21 - 2017 PM 23 - 2017	Single stage – XX March 2017 at 17.00.00 Brussels time	8 19 19 8.26	SME instrument The thresholds for each criterion in a single stage process will be 4, 4 and 3. The cumulative threshold will be 12.

Co-ordination activities

H2020-HCO-2016/2017

HCO 01 – 2016 - Valorisation of FP7 Health and H2020 SC1 research results [RTD]

Specific challenge:

Over 1,000 projects have been funded under the Health theme of Framework Programme 7 (FP7, 2007-2013) and close to 100 projects are already supported under the SC1 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 for these EU FP7 Health and Horizon 2020 SC1 projects.

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 shall 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 shall 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 shall 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 project outcomes in EU-13 countries. Whenever relevant, the marketplace should build and /or complement existing initiatives (for example the NIH OTT, EEN).

Expected impact:

- Development of a sustainable one-stop-shop innovation marketplace promoting primarily EU FP7 Health and Horizon 2020 SC1 project outcomes.

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

- Identification of innovative, sustainable business models.

- In-deep analysis and action plans targeting European biotech start-ups.

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.

HCO 02 – 2016 - Standardisation of pre-analytical and analytical procedures for in vitro diagnostics in personalised medicine [RTD]

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

Expected impact:

- 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 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.

HCO 03 – 2017 - To implement the Strategic Research Agenda on Personalised Medicine [RTD]

Specific challenge:

By providing the right intervention to the right person at the right time, personalised medicine 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 Support and Coordination Action "Personalised Medicine 2020 and beyond – Preparing Europe for leading the global way (PerMed)[23]" 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 co-fund is therefore a suitable and timely tool to implement relevant parts of PerMed's Strategic Research and Innovation Agenda, 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 EU co-funding in this area.

This call should aim at implementing a key area of the PerMed Strategic Research Agenda and be complementary with other funding programmes and activities on 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 HCO 5 2016 - Coordinating personalised medicine research without duplicating any of its work.

23 www.permed2020.eu

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 strongly encouraged.

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 action

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

HCO 04 – 2016 - Towards globalisation of the Joint Programming Initiative on Antimicrobial resistance [RTD]

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 implementation 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 proposal, 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 & innovation resources in the area of antimicrobial resistance;

- Attract global capacities towards JPAMR 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 to 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- 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 & 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.

HCO 05 – 2016 - Coordinating personalised medicine research [RTD]

[NOTE:** Topic may be further elaborated after outcome of discussions with Member States' representatives in the 22 May workshop on personalised medicine research funding**.]

Specific challenge:

By providing the right intervention to the right person at the right time, personalised medicine[24] 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.

Support the development and operations of a European platform for collaboration between funders of personalised medicine research, possibly based on the International Consortium model[25]. 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 commonly accepted research standards, policies and guidelines aiming to speed up the development and implementation of personalised medicine (addressing e.g.

[24] 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.

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

policy-related, economic, and socio-cultural factors). The participation of both public and private research funders is encouraged. The platform should aim to create synergies with ongoing activities on European and national levels (e.g. research infrastructures[26], ERA-NETs, personalised medicine pilot projects, EIT Health KIC[27]). 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.

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 standards, policies and guidelines aimed at accelerating research and implementation efforts.
- Development of a framework for data management, linking existing infrastructures, databases and biobanks, 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.
- Improved use of funds in the implementation of personalised medicine.

Type of action: Coordination and Support Action

HCO 06 – 2016 - Towards an ERA-NET on public health research [RTD]

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, it still remains that Member States face many similar challenges. There are many public health problems common to most countries, such as obesity and mental health issues. Similarly, a majority of European health care systems face challenges of an ageing population and rising costs. 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.

[26] http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=esfri

[27] http://eit.europa.eu/eit-community/eit-health

Scope:

To pave the way to an ERA-NET co-fund action on public health research research, this Coordination and Support Action (CSA) will develop a structured system of exchange of information between public health research funders and other relevant bodies 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 scientific-technological or socio-economic objectives, supported by an appropriate analysis.

This action implies the preparation and organisation of meetings as well 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 to 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- 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, 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.

HCO 07– 2017 - Global Alliance for Chronic Diseases (GACD) [RTD]

[NOTE: *Topic details will be developed in line with the timetable of the GACD priority setting process and will be included at the same time as the financing decision for 2017 is adopted.* ***]***

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

HCO 08 – 2017 - Remedial actions to bridge the divide in European health research and innovation [RTD]

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:

Support is proposed to any type of actions that can help less performing countries and regions to build capacities and exploit opportunities to eventually increase their participation in EU funded collaborative projects.

Beneficiaries of the actions should be low performing[28] 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 research and innovation, including those related to capacity, skills, policy, regulatory environment, and economic and socio-cultural factors.

The Commission considers that proposals requesting a contribution from the EU of up to EUR 1.000.000 would allow this specific challenge to be addressed appropriately. Nonetheless this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

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.

HCO 09 – 2016 - EU m-health hub including evidence for the integration of mHealth in institutional care [CNECT]

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

Specific challenge

Exchange of best practices and innovation monitoring are essential to support wider deployment of mHealth solutions on non-communicable diseases (NCDs) within the Member States.

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 EC action in mHealth by streamlining efforts in research and innovation, passing the difficult stage from research to large scale deployment.

The World Health Organization (WHO) and International Telecommunications Union (ITU) would be in charge of developing this hub. They have a unique expertise in the field of developing e-Health innovation hubs as reflected by their successful ‘knowledge and innovation hub’ models. The cooperation between these two international organisations is crucial to mHealth as they have a complementary role, bringing together both the health and the telecommunications angle at the international level. Such cooperation has proven to be very successful with the "Be Healthy be mobile initiative" where they ensured the development of several mHealth strategies, involving Member states at their highest level.

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.

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.

The hub should gather evidence on health outcomes, quality of life, care efficiency gains of mHealth solutions to support treatment and prevention of Non-Communicable Diseases through the creation of a central database, 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 consortium will define a selection process open to ministries of health and innovation institutes in the EU, ensuring a transparent selection of the hub premises, and taking due care of ensuring a good geographical balance. The hub will help 4 Member States to fully implement their mHealth national programme or strategy, 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.

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 in four champion countries, 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 EC EIP on Active and Healthy Ageing. (requirement, scope, impact)

Instrument

Coordination and Support Action

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

HCO 10 – 2016 - Support for Europe's leading Health ICT SMEs [CNECT]

Specific challenge

The business environment and sustainable business models for the eHealth SMEs has been a major challenge when introducing innovations in new healthcare delivery. Helpful findings are already

available in similar support measures, e.g., Get eHealth[29], iLink[30] 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 SME Companies, 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 opportunism 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 the legal challenges

f) Support addressing issues related to registration and certification

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.

[9] Delivering Growth to eHealth business, http://www.get-ehealth.eu/
[10] European Network of ICT Law Incubators, http://lincup.eu/

Instrument

CSA

Indicative budget: EUR 3 million (2016) for a duration of 4 years for one project only

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

HCO 11– 2016 - Coordinated Action to support the recognition of Silver Economy opportunities arising from demographic change [CNECT]

Specific Challenge:

The ageing of European populations coincides with the increasing digitalisation of both, the economy and the society. The emerging European Silver Economy (SE) 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.
This shall be achieved by establishing a widely recognised European annual award scheme for innovative solutions that serve the ageing population and which can demonstrate a significant impact improving the quality of life of the ageing population 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.

Scope:

Proposals should develop and implement an integrated communication and innovation concept, built upon an 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.

Proposals 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.
Proposals 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. Proposals may use a share of the action budget for that purpose during the project until alternative long-term funding sources are defined and secured.
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…).

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, etailers, 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*.**

HCO 12 – 2016 - Digital health literacy and workforce IT skills [CNECT]

(a) 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 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"), 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, i.e. taking into account demographic, social and cultural differences and address critical and/or interactive skills and competencies, as well as support peer learning.

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;
- 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;
- Positive impact at the personal level (knowledge, motivation, self-confidence, stronger feelings of control);
- Strengthened evidence base on health outcomes, quality of life, 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;

Instrument

CSA

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

(b) 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 the need 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[31] and other international cooperation in this area. They should also demonstrate knowledge of existing curricula and training, identify gaps and propose solutions to bridge them. A familiarity with the ICT Skills' European eCompetence Framework for healthcare is also important.

Expected impact

- Identification of the main gaps in IT skills and training needs of the healthcare workforce for optimum use of eHealth solutions
- Improved access to training programmes and upgrading of skills for all types of actors in healthcare workforces
- Assessment of the effectiveness of training programmes
- Strengthened international collaboration in the area of healthcare professionals IT skills including contributions to the actions of the EU-US MoU eHealth Roadmap.

Instrument

CSA

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

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

HCO 13 – 2016 - EU-US interoperability roadmap [CNECT]

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. Proposals 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[32] 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.

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.
- Improved international interoperability of eHealth Systems in the US and in Europe.

Instrument:

CSA

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

HCO 14- 2016 - EU eHealth Interoperability conformity assessment [CNECT]

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 (eHealth EIF). 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.

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

Scope:

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 a corresponding trusted label/certificate should be considered. It is expected that this CSA will bring together a wide range of relevant stakeholders with expertise in the development, implementation, assessment, maintenance and dissemination of such a conformity scheme.

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

Instrument:

CSA

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

HCO 15- 2016 – Standardisation needs in the field of ICT for Active and Healthy Ageing [CNECT]

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

Proposals are 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 integration profiles for independent living33.
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.
- 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.

Expected Impact

- Engagement of required stakeholders to ensure lasting impact.

[33] 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 that they are talking about the same solution without having to restate all the technical details that establish actual interoperability.

- 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 THESE CALLS

Publication date: XX month 2015

Deadline[34],[35]: XX month 2016 and XX month 2017

HCO 01 - 2016 HCO 02 - 2016 HCO 04 - 2016 HCO 05 - 2016 HCO 06 - 2016	XX month 2016 at 17.00.00 Brussels time	Budget EUR million 2 2 2 2 2	Single stage The thresholds for each criterion in a single stage process will be 3, 3 and 3. The cumulative threshold will be 10
HCO 03 - 2017 HCO 07 - 2017 HCO 08 - 2017	XX month 2017 at 17.00.00 Brussels time	Budget EUR million 5 24 1	Single stage The thresholds for each criterion for the ERA-NET Cofund will be 3, 3 and 3. The cumulative threshold will be 10

DG CNECT

HCO 11 – 2016 HCO 15 - 2016	[draft date] 16 February at 17.00.00 Brussels time	Budget EUR million 1 1	Single stage
HCO 09 -2016 HCO10 - 2016 HCO 12- 2016 HCO 13 - 2016 HCO 14 - 2016	1st March 2016 at 17.00.00 Brussels time	3 3 2.5 1 1	Single stage The thresholds for each criterion will be 3, 3 and 3. The cumulative threshold will be 10.

HOA x – eHealth Week 2016		0,3	

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

[35] Any deadlines provided in brackets are indicative and subject to a separate financing decision for 2017.

Indicative budget :

- EUR XX million from the 2016 budget[36]
- EUR XX million from the 2017 budget[37]

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

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

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

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

- Indicative timetable for evaluation and grant agreement:

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

[36] Subject to the availability of the appropriations provided for in the draft budget for 2016 after the adoption of the budget for 2016 by the budgetary authority or if the budget is not adopted as provided for in the system of provisional twelfths.

[37] The budget amounts are indicative and will be subject to a separate financing decision to cover the amounts to be allocated for 2017.

Other Actions

HOA 01 – 2016+2017: Subscription fee: Human Frontier Science Programme Organisation [RTD]

An annual subscription to the international Human Frontier Science Programme Organisation (HFSPO)[38] 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[39] in research and innovation.

Type of action: Subscription

Indicative timetable: 2016 and 2017

Indicative budget: EUR 4 958 000 from the 2016 budget and EUR [5 000 000 TBC, placeholder] from the 2017 budget

HOA 02 - 2016 + 2017 Infectious Diseases Finance Facility (IDFF) Pilot

Specific challenge: Infectious diseases (ID) pose a major global health threat as they are the second leading cause of mortalities, accounting for approximately 17% of deaths with the highest burden in low and middle-income regions. ID R&D is confronted with a more accentuated funding gap which hampers the development of novel interventions, and a lack of investment from industry. In addition, many existing ID treatments are jeopardised by the emergence of antimicrobial resistance, which threatens the effective prevention and treatment of an ever-increasing range of infections. The support for the fight against infectious diseases constitutes a key public health priority for the European Union.

Scope: This action will contribute to the IDFF pilot established under the InnovFin[40] umbrella which is developed jointly by the European Commission and European Investment Bank. It aims to finance the development of innovative drugs, vaccines, medical and diagnostic devices and infrastructures for combatting infectious diseases, including those with uncertain commercial prospects. It will make loans of between [x] and [x] to large pharmaceutical companies for financing the development of pre-identified medical products on a risk-sharing basis, and of between [x] and [x] to midcaps, SMEs, project vehicles or research institutions for the purpose of corporate or project finance transactions. Other forms of finance may also be possible.

Expected impact: **InnovFin IDFF Pilot** will help in:

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

39 COM(2012)497

40 http://www.eib.org/products/blending/innovfin/index.htm

- Increase the EC investment in infectious disease research. A multiplier effect of at least 5x (total investment cost / EC investment) is expected over the initial investment period e.g. an investment of EUR 300 would those generate at least a total investment of Euro 1.5bn

- 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; This action is expected to deliver at least X new medical interventions within the first 36 months

- fostering the healthcare sector and hence creating jobs and growth in the EU.

Indicative timetable: [placeholder]

Selection procedure: [place holder]

Indicative budget: EUR 50 million from the 2016 budget and EUR 50 million from the 2017 budget. This contribution is expected to be replaced or complemented by EFSI and/or from other investors as well as by reflow from IDFF.

HOA 03 - 2016: 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 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 150 000 from the 2016 budget

HOA 04 - 2016: 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 150 000 from the 2016 budget

HOA 05 - 2016: European registry for human embryonic stem cell lines

A contribution 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 hESC lines derived in Europe and beyond, thereby also avoiding needless creation of new cell lines. This registry operates through an internet website that will continue to provide high quality data about the lines (e.g. cell characteristics), details regarding their source and contact information regarding their location.

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

Type of action**:** CSA – Grant to identified beneficiary

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 1 000 000 from the 2016 budget for a duration of 4 years

HOA 06 – 2016/2017: Tenders studies, activities of the Scientific Panel for Health, and for 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[41]), 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 invited as appropriate.

Type of action: Public procurement

Indicative timetable: Second semester 2016; 2017

Indicative budget: EUR 0.50 million from the 2016 budget; EUR 0.5 million from the 2017 budget.

HOA 07 – 2016/17: Independent experts assisting in proposal evaluations and assessment, and project reviews

This action will support the use of appointed independent experts for the evaluation of project proposals and, where appropriate, for the monitoring of running projects, as well as for the assessment of proposals submitted to the Inducement Prize competitions.

Type of action: Expert contracts

Indicative budget: EUR 2.0 million from the 2016 budget; EUR 2.0 million from the 2017 budget.

HOA 08 – 2017*:* Inducement prize on Maternal and Child Health research*

Under the Millennium Development Goal 5 (MDG5), countries committed to reducing by 2015 the 1990 maternal mortality rate by three quarters, and under the MDG4, to reduce by two thirds the under-five children mortality levels. As a result of the global coordinated and targeted effort since 1990, maternal deaths worldwide have dropped by 45% and the child mortality rate has dropped by 51%, from 90 deaths per 1000 live births in 1990, to 46 in 2013. However the rate of these reductions is still insufficient, and following the World Health Organisation in 2013 approximately 300 000 women died from preventable causes related to pregnancy and childbirth - maternal and perinatal conditions being the seventh contributors to the global burden of disease[1], and 6.3 million children died under the age of five. These deaths are disproportionately concentrated in the developing world[2], where 99% of maternal deaths occur, three-quarters due to preventable or treatable conditions such as haemorrhage, hypertensive disorders of pregnancy and sepsis. It is also in the Low and Middle Income countries where more than half of the children under five die due to infectious diseases, mainly pneumonia, diarrhoea and malaria [3]. The Maternal and Child Health Inducement prize will encourage solutions to reduce this global burden. The specific objectives to be fulfilled, the targeted audience, etc. will be determined on the basis of the outcome of the on-going work.

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

[1] 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

[2] Dr 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

Expected results: TBD

Launch of contest: TBD

Type of action: Inducement prize

Eligibility criteria: The common Rules of Contest for Prizes, including processing of personal data, sole liability of contestants, applicable law and competent jurisdiction, conditions for participation, applicability of penalties and exclusion criteria, will be provided in part F of the General Annexes once the prize will be defined.

Essential award criteria: 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.

Rules for exploitation and dissemination of results: TBD

Indicative budget: EUR 1 000 000 from the 2017 budget

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

HOA 09 - 2017: 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 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[42] in research and innovation.

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

Type of action**:** CSA – Grant to identified beneficiary

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 240 000 from the 2017 budget

[42] COM(2012)497

HOA xx – 2016/2017: 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:

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

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 – Co-ordination and support actions.

Evaluation and rate of co-financing: 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 300 000 from the 2016 budget, EUR 300 000 from the 2017 budget

Other Actions

Under the Internet of Things (IoT) Focus Area Call a topic entitled "Pilot 1: Smart living environments for ageing well" will be jointly funded by ICT-LEIT "Leadership in enabling and industrial technologies Information and Communication Technologies" and SC1 "Health, Demographic Change and Wellbeing". A budget of max. 10 M EUR will be equally contributed by SC1 and ICT-LEIT. Thus, the max. total budget for Pilot 1 is 20 M EUR.

The SC1 WP will include a reference to a separate part of the WP dedicated to the IoT Focus Area.

- Internet of Things (IoT) Focus Area Call

Internet of Things

Internet of Things - Focus Area (IoT- FA) ambition is to take the IoT evolution to the next level, and to enable the emergence of IoT ecosystems supported by open technologies and platforms. It will be addressed through a complementary set of activities structured around Large Scale Pilots.

IoT Pilots will make use of the rich portfolio of technologies and tools so far developed and demonstrated in reduced and controlled environments and extend them to real-life use case scenarios with the goal of validating advanced IoT solutions across complete value chains with actual users and proving its enormous socio-economic potential.

Support actions provide consistency and linkages between the pilots and complement them by addressing challenges critically important for the take-up of IoT at the anticipated scale. These include ethics and privacy[43], trust and security, validation and certification, standards and interoperability, user acceptability, liability and sustainability. A coordination body will ensure an efficient interplay of the various elements of the IoT-FA and liaise with relevant initiatives at EU, Member States and international levels.

Research and innovation effort in specific IoT topics will ensure the longer-term evolution of Internet of Things.

IoT1 – 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, security and privacy in the specific real-life scenarios of the pilot, in the context of pre-defined privacy and security impact assessments; 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 with real users, across multiple sites, scalability to large amount of heterogeneous devices and systems, as well as large amount of users are expected. Pilot work plans should

[43] In the context of this call, the concept of privacy refers to the EU legal provisions applicable at the moment of pilot implementation in relation to both the "right to privacy" (right to respect for private and family life) but as well to the "right to protection of personal data".

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[44], 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.

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. It is expected that one pilot is funded for each area:

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.

Pilot 2: Smart Farming and Food Security

The implementation of Precision Agriculture has become possible thanks to the development of sophisticated sensors, robots and sensor networks combined with procedures to link mapped variables to appropriate farming management actions. Those sensors, either wired or wireless, integrated into a IoT system gather all the individual data needed for monitoring, control and treatment on farms located in a particular region. Such future Internet of Things scenario would bring data management to a new level by establishing interaction between the concerned objects, help them exchange information in efficient ways and enable them to execute autonomously appropriate interventions in different agriculture sub-sectors (arable crops, livestock and horticulture) and their associated post-production value chain through to the consumer. The introduction of the IoT scenario would allow monitoring and

[44] Future Internet Research and Experimentation

control of the plant and animal products during the whole life cycle from farm to fork. The challenge is to design architectures to "program" each object for optimal behaviour, according to its role in the Smart Farming system and in the overall food chain, lowering ecological footprint and economical costs and increasing food security. It also enables consumers to access trustworthy traceability information throughout the whole food chain.

Proposals shall include an adequate combination of different farms to ensure that the deployment of the technology is adapted to the needs of different types and sizes of farms across Europe. Activities should allow for a wide geographic coverage within Europe. In addition, proposals shall cover at least the three mentioned sub-sectors: arable crops, livestock and horticulture.

Proposals should fall under the concept of multi-actor approach[45] and allow for adequate involvement of the farming sector in the proposed activities.

Pilot3: Wearables for smart ecosystems

Demonstration of innovative wearable solutions and services integrated in interoperable IoT ecosystems. Wearables are integrating key technologies (e.g. nano-electronics, organic electronics, sensing, actuating, localization, communication, energy harvesting, low power computing, visualisation and embedded software) into intelligent systems to bring new functionalities into clothes, fabrics, patches, watches and other body-mounted devices. They assist humans in monitoring, situational awareness and decision making. Particular attention should be devoted to actuating functions providing whenever feasible fully automated closed-loop solutions. Prototype development and demonstration are expected for healthcare, well-being, safety, security and infotainment applications. Actions should be driven by concrete business cases and user requirements, taking into account data protection and liability concerns. They should involve the actors of the entire innovation value chain and aim at demonstrations in real world settings. The number of users involved should be sufficient to ensure statistical significance in impact analysis.

Pilot 4: Reference zones in EU cities

Building on the past results and achievements[46] in some cities in Europe, a large scale pilot will cover a series of cities to operate as reference zones for showcasing and experimenting new citizen-centred IoT services. Starting from users' expressed preferences and needs, these cities will experiment and test similar new services and solutions and gather experience at scale and evaluate citizens' acceptability and endorsement. It will enable SMEs to use open demonstrators to test innovative new services. This includes advanced solutions that are at the edge of authorised business practices or regulation (ex: sharing of electricity, autonomous vehicles) and thus require dedicated testing zones. Whenever applicable, pilots will provide evidence of access to city areas where legal contexts are adapted to the demonstration requirements (i.e. 'reference zones'). Federation and interoperability between platforms may be considered as appropriate, as well as the ability to integrate data from different service providers. 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.

[45]The multi-actor approach aims at more demand-driven innovation through the genuine and sufficient involvement of various actors (end-users such as farmers/farmers' groups, fishers/fisher's groups, advisors, enterprises, etc. As a minimum, this material should feed into the European Innovation Partnership (EIP) 'Agricultural Productivity and Sustainability' for broad dissemination as 'practice abstracts' in the common EIP format for practitioners. Facilitation/mediation between the different types of actors and involvement of relevant interactive innovation groups operating in the EIP context, such as EIP Operational Groups funded under Rural Development Programmes, are strongly recommended.

[46] E.g. FIRE and FIWARE

Pilot 5: Autonomous vehicles in a connected environment

Connectivity is expected to revolutionize the environment and economics of cars in the future: first through connection among cars and intelligent infrastructures, second through the emergence of an ecosystem of services around smarter and more autonomous vehicles. The pilot addresses these two complementary perspectives through:

- successful deployment of safe and autonomous vehicles (SAE[47] international level 5, full automation) in various representative use case scenarios, exploiting local and distributed information and intelligence. Core technologies include reliable and real-time platforms managing mixed criticality car services, advanced sensors, efficient navigation and improved decision-making technology, interconnectivity between vehicles, vehicle to infrastructure communication. The selected scenarios will provide proofs of concept showing how such technology provides benefits affecting users on a daily basis, for instance on the highways or in urban congested environment, either on dedicated lanes or mixing autonomous connected vehicles and legacy vehicles. To make a real step towards future large scale deployment and to demonstrate dependability, robustness and resilience of the technology over longer period of time and under a large variety of conditions, priority will be given to permanent installations and sustainable pilots rather than temporary prototype or demonstrator.

- enabling the development of service ecosystems around cars/vehicles and mobility, taking into account the fact that vehicles also includes multiple embedded information sources around which information services may be constructed. This information may be used for services as diverse as intelligent maintenance, personalised insurance, car organs behaviour monitoring, advanced security and autonomous trip management as typical but non exhaustive examples.

These evolutions are expected to be supported by an open service platform which may have access to all in vehicle embedded information sources and to car surrounding information, in view of providing personalised services to drivers while driving or not. Key barriers to the deployment of such vehicles and ecosystems such as robustness of the perception, how to keep users of highly and fully automated vehicles sufficiently engaged and overall user acceptance are in scope, as well as economic, ethical, legal and regulatory issues.

Pilot 6: Water management for resilient cities

Innovative IoT solutions are crucial to meet water demand from increased urbanisation, to improve water efficiency, to monitor and control surface water retention from storm water and to manage flooding. Reducing the leakage levels from water distribution networks (that in several Members States is more than 50%), is also key. The focus is on improving water efficiency in the distribution and associated processes. The pilot should be deployed in the urban context and in addition to water distribution should tackle the integration with other water related applications, in particular water treatment, re-utilisation and quality. The integrated solutions should enable real-time interconnection of heterogeneous sensors and actuators, geo-localisation and data fusion including data from meteorological forecast. High reliability and low maintenance costs are key parameters. The overall objective is to deploy IoT applications and services making our cities more resilient to climate change.

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

[47] Society of Automotive Engineers, J3016 standard

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 thousands to 300 Thousands 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.
- 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);
- 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;
- 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.).

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.
- 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 instrument(s):
Innovation Actions: One pilot per area is expected. 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 10 million (pilots 5, 6) 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 pilot is supported for each area.

Budget per type of instrument(s):
LEIT ICT Contribution: EUR 75 million; SC1 Contribution[48]; EUR 10 million; SC2[49] contribution: EUR 15 million

IoT2 – 2016: IoT Horizontal activities

Specific Challenge:
The challenge is to ensure a sound coherence and exchanges between the various activities of the Focus Area, and notably cross fertilisation of the various pilots for technological and validation issues of common interest across the various use cases. Issues of horizontal nature and topics of common interest, such as privacy, security, user acceptance, standardisation, creativity, societal and ethical aspects, legal issues and international cooperation, need to be coordinated across the pilots to maximise the output and to prepare the ground for the next stages of deployment, including pre-commercial or joint public procurement. A related challenge is to foster links between communities of IoT users and providers, as well as with Member States' initiatives, and to connect with other initiatives including contractual Public-Private-Partnerships (e.g. in the area of Big Data, Factories of the Future, 5G-infrastructure), Joint Technology Initiatives (e.g. ECSEL), European Innovation Partnerships (e.g. on Smart Cities), other Focus Areas (e.g. on Autonomous transport), and RRI-SSH issues.

A related challenge addresses inter-operability and integration, through open IoT platforms across application areas such as FIWARE or CRYSTAL. It addresses the reference implementation of promising IoT standards serving the interoperability and openness objectives, by consolidating results obtained through standard implementation and pre-normative activities at the platform and/or pilot levels.

Scope:
The scope includes two support levels:

- Programme level coordination ensuring consistent exploitation of the outcomes of the various projects forming the FA:, coordination of the projects and related pilot areas through mapping of pilot architecture approaches, interoperability and standards approaches at technical and semantic levels for object connectivity, protocols, data formats, privacy & security, open APIs, exchange on requirements for legal accompanying measures, development of common methodologies and KPI for design, testing and validation and for success and impact measurement; federation of pilot activities and transfer to other pilot areas, facilitating the access for IoT entrepreneurs/API developers/Makers and SME in general. The corresponding activities will be developed and consolidated together with the pilots at programme level, and include where appropriate results from other relevant activities in the Factory, smart city, and vehicle domains.
- Horizontal support: further development and exploitation of security and privacy mechanisms towards best practices and a potential label (“Trusted IoT”); legal support in relation to data ownership and

[48] Pilot 1 will be jointly funded by ICT-LEIT "Leadership in enabling and industrial technologies Information and Communication Technologies" and SC1 "Health, Demographic Change and Wellbeing". A budget of max. 10 M EUR will be equally contributed by SC1 and ICT-LEIT. Thus, the max. total budget for Pilot 1 is 20 M EUR

[49] Pilot 2 will be jointly funded by ICT-LEIT "Leadership in enabling and industrial technologies Information and Communication Technologies" and SC2 "Food security, sustainable agriculture and forestry, marine and maritime and inland water research and the bioeconomy". A budget of max. 15 M EUR will be equally contributed by SC2 and ICT-LEIT. Thus, the max. total budget for Pilot 2 is 30 M EUR

protection, security, liability, sector-specific legislations; contribution to pre-normative activities and to standardization both horizontally and in various application areas, also linked with IoT Governance. The corresponding activities will be developed and addressed in the pilots and consolidated at programme level under this horizontal support activity line. Promotion for sharing of conclusions and road-mapping with similar activities in countries and regions outside Europe, including convergence and interoperability of European and non-European IoT reference architectures/platforms. Exploitation of the combination of ICT & Art for stimulating innovation and acceptance; preparation for the next stages of IoT deployment including through pre-commercial or joint public procurement.

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

- RRI-SSH support: pilots shall be citizen-driven, involving existing and local communities at an early stage and addressing a combination of sustainability areas. The corresponding activities should accompany the pilots, analyse societal, ethical and ecological issues related to the pilots, and develop recommendations for tackling IoT adoption barriers including educational needs and skill-building. Consortium participation requires at least two entities from domains different than ICT technologies (e.g. social sciences, psychology, gerontology, economy, art, etc.).

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

- Ensure efficient and innovative IoT take-up in Europe, building on the various parts of the initiative (pilots, research, horizontal actions)
- Efficient information sharing across the programme stakeholders for horizontal issues of common interests
- Extension and consolidation of the EU IoT community, including start-ups and SMEs
- Validation of technologies deployment, replicability towards operational deployment
- Validation in usage context of most promising standards and gap identification
- Strengthening of the role of EU on the global IoT scene, in particular in terms of access to foreign markets.

Type of instrument(s):
Coordination and Support Action

Budget per type of instrument(s):
LEIT ICT Contribution: EUR 4 million

IoT3 – 2017: R&I on IoT integration and platforms

Specific Challenge:
The future design of the Internet of Things applications will depend crucially on the development of sophisticated platform architectures for smart objects, embedded intelligence, and smart networks. Most of the today's IoT systems are however mainly focused on sensors, whereas in the future actuation and smart behaviour will be the key points.

Research driven by ambitious use cases and benefiting from existing technologies from related innovation areas in components, systems and networking needs to be carried out to respond to the ever increasing needs of future IoT systems in terms of scalability, heterogeneity, complexity and dynamicity. Due to the importance of innovations coming from third parties, IoT platforms should be open and easy-to-use.

Scope

- Architectures, concepts, methods and tools for open IoT platforms integrating evolving sensing, actuating, energy harvesting, networking and interface technologies. Platforms should provide connectivity and intelligence, actuation and control features, linkage to modular and ad-hoc cloud serv ices, Big Data analytics and open APIs as well as semantic interoperability across use cases and conflict resolution.

  Platforms should be compatible with existing international developments addressing object identity management, discovery services, virtualisation of objects, devices and infrastructures and trusted IoT approaches. Proposed research and innovation should take advantage of previous work and build on existing platforms, such as FIWARE and CRYSTAL, if appropriate.

- IoT security and privacy. Advanced concepts for end-to-end security in highly distributed, heterogeneous and dynamic IoT environments. Approaches must be holistic and include identification and authentication, data protection and prevention against cyber-attacks at the device and system levels. They should address relevant security and privacy elements such as confidentiality, user data awareness and control, integrity, resilience and authorisation.

Proposals should address above mentioned topics, verification and testing, and identify the added value of the proposed approach specific to IoT in comparison to generic solutions. They are expected to include two or more usage scenarios to demonstrate the practicality of the approach.

Expected Impact:
Two or more of the following criteria should be addressed, with success metrics where appropriate.

- Evolution of platform technologies and contribution to scientific progress enabling novel, advanced semi-autonomous IoT applications.
- Strengthen the industrial EU technological offer of innovative IoT solutions
- Contribution to emerging or future standards and pre-normative activities
- Increase of IoT usability and user acceptance, notably through strengthened security and user control
- Promote the adoption of EU platforms in European and international context

Type of instrument(s):
Research and Innovation Action – The Commission considers that proposals requesting a contribution from the EU 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

Budget per type of instrument(s):
LEIT ICT Contribution: EUR 35 million