Personalised Medicine

H2020-PM-2016/2017

1.1 Understanding health, well-being and disease

PM 1 – 2016 - Stratification for personalised therapies [RTD]

Specific Challenge

The challenge is that despite the major advances in the post-genomic era, there is still large unmet medical need in providing preventative, diagnostic and therapeutic interventions. For example, still 90% of the drugs are effective in 40% of the patients.

Implementing knowledge-based decisions on what are the optimal interventions for which patients and in which combinations, will lead to innovation in the area of personalised medicine. As one approach, the stratification of patients into disease groups holds the potential to the development of targeted diagnostic, therapeutic and/or prophylactic interventions, specifically directed to the relevant phenotypes.

Due to the complexity of human physiology and pathophysiology, in the last years the biomedical research community has been adopting a combination of –omics, systems biology and integrative analysis methods to understand the mechanisms of health and disease including disease progression. There is increasing evidence that interaction with the environment, as reflected in genome-epigenome-metabolome-microbiome crosstalk play an important role in disease development and progression. Combining data and knowledge from different areas, using systems medicine approaches and pooling resources will pave the way for designing novel more personalized interventions.

Scope

The scope of the topic will be:

i. Either to create strategic synergy between scientists across disciplines and sectors in the context of international initiatives. Proposals should build on the data, results and sources produced of existing and/or new international initiatives (e.g. ICGC, IHEC, IHMC, HUPO etc. excluding IRDiRC). Proposals should deploy whole genome sequencing data, high-quality epigenomics maps, and relevant -omics data and combine these with disease-oriented functional analysis to develop new therapeutic concepts for multifactorial diseases.

ii. Or to support multidisciplinary research projects integrating diverse types of biomedical data combined with the power of -omics, pharmacogenomics, systems biomedicine approaches and of computational modelling. Proposals should deliver novel concepts for patient stratification for the delivery of personalized and/or preventive therapeutic interventions for multifactorial diseases. Proposals should integrate, where appropriate, multidimensional, longitudinal, quantitative data and validate their discoveries in clinical studies.

Expected Impact

- Build European and/or International initiatives to pave the way for the implementation of personalised medicine.
- Develop novels concepts for patient stratification to enable redefinition of disease taxonomy and/or novel concepts for targeted therapeutic interventions.
- Accelerate the translation of research results into clinical practice, and increase research & innovation opportunities in this SME-intensive field.

Type of Action

RIA

PM 2 – 2016 – "Solving the unsolved"- Genomic characterisation of undiagnosed rare diseases [RTD]

Specific Challenge

Rare diseases are diseases which affect not more than 5 per 10 000 person in the European Union. It is estimated that rare diseases encompass between 6 000 and 8 000 different diagnoses 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 molecular diagnosis. An accurate molecular diagnosis is essential for informed 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 approaches for the molecular characterisation of rare diseases in view of developing molecular diagnoses for a large group of undiagnosed rare diseases. Genetic variability due to geographical distribution and/or different ethnicity should be taken into account as well as genotype-phenotype correlation whenever applicable. This large-scale project should promote common standards and terminologies for rare disease classification and support appropriate bioinformatics tools which facilitate data sharing. Wherever possible, existing resources should be used for depositing data generated by the projects.

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).

Expected Impact

- Providing better and faster means for the correct diagnosis of rare diseases for which there is no or unsatisfactory diagnosis available.
- Contribute towards the IRDiRC objectives.

Type of Action

RIA

PM 3 – 2016 - Networking and optimising the use of population cohorts at EU level [RTD]

Specific Challenge

The stratified approach to healthcare that underpins personalised medicine is dependent upon obtaining a detailed description of individual biological variation in connection with environmental, societal, and lifestyle factors that influence the development of disease. Europe currently boasts some of the most valuable population and patient cohorts. The methods used to collect data change over time, and new questions arise that require analysis of different patients or demographic groups.

Scope

Building on European leadership in cohorts the aim of this topic is to compare practices, identify common needs and gaps and establish best practices and harmonised approaches with a view to maximise the effective exploitation of large data sets and provide the basis for studying co-morbidity and co-infections

Expected Impact

- stronger epidemiological basis for policy support, through increased power of studies, better quality of epidemiological data in Europe and beyond,
- enhanced exploitation of data through better comparability between studies.
- improvement of future studies, through increased harmonisation of studies, for instance by defining sets of minimum common data elements and agreed methods of and tools for harmonisation and integration of data.
- new opportunities for prevention and intervention studies.

Type of Action

RIA

PM 4 – 2016 - The European Human Biomonitoring Initiative [RTD]

Specific challenge:

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 accumulated in the body, the health impact is still unknown but some of these chemicals are suspected to have long-term health effects. A major hurdle in reliable risk assessment and management of chemicals is the lack of harmonised information about the exposure of citizens, including workers, and any impact on their health. 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 would be to gather harmonised and comparable information on population exposure to chemicals in Europe through human biomonitoring (HBM) and to promote research on the exposure-response relationships in humans.

Scope:

The objective is to create a sustainable structure and a European joint programme for monitoring and scientific assessment of health impacts of human exposure to chemicals in Europe. This European Human Biomonitoring Initiative (EHBMI) should be achieved through coordination of HBM initiatives in Europe 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 throughout Europe. The EHMBI should provide a platform though which harmonised and validated information and data collected at national level can be accessed and compared. It should support R&I in various ways, e.g. by improving underlying methods and procedures (e.g. for sampling, analysis, data management), by improving the understanding of the impact of the exposure on human health (e.g. by development of validated exposure and effect biomarkers). The acquired knowledge should support informed decision taking and policy making in a wide variety of sectors. Thus the programme should be structured along four main axes: support for field sampling and analytical work by competent national laboratories; data infrastructure; a research programme to assess impact on human health; and translation of programme results into policy.

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 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

Type of Action

Programme Co-fund Action (European Joint Programme)

PM 5 – 2016 - Vaccine development for poverty-related and neglected infectious diseases: malaria and neglected infectious diseases [RTD]

Specific Challenge

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

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

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

Scope

The topic addresses bottlenecks in the discovery, preclinical and early clinical development of new vaccine candidates for malaria or neglected infectious diseases[1].

Depending on the maturity of the research landscape for each disease, proposals may range from large research platforms assessing multiple vaccine candidates or multiple diseases, to proposals specifically focused on one disease. The larger platforms should address the following elements:

1. Establishment of methodology for the discovery of new antigens and new approaches for new formulations for the selection of several diverse and novel vaccine candidates, and their pre-clinical and early clinical testing. Proposals should include the draft methodology for discovering new antigens and the draft algorithms for developing suitable formulations for the new antigens.

1 Neglected Infectious Diseases for the scope of this call: Schistosomiasis, Leishmaniasis, Chagas, Onchocerciasis, as well as neglected viral emerging epidemic diseases like West Nile Virus, Chikungunya, and Crimean-Congo Haemorrhagic Fever. Filoviruses diseases are excluded from this topic.

2. The major bottlenecks in vaccine development should be addressed; in particular better ways for early distinction between successful candidates and those that will eventually fail in late stage clinical trials. Proposals should draft the algorithm for down selection of candidates. To the extent feasible, the predicted cost and affordability of final vaccine products should be evaluated. Proposals should include a systematic approach and key definitions for benefit-risk assessment across the whole research and development. Based on these criteria the most promising new vaccine candidates, will be able to be compared and selected in an objective and transparent process according to their merit in line with effective vaccine portfolio management.
3. The successful proposal shall continue its vaccine development in the context of the Art.185 initiative on European and Developing Countries Clinical Trials Partnership (EDCTP), and a pathway and commitment towards this direction must form an integral part of the proposal.

Expected Impact

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

Type of Action

RIA

PM 6 – 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 physical illnesses. Given the current limitations in the effectiveness of treatment modalities for mental and behavioural disorders, the only sustainable method for reducing the burden caused by these disorders is prevention. While promising, the evidence on the role subjective well-being plays in recovery from mental health problems is still limited, so is the evidence on its effectiveness in protecting against future mental and physical illness and increasing longevity, healthy life years and productivity. There is a need for more robust evidence 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, thanks to early experience-dependent neuroplasticity

Scope

The project will develop, through a holistic approach, innovative interventions to promote mental health and well-being of young people (age frame to be determined). The interventions will address

medical and social determinants of mental health (societal, cultural, epidemiological, economic and environmental perspectives). The research design will be developed using a multidisciplinary approach and involving relevant stakeholders such as policy makers, the educational sector and civil society organisations

Expected Impact

- The direct impact will be an improved understanding of the different determinants of well-being in youth. This understanding, coupled with the innovative interventions that will be developed, will create a strong basis for well-being promotion programmes in Europe.

- Improved well-being in youth should also reduce school dropout through an increased perception of their self-worth and capacities. This will, in turn, widen their spectrum of professional career possible choices and improve the European workforce

- A longer- term impact would be the reduction of the occurrence of NCD (Non Communicable Diseases) and mental disorders later in life through improved mental health and well-being while young. Thereby increasing productivity and reducing the economic burden on European social security systems.

Type of Action

RIA

PM 7 – 2017 - New therapies for rare diseases [RTD]

Specific Challenge

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

Specific problems posed in therapy development for rare diseases include the small and dispersed patient populations and the nature of the therapies proposed, which are often highly specialised and novel. Amongst other challenges, this leads to the requirement for seeking advice of regulatory authorities during development. In addition, despite the special incentives for the development of orphan medicinal products, the limited market for such therapies may in some instances lead to a low commercial return.

Scope

Support will be provided to clinical trials on substances where orphan designation has been given by the European Commission and where the proposed clinical trial design takes into account recommendations from protocol assistance given by the European Medicines Agency and where a clear patient recruitment strategy is presented. The orphan medicinal product must have been granted the EU orphan designation at the latest on the date of the Stage 1 call closure. A concise feasibility assessment justified by available published and preliminary results and supporting data shall also be provided. Appropriate plans to engage with patient organisations and considerations of effectiveness/potential clinical benefit should be integrated in the application. In addition to the clinical trial, the proposals may also include limited elements of preclinical research, which must be complementary/contribute to the clinical trial(s) carried out within the project. The centre of gravity must clearly be the clinical trial(s).

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

Expected Impact

- Advancing the development of new therapeutic options for patients living with rare diseases.
- In line with the Union’s strategy for international cooperation in research and innovation, proposals shall contribute towards IRDiRC objectives.

Type of Action

RIA

PM 8 – 2016 - Patient-centred therapies for chronic diseases [RTD]

Specific Challenge

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

Scope

Proposals should focus on clinical trial(s) supporting proof of concept in humans to assess the clinical safety and efficacy of novel therapies (pharmacological as well as non-pharmacological) and/or the optimisation of available therapies (e.g. repurposing) for chronic diseases. Preclinical research should be completed. Proposals should provide a sound feasibility assessment, justified by available published and/or convincing preliminary results. Gender must be considered whenever relevant. Rare diseases, regenerative medicine, smart implants, bioartifical organs and replacement technologies are not within the scope of this topic[2][3].

Expected Impact

- New therapeutic strategies, adapted where relevant to the different needs of men and women, with the highest potential to generate advances in clinical practice for chronic diseases.
- Improving the therapeutic outcome of major chronic health issues for individual patients.

Type of Action

RIA

PM 9 – 2017 - Comparing the effectiveness of existing healthcare interventions in the adult population [RTD]

Specific Challenge

Effective health care is often hampered by the lack of evidence as to the most effective health interventions. Growing numbers of patients affected by chronic diseases also call for efficiently managing comorbidities.

2 See topic PM7 addressing new therapies for rare diseases

3 See topic PM10 addressing clinical research on regenerative medicine and topic PM11 addressing clinical validation of smart implants, bioartifical organs and replacement technologies

Scope

Proposals should compare the use of currently available (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, 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. Given the focus on existing interventions, proposals will aim to contribute to decisions about the discontinuation of interventions that are less effective or cost-effective than others. A comprehensive array of clinical and safety parameters, as well as health and socio-economic outcomes (e.g. quality of life, patient mortality, morbidity, costs, and performance of the health system) for chosen populations should be assessed. Agreed core outcome sets (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 balance where relevant.

Expected Impact

This topic is to provide the required evidence base for:

- more effective and safer interventions;
- 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 diseases and the management of comorbidities.
- Support to regulatory guidance and provision of more accurate information to patients and prescribers.

Type of Action

RIA

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

Specific Challenge

Translating basic knowledge on regenerative medicine into the clinic is held up 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 is particularly scarce since being a new therapeutic field regenerative medicine lacks 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 and clinical work should represent the core of the project. 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.

Expected Impact

- Obtain results of in-patient regenerative medicine research so that new therapies can be taken to the next level of testing
- Stimulate growth and competitiveness of European regenerative medicine including European small and medium sized enterprises and industry operating in the sector
- Increase the attractiveness of Europe as a location of choice to develop new therapeutic options.
- Lever existing investments in fundamental research in regenerative medicine.
- New approaches to currently untreatable diseases.

Type of Action

RIA

PM 11 – 2017 - Clinical validation of smart implants, bioartifical organs and replacement technologies [RTD]

Specific Challenge:

The demand of organs for transplantation exceeds by far the number of available organs in Member States and is increasing faster than organ donation rates. The development of bio-artificial organs, an innovative approach at the interface of medical technology, regenerative medicine and tissue engineering, is a promising solution to respond to this need. The design, modification, growth and maintenance of living tissues embedded in natural or synthetic scaffolds have paved the way to the construction of biological substitutes for the repair or replacement of tissue or organ functions. However, there are challenges to be overcome, such as: rejection by the human body, long-term acceptance, GMP conform production and clinical validation

Scope:

The term bio-artificial organs relates to bio-artificial constructs that use cells or tissue for the replacement of biological function. Support is proposed to translate such bio-artificial constructs into the clinic and to bring them to the patients. This includes work on the regulatory needs, GMP conform production, first in-man clinical testing and further clinical validation. Projects should be at a stage where developmental work is finished and evidence of safety, function and efficacy has been established in animal models. The proposed research should focus on the uptake of such organ replacement constructs into clinical practice.

Expected impact:

- Boost growth of the European medical technology industry with special emphasis to the SME sector (25.000 companies whereof 95% SMEs, world market is estimated to amount to $514 billion by 2020).
- Enhance European competitiveness in an emerging area at the interface of medical technology and regenerative medicine.
- Delivery of organ replacement technologies ready for implantation.
- Improvement of quality of life of patients.
- Supporting regulatory-compliant new technologies.

Type of Action

RIA

PM 12 – 2016+2017 - Cell technology in medical applications technologies [RTD - SME Instrument]

Specific Challenge

The challenge of cell technologies is to harness the power of cells, which are of increasing importance to medical research, diagnostics and therapy. Technology needs to be found to exploit this power and to bring reliable and cost-effective products to the market and to the patient. The complex and variable nature of cells as biological raw material represents an inherent challenge, making the development of cell technologies often long, costly and risky. The diversity and pace of new developments pose further challenges in terms of navigating regulatory pathways and identifying business models. For cell technologies to move from proof of concept to practical application, considerations such as scale-up and automation need to be addressed. The challenge overall is to assist SMEs to overcome these barriers to developing cell technologies which in turn can lead to useful products and processes.

Scope

Cell technology refers to a wide range of processes spanning from cell manufacturing (culturing, multiplication and scale-up), to preservation, banking and transport; identification, cell sorting and delivery, imaging and tracking; genetic engineering and gene editing; production of therapeutic biomolecules, including GMP compliance.

Areas of application may include diagnostics, biosensors; cell and gene therapy, tissue engineering, immunotherapy, and vaccine and antibody production; predictive toxicology; synthetic biology; and modelling development and disease processes.

Where cell technology represents an enabling step in a longer process or more distant product, proposals may focus exclusively on that step and do not have to cover the whole innovation chain to the final product. For example, in a modified T-cell therapy for cancer, the proposal might be limited to the cell modification step; or in the case of cell-based monoclonal antibody production, the proposal might focus on cell culture scale-up or automation.

Proposals may focus on cells from human or animal origin though their eventual application must be to human medicine.

No TRL limitation will be applied to this topic.

Expected Impact

- Stimulate growth and competitiveness of European cell technology based medical applications.
- Strengthen European small and medium sized enterprises and industry operating in the sector.
- Foster development of innovative therapeutic approaches

Type of Action

SME Instrument (100% funding)

1.4 Active ageing and self-management of health

PM 13 – 2016 + 2017 - Support for eHealth related European SMEs stimulating innovation, investments and growth, including clinical validation of VPH solutions [CNECT- SME Instrument]

Specific challenge

The challenge is delivering new 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. EC supported within FP7 the VPH multi-scale computer modelling with clinical applications coupled with a set of infostructures, networking and road-mapping projects. Users trust and commercial exploitation are highly dependent on the clinical assessment of proposed prototypes. Performing extensive clinical validation will allow looking at the evidence for VPH projects results, accelerating the re-use of validated models and obtaining both clinical and European industrial/IT benefits. A solid financial foundation of SME's in this area would allow the coherence of the EC programs that aim to support both research and an economy prepared to reap the rewards of technological innovations.

Scope

The scope is to support:

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, and c) well-being solutions for healthy citizens. The target market should be clearly indicated in the proposal.

ii) Projects should focus on validating existing 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 projects should demonstrate sensibility, sensitivity, specificity and clinical benefits of models for relevant clinical applications in diagnosis and treatment.

Expected impact

- Stimulation of innovation, investments and growth in SMEs
- Promotion of healthy ageing and personalised healthcare to drive 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 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 of potential of re-use for other diseases
- Participation to building a sustainable healthcare

Instrument

SME instrument

PM 14 - 2016- 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 active and healthy for as long as possible. A key design goal is to achieve easy integration of a range of required services, independent, accessible and customisable user interfaces, and flexible adaptation of specific services as individual needs changes during the life course.

In order to reach this goal, new approaches for application design and delivery are required, which build on open service platforms[4], which are emerging and which have the features needed to support the requirements set out in this challenge.

The challenge is to support rapid development and market validation of new ICT products 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 service platforms is key to success and competiveness.

Scope

[4] 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.

Proposed projects will be supported through the Horizon 2020 SME instrument and should have a potential for disruptive innovation and fast market up-take in ICT for ageing well. In particular it will be interesting for entrepreneurs 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 and the business plan;
- The selection of the best platform to address this specific challenge;
- How they will contribute to – and benefit from the innovation ecosystem related to the chosen platform.

Expected Impact

- Creation of ICT innovation ecosystems around relevant open service platforms suitable for addressing the needs and desires of an ageing population;
- Enhancing profitability and growth performance of SMEs by building on open service platforms as an efficient means for rapid product and service development;
- Combining and transferring new and existing knowledge into innovative, disruptive and competitive solutions seizing European and global business opportunities;
- Increased availability and market uptake of ICT innovations for ageing well;
- Improved opportunities for EU industry to develop tools and compete on global scene of the Silver economy
- 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;
- The expected impact should be clearly substantiated in qualitative and quantitative terms (e.g. on turnover, employment, market seize, IP management, sales, return on investment and profit).

Type of Action

SME Instrument

PM 15 – 2016 - eHealth innovation initiated by healthcare service providers in empowering the hospitalised patient [CNECT]

Specific challenge

Empowering the hospitalised patients to manage their own disease and health is expected to result in more cost-effective healthcare systems by improving utilisation of healthcare and health outcomes. The support for a hospitalized patient should be understood broadly covering a continuum of care before and after the hospitalisation. The eHealth action plan and the outcome of the mHealth Green paper pave the way towards empowerment of the patient with the assistance of ICT.

Scope

Proposals should focus on the development of new services with relevant elements e.g., proof of concept, user acceptance, use of the service, training of the professionals including online courses, trust and security and consent of the patient allowing 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.

Expected impact

- Increasing the role and the responsibility of the patient
- 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

Instrument

PCP

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.

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;
- 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 project;
- Engage public and/or private procurers from each country participating (at national, regional or local level) that have responsibilities and budget control in the relevant area of care or supply of services;
- Be based on a complete set of common specifications for end to end services;
- Demonstrate that the implementation phase will reach "large scale" (i.e. sufficient scale to achieve statistical significance) through region-wide deployment across multiple regions of Europe;
- Contribute to the use of interoperable solutions based on open platforms and take into account existing best practices and standardisation initiatives;
- Provide robust safeguards to ensure compliance with ethical standards and privacy protections and take account of the gender dimension;

- Contribute good-practices to be made available for replication across other regions (e.g. "detailed plans" for larger scale sustainable uptake of innovative solutions for active and healthy ageing, reference material and guidelines, manuals and education materials).

The European Commission considers that proposals requesting a contribution from the EU of between EUR 1 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.

Type of Action

Public Procurement of Innovative Solutions co-fund actions.

PM 17 - 2016- EU-Japan Research and Development Cooperation in ICT for Active and Healthy Ageing [CNECT]

Specific Challenge

This activity should foster the EU-Japan cooperation in the area of ICT for active and healthy ageing and benefit from sharing intercultural expertise and creation of scalable markets.

It aims to build an active community for EU-Japan cooperation in the field of ICT for active and healthy ageing by launching a first set of joint initiatives to develop and demonstrate common ICT solutions and benefits for active and healthy ageing.

Proposals with balanced participation of EU and Japanese partners should make a substantial contribution to the identified theme indicating clearly the benefits of a joint effort.

Scope

The call will address strategic research and innovation projects to develop and demonstrate advanced ICT based solutions supporting active and healthy ageing in the home setting. The focus is on demonstrating substantial improvements in health, well-being, quality of life and extended functional capabilities by offering personalised and integrated ICT based services for older adults and their careers.

There should be realistic test sites in both the EU and Japan with to validate the expected benefits and impact. Due account should be taken regarding ethical issues such as informed consent and protection of privacy. Relevant contributions to standardisation are expected.

[To be further developed in cooperation with the partners in Japan]

Proposals are invited against the following topic:

EUJ X – 2016: New ICT based solutions for active and healthy ageing at home

Expected Impact

[To be developed in cooperation with the partners in Japan]

Type of Action

RIA

PM 18 - 2017- Research activities in 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 maintain their well-being, independence, functional capacity and health status.

Scope

Proposals should develop a proof of concept of a "virtual" personalised "3600 coach", building upon highly intelligent environments, new forms of accessible interaction based on tangible user interaction concepts, open platforms and emotional computing. Solutions should be capable of autonomous learning and adaptation to the personalised needs, emotional and behaviour patterns, conditions and preferences as well as the users' living environment and their social connections.

The "coach" should provide personalised suggestions for diet, physical activity, entertainment, social participation and lifestyle management to the person concerned, with the aim of preserving their physical, mental and social well-being. The proposed application should build on state of the art of existing or emerging dedicated applications and apps in different domains such as lifestyle, health, entertainment and social support.

Expected Impact

TO DO ***

Type of Action

RIA

PM 19 – 2017- In-silico clinical trials [CNECT]

Specific challenge

In the biomedical, pharmaceutical and toxicology research, the safety and efficacy of biomedical products are ultimately tested in humans via clinical trials. The complete chain of development of a new pharmaceutical product and its introduction to the market is very long and expensive. Alternative methodologies that can 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. A research and technological roadmap on the in-silico clinical trials is currently developed. Preliminary results show the strong interest/potential benefit to expand the computer-modelling in drugs and other biomedical products research by developing new ways of in-silico testing.

Scope

The projects will develop new in-silico clinical trials (ISCT) as a complement of a clinical trial on real human patients. They will be able to simulate the individual physiology and physiopathology at the biological levels relevant for the studied biomedical product thus taking into account the variability of individuals (for e.g. molecular pathways, genetics, behaviours, comorbidities). Virtual populations will be built for e.g. from the patient-specific models by variations of various parameters and will allow simulating the action of the treatments/procedures and predicting the outcomes. The proposed ISCT will explore and inform on the reasons for fails and suggest improvements. The benefit for human health, environment and animal welfare should be analysed and quantified.

Expected impact

- Reducing the size and the duration of the clinical trials for faster and cheaper results
- Being a viable alternative to the animal testing
- Improved predicting human risks for new biomedical products
- Improving drug repositioning
- A more effective clinical trials design
- Providing libraries of virtual patients that can be re-used in pre- and post-competitive testing of biomedical products

Instrument

RIA

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. This requires secure storage of information including personal data but also guaranteeing safe exchange of these data over a number of architectures of differing security levels preventing unauthorised access, loss of data and cyber-attacks. A systemic approach to security will increase patients' empowerment, help protect their health also while abroad, and possibly encourage a larger number of Member States to apply it and adapt national legislations.

Scope:

Proposals would provide a holistic approach to address challenges of secure storage and exchange (including cross-border) of data, protection and control over personal data, and security of health related data gathered by mobile devices. 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.

Expected impact:

- Further empowerment of the patient
- Encouraging Member States to widen the use of eHealth
- Ensuring the right of patients to cross-border healthcare
- Better protection against cybercrime

Action:
RIA

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

Specific challenge

There is continuous progress in systems medicine, multi-scale modelling and patient-specific modelling aspects. But these opportunities have been inconstantly explored for the entire chain of health and disease. Thus, there are very few in well-being, prevention or rehabilitation while these areas are crucial for reducing healthcare needs, building sustainable healthcare and for assuring a

healthy and motivated workforce. More, new innovative methods of diagnosis and prognosis are needed today. In any stage of disease management people deserve the maximum possible physical and psychic well-being. Maintaining health and preventing unsafe conditions contribute to well-being. Thus well-being is consequence of better prevention adapted to predispositions and behaviours, of better consideration given to the functional troubles, of an earlier diagnosis of disease and complications, of increased attention accorded to surgical or medical acts' consequences and rehabilitation.

Scope

The proposals should aim at the development of new integrative dynamic computer-models and simulation systems of predictive value with application in well-being and related health and disease management aspects from prevention to rehabilitation. The projects have to support patient-specific modelling and simulations able to aggregate various information sets e.g. molecular, biochemical, environmental, sensing, imaging into robust predictors for not harmful well-being, health and disease. They will process and apply patient-specific information in a multi-scale approach required for integrating information at a certain level within a wider context (at least one biological level from molecule to entire body). When relevant, projects should take advantage of existing large databases in clinical medicine, biomedical research, environmental sciences and SSH, so enabling and facilitating the accumulation and relinking of complex and heterogeneous data collections.

Expected impact

- Benefit for health: new interventions for increasing well-being in all the steps of disease management from prevention to rehabilitation, for feeling good and living and working safely and healthy.
- Better diagnosis and prognosis
- Advancements in medical computer-modelling and simulation that takes into account time and spatial scales
- Improving the personalization by the holistic approach and by the integration of patient-specific data
- Supporting the predictive medicine, neurosciences and life sciences
- Improving knowledge about well-being and associations with the life circumstances: medical, occupational, social and environmental.

Instrument

RIA

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.

Scope:

Rather than improving existing isolated systems, proposals should focus on developing integrated solutions that support public health authorities in policy making. These solutions include for e.g. automated early warning, outbreak detection and preparedness operations or will help understanding of the process of automated health threat identification (health behaviour), verification and control.

Expected impact

- Mapping a comprehensive big data for public health strategy;
- Emerging methods to study causal mechanisms of ill-health and disease;
- Turning large amounts of data into actionable information to authorities for planning public health activities
- Cross-border coordination and technology integration facilitates interoperability among the components of Big Data value chain.

Instrument

RIA

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
- 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

Instrument

PPI

PM 24 - 2016- Implementation research for scaling-up of evidence based innovations and good practice [RTD]

Specific Challenge

Research evidence and technological progress during the past decades present a large innovation potential for health systems. However, the uptake of well-researched and proven interventions addressing current challenges is slow and sometimes does not take place at all. Implementation research on scaling up evidence- based good practices should facilitate the wider adoption of these practices across Europe and beyond.

Scope

Proposals should seek to scale up an innovative and evidence based health systems & health services intervention. The selected intervention to be scaled up should be one that makes health systems and services more responsive, safe and efficient. Implementation research and system-wide close scientific monitoring should allow researchers and policy makers to judge the overall outcome of the introduction of these interventions. The research should identify the bottlenecks for large scale implementation and come up with practical solutions. These will have to be tested and implementation strategies worked out. Relevant stakeholders and end users of research should be involved in the design of the proposal.

Expected Impact

- A larger group of citizens will benefit from an effective health services intervention.
- A validated framework and strategy for larger scale implementation of an effective evidence based health services intervention will be available to policy makers.
- In medium and long term the health services will be more effective and efficient, health services being more responsive to the needs of its users

Type of Action

RIA

Co-ordination activities

H2020-HCO-2016/2017

HCO 1 – 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. Those projects 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 those EU FP7 Health and Horizon 2020 SC1 projects.

Scope

The objective of this CSA is to develop a European marketplace referencing all type of innovations, including products, technologies, patents, licensing opportunities, spin-outs etc., with a potential for future exploitation and/or commercialisation of results generated by FP7 Health and Horizon 2020 SC1 programmes.

The marketplace should aim to become a one-stop-shop between innovation providers (mainly academic research organisations, but also research intensive SMEs) and innovation developers (such as venture capitalists, EU-supported research infrastructures, business development centres, small, medium and large companies active in the healthcare area). The further assessment and/or validation of any high-value discovery shall not be performed within the framework of the project.

TTOs with proven track records in exploitation of research results as well as business development departments from biopharmaceutical companies should be involved in the consortium to ensure a coherent and consistent approach between innovation providers and innovation developers. Special attention should be made towards the participation of organisations based in EU-13.

Expected Impact

- Identification of the commercial potential of scientific discoveries and advice on the possible valorisation strategies.
- Promotion of exploitation to innovation developers.

Type of Action

Coordination and Support Action

HCO 2 – 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 project should contribute to accreditation and certification, and participate in standardization activities at European level. Outcomes could be validation of methods and technologies, training, counselling, quality procedures and guidelines.

Involvement of industry 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

HCO 3 – 2017 - To implement the Strategic Research Agenda on Personalised Medicine [RTD]

Specific Challenge

By providing the right treatment to the right person at the right time, personalised medicine[5] can improve quality of life and can help reduce the costs 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 sectors, regions and Member States due to fragmented activities, insufficient communication and lack of commonly accepted solutions.

The FP7 funded Support and Coordination Action "Personalised Medicine 2020 and beyond – Preparing Europe for leading the global way (PerMed)[6]" was launched in 2013 with the objective to develop a Strategic Research Agenda to progress personalised medicine in Europe. PerMed partners include more than 10 ministries and funding bodies that have strived to focus their strategy on concrete research actions, many of which should be addressed through transnational collaborative health research.

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

Scope

The ERA-NET should coordinate national and regional programmes for research on personalised medicine by preparing and implementing a transnational call with EU co-funding, resulting in grants to third parties. 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.

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.

The proposed ERA-NET should also aim at implementing other joint activities including training and additional joint calls without EU co-funding in line with the PerMed Strategic Research Agenda.

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.

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

6 www.permed2020.eu

- Increased interoperability of national research programmes.
- Increased sharing of data and knowledge.
- Increased networking of infrastructures and databases.

Type of Action

ERA-NET Cofund action

HCO 4 – 2017 - Clinical validation of photonic platforms for in vitro diagnostics [RTD]

Specific Challenge

Photonics belong to the European Key Enabling Technologies that play an important role in research, innovation and for the competitiveness of European health diagnostics industry. The potential of photonics science should be exploited for personalised medicine, and Europe's photonics sector should be stimulated to foster and implement medical applications in practice. EU funded photonic devices and platforms for personalised in vitro diagnostic purposes need the translation of scientific and technological breakthrough knowledge from diverse fields into clinical validation of products.

The clinical validation of innovative photonic devices and platforms will lead to improved clinical decisions, easier biomedical analyses and better health outcome while contributing to the sustainability of the health care system.

Scope

Proposals should provide coordinated support to the clinical validation of photonic devices and platforms. The performance of diagnosis, prediction, monitoring, intervention or assessment of therapeutic response should be improved, with a significant impact on clinical decisions, biomedical analyses and health outcomes. Validated photonic devices could bring easier, faster, more sensitive and portable diagnostic opportunities at low cost.

The support may relate for example to coordination and collaboration of relevant stakeholders, the communication among partners and other healthcare providers and centres.

Expected Impact

- Better coordination and alignment of national research programmes in photonics.
- Accelerated progress in the translation of photonics science into clinical applications and products.

- Increased commitment to validated, more sensitive, more reliable and cost effective photonics devices and platforms for earlier disease diagnosis, patient stratification and/or prognosis of disease outcome leading to improved clinical decisions and health outcomes.

- Contribution to the sustainability of the health care systems.

- Growth of the European photonics industry and the health diagnostics sector, in particular for SMEs.

Type of Action

Coordination and Support Action

HCO 5 – 2016 - Coordinating personalised medicine [RTD]

[NOTE: Topic to be further elaborated after outcome of discussions with Member States' representatives in the 6 March workshop on personalised medicine research funding.]

Specific Challenge

By providing the right intervention to the right person at the right time, personalised medicine[7] can improve quality of life and can help reduce the costs 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 sectors, regions and Member States due to fragmented activities, insufficient communication and lack of commonly accepted solutions.

Scope

Develop and put in place an efficient system for the exchange of information between funders of personalised medicine research approaches. Coordinate research and innovation efforts across borders, regions and countries.

The participation of both public and private research funders is encouraged.

Expected Impact

- Faster development of personalised medicine within EU and beyond.

- Synergistic effect of using public funds.

Type of Action

Coordination and Support Action

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

HCO 6 – 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.

Scope

Develop a structured system of exchange of information between public health funders to better align research agendas and pave the way to an ERA-NET Cofund action for public health research. The proposed action should ensure a broad geographical representation of European Countries.

Expected Impact

- 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

HCO 7– 2016+2017 - Global Alliance for Chronic Diseases (GACD) [RTD]

[NOTE: Topics to be decided by the GACD Members in Q2 2015]

Specific Challenge

Topic details will be provided in line with the timetable of the GACD priority setting process.

Scope

Expected Impact

Type of Action

RIA

HCO 8 – 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 remedies 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[8] 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 are expected to capitalise on the analytical work carried out by previously funded projects.

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

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

HCO 9 – 2016 - EU m-health hub including evidence for the integration of mHealth in institutional care [CNECT]

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.

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-Communication 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 ensure 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

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[9], iLink[10] and existing private support activities for SMEs.

Scope

The scope is co-ordinating post R&D and offering support for developing business models, improves 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 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

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 and consumer health across Europe.
- Successful legal outcome fostering the innovation in eHealth sector.
- Self-sustaining support structures for eHealth SMEs.

Instrument

CSA

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

HCO 11– 2016 - Market take-up of ICT Innovations in Active and Healthy Ageing [CNECT]

Specific Challenge

The area of active and healthy ageing is a new cross-sectorial domain. Policy makers and stakeholders involved in the health care or long-term care domains often face lack of information on the market take-up of ICT innovations. Also the solution providers lack guidance on the market introduction. Therefore, a system for a collection of evidence from different fields through various information channels needs to be established.

Scope

Proposals should present ways to promote the take-up of ICT solutions in active and healthy ageing such as integrated care, fall prevention, cognitive decline prevention, through:

- coordination of various activities in the field focusing on new business models, market expansion and internationalisation to accelerate the market take-up of the active and healthy ageing solutions;
- collection and analysis of best practices in commercialising solutions to both care provider organisations and consumers;
- coaching of innovators, notably SMEs, in order to help them to introduce their solutions in the market;
- identifying the major market players and trends in the EU and worldwide;
- organisation of networking and match-making among owners of the project results and investors, as well as support to ecosystems that help nurture business opportunities.

Expected Impact

Proposals should present quantitative or qualitative indicators to quantify:

- accelerated progress in the establishment of favourable framework conditions to introduce the active and healthy ageing solutions into the market;
- higher awareness of the key success factors for commercialisation;
- established repository of best practices in commercialising solutions and information on the markets;
- networking and match-making among owners of the project results and investors.

Type of Action

Coordination and Support Action

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 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.

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

(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[11] 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
- 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

11 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[12] 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

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.

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

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

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

Instrument:

CSA

Other Actions

HOA 1 – 2016+2017: Subscription fee: Human Frontier Science Programme Organisation [RTD]

Scope

An annual subscription to the international Human Frontier Science Programme Organisation (HFSPO)[13] 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[14] in research and innovation.

Type of action:

Subscription

Indicative timetable: 2016 and 2017

The following topic description serves as a reference to the Internet of Things Pilot currently under development as a joint activity with ICT-LEIT.

2016- Large-scale pilots in Smart Living Environments for the elderly [DG CNECT]

Smart homes and smart living environments can support people in staying active, independent and out of institutional care settings for longer and at the same time lead to reduced costs for care systems and better quality of life for older citizens. The challenge is to deploy innovative and user led ICT pilot projects supporting independent living at home and outside based on Internet of Things (IoT) technologies and translating the promising results into scalable practice across Europe. The solutions should be based on state-of-the art technologies and services with a high potential for future markets in Europe.

Any solution needs to be based on user engagement from the beginning of the project and apply state-of-the-art expertise in ethics, gender studies, social diversity and inclusion of older persons. It needs to show clear improvements in comparison to current practices in order to achieve the expected impact. The solutions shall build upon the IoT, using and extending available open service platforms, standardised ontologies and open standardised APIs.

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

14 COM(2012)497

Based on quantitative and qualitative output indicators related to independent living and active and healthy ageing, the pilot is expected to demonstrate relevant contributions to the following expected impacts:

- Evidence of the benefits of applied IoT technologies and services based on large-scale deployment and involvement of relevant stakeholders;

- Compliance of smart living environments with all usability, privacy and security user requirements and measures for mid- and long-term risk assessment, user-centred data management strategies.