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COUNCIL DECISION ESTABLISHING THE SPECIFIC PROGRAMME IMPLEMENTING HORIZON 2020 - THE FRAMEWORK PROGRAMME FOR RESEARCH AND INNOVATION (2014-2020)

WORK PROGRAMME 2014 – 2015

Health, demographic change and wellbeing

INFORMAL DRAFT DISCUSSION DOCUMENT

Important notice:
The present document is intended to facilitate discussion towards the preparation of the work programme 2014 – 2015. It does not at this stage cover all relevant aspects and it does not prejudge the outcome of the on-going inter-institutional negotiations on Horizon 2020, or internal work on cross-cutting aspects. Hence, it remains subject to change. Information, such as indicative budgets per call/area, will be provided at later stage.

Introduction to health, demographic change and wellbeing

The Horizon 2020 societal challenge of 'health, demographic change and wellbeing' for the years 2014 and 2015 includes 32 topics in the 'personalising health and care' focus area call, and 10 topics in the 'co-ordination activities' call. A small number of additional topics designed to support the implementation of the challenge will be included later and will not be subject to calls for proposals. The total budget available is approximately €1.06bn.

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

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

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

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

Activities which have co-ordination as their primary focus are listed in the "co-ordination activities call", with actions not subject to calls for proposals listed thereafter. Societal challenge 1 is also implemented by the innovative medicines initiative (IMI), the European and developing countries clinical trials partnership (EDCTP), and the active and assisted living programme (AAL) details of which may be found on their dedicated websites.

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

Call for personalising health and care

H2020-PHC-2014/2015

Understanding health, ageing and disease

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

Specific challenge: Common diseases result from varying degrees of interaction between the genetic make-up of individuals and behavioural, environmental, occupational and other factors. Better knowledge of these factors will improve risk identification and validation, and allow better diagnosis, risk-based prevention strategies and policies, as well as stratified treatment. This is particularly important given Europe's ageing population, and its need for improved preventive and therapeutic measures providing good health and prolonged independence.

In this context, the two following specific challenges have been identified:

- Exploring the combined role of genetic and non-genetic factors (e.g. environmental, occupational and behavioural) in disease development
- Better understanding of the mechanisms underlying the process of ageing

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

- The identification and validation of determinants of health and risk factors for disease through the generation, integration and validation of data derived from different sources (e.g. molecular, clinical and/or environmental epidemiology, exposure sciences, genetics etc). This should involve the exploitation of existing longitudinal studies and the assessment of the necessity to establish new ones.

- Identification of molecular and pathophysiological pathways characteristic of healthy ageing as well as health deterioration caused by time, exposure to environmental factors and disease accumulation.

Expected impact: Provides the knowledge base for:

- Clinically relevant re-classification of diseases under study
- Effective patient stratification
- New pathways for clinical research for better disease prevention, better and earlier diagnostics, health promotion and therapy development

As a result of:

- A better understanding of the combined effects of various intrinsic and extrinsic factors causing disease, and contributing to health and healthy ageing
- A better understanding of disease pathways or pathways of healthy ageing

Type of action: Collaborative Projects (100%)

PHC 2 - 2015) Understanding health, ageing and disease: systems medicine

Specific challenge: The development of new, evidence-based treatments relies on an improved understanding of the, often very complex, pathophysiology of diseases. Systems (bio) medicine approaches have the potential to tackle this complexity through the integration of a variety of biological and medical research data and computational modelling.

In this context, the two following specific challenges have been identified:

- Better understanding mechanisms that are common to several diseases.
- Developing the necessary multidisciplinary expertise (e.g. modern biology, medicine, mathematics, computational technologies) for implementing systems (bio) medicine approaches.

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

- Development/optimisation and/or application of systems medicine approaches, and integration of biomedical and clinical data to produce or refine disease models using advanced statistical, computational and mathematical approaches. The predictive value of such models should be validated in well-phenotyped patient cohorts and their clinical significance proven. Consortia should clearly demonstrate why a systems medicine approach would be an improvement over the already established ways of tackling clinical needs in specific disease(s).

- The integration of pre-clinical and clinical studies for the identification of mechanisms common to several diseases. The relevance of those findings on the development of disease-specific pathophysiology should be assessed and validated.

Expected impact: This will provide:

- Leverage of existing investments in Europe in the field of systems biomedicine
- A better understanding of disease pathways and / or mechanisms common to a number of diseases
- New directions for clinical research for better disease prevention, health promotion and therapy development
- Systems medicine tools and approaches tailored for medical research and/or the clinic which represent an improvement over established practice.

Type of action: Collaborative Projects (100%)

Effective health promotion, disease prevention, preparedness and screening

PHC 3 - 2015) Health promotion and disease prevention: improved inter-sector co-operation for environment and health based interventions

Specific challenge: Better health promotion and disease prevention interventions can make a significant contribution to the sustainability of health and care systems. The design and implementation of such 'health in all policies' approaches is however hindered by the variety and complexity of factors which impact health, and the consequent difficulty in assembling multi-sector teams to work on such interventions. These factors include but are not limited to: housing, water and sanitation systems, transportation, communication, education and information, workplace, nutrition, environment, and behaviour.

Scope: Given the breadth of factors, the specific focus of this topic for 2015 is the integration of environment and health sectors (including but not limited to climate change, air quality, water and sanitation, the food chain, workplace) for the development and evaluation of inter-sector interventions for health promotion and disease prevention.

Using a multidisciplinary approach and involving relevant stakeholders such as policy makers, the private sector, civil society organisations etc., proposals will develop and evaluate inter-sector interventions and/or policy initiatives to promote health or prevent disease linked to key environmental stressors for which changes in relevant EU and international policies related to environment and health would have the greatest impact.

Success characteristics of interventions will be documented, including those which overcome known barriers to inter-sector co-operation, and those which build on existing successful initiatives. Contextual factors such as the interplay between politics and economics should be addressed.

Research activities will be developed as a European contribution to existing international activities and those under development.

Expected impact:

- On the basis of quantitative and qualitative indicators, evidence on effective interventions taking a 'health in all' approach, linking environment and health, allowing informed decisions on the reorganisation of health and care systems towards their sustainability,
- Contribution to the EU commitment to the Rio+20 agenda and the Parma declaration 2010, protecting health in an environment challenged by climate change

Improved health and well-being of individuals or groups targeted by such interventions

Type of action: Collaborative projects (100%)

PHC 4 - 2014) Health promotion and disease prevention: translating 'omics' into stratified approaches

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

Scope: Proposals will:

- Develop and assess a personalised / stratified health promotion or disease prevention programme, taking into account the 'omics' characteristics of individuals, complemented by environmental and/or lifestyle factors. Work will include the development of tools and methods for the use of 'omics' data in such programmes and will address risk-benefit communication to various groups including individuals, policy makers and regulators.
- Include a multi-disciplinary approach to assess the validity and utility of 'omics' data in preventive medicine. This will include:
    - Assessment of the predictive value of such programmes in identifying at-risk groups throughout their lives, as compared with conventional methods
    - Assessment of the usefulness of 'omics' data for improving the health of individuals or populations
    - Assessment of the behavioural, ethical, legal, or social implications, as well as of the cost-effectiveness of the programme
- Preference will be given to proposals focusing on diseases with either high prevalence or which present a high risk to the individual, or a high cost to society.

Expected impact:

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

Type of action: Collaborative Project (100%)

PHC 5 - 2014) Evaluating existing screening and prevention programmes

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

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

Scope:

- Proposals will assess existing screening and disease prevention strategies and programmes, on the basis of health outcomes, equity and cost-efficiency, at the level of the individual or stratified population groups, across Europe.
- Comparison between different countries/regions, demographic groups and cultures will be made in order to identify specific contextual link elements as well as to identify opportunities for exchange of knowledge and experience between countries and regions.
- Research may include the development of new methods or the adaptation of existing ones for this type of assessment. These methods and tools (including self-assessment tools) should be applied in different health systems and organisational infrastructures to test their applicability in different political, economic and societal contexts.
- Due attention will be paid to the further development and dissemination of methodological expertise, including capacity building across Europe, from the outset in order that the expertise generated is not lost.

Expected impact:

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

Type of action: Collaborative Project (100%)

PHC 6 - 2014) Improving the control of infectious epidemics and foodborne outbreaks through rapid identification of pathogens (see also SC2)

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

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

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

The system will improve pathogen monitoring by rapid identification, comparison, and geographical mapping. It will include predictive models on RA, to identify 'high-risk' areas and disease-emergence patterns, by analysis of the drivers of spread, their synergism and impact. It will ensure links and consistency with existing networks and databases (TESSY, RASFF, EWRS, EFSA/ECDC[1], molecular testing database) and data protection requirements. Access to the system will be granted to relevant animal, food safety and human health service stakeholders (including EFSA and ECDC).

Harmonised standards for sampling, sequencing, (meta-) data collection, management and sharing should be developed. Likewise, better management tools for authorities, businesses and citizens and risk communication tools for authorities should be developed. The cost effectiveness of the tools and methods will be assessed. The initiative will structure the European contribution to existing international activities and those under development.

Expected impact:

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

Type of action: Collaborative project (100%)

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

PHC 7 - 2014) Vaccine development for poverty-related and neglected infectious diseases: Tuberculosis

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

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

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

Note: this topic will be implemented over three years with focused calls on vaccine development for tuberculosis (2014), HIV/AIDS (2015) and malaria and neglected infectious diseases (2016)

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

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

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

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

Expected impact:

- Reduction in the cost associated with late stage vaccine failure, increasing the number of other candidates which can be tested with the same resources, thus increasing the chance of discovery of an effective vaccine
- Support to a global initiative for the development of tuberculosis vaccines, (currently under development in collaboration with European Investment Bank and Bill and Melinda Gates Foundation) including the establishment of close links with the European and Developing Countries Clinical Trials Partnership (EDCTP).

Type of action: Collaborative Project (100%)

PHC 8 - 2015) Vaccine development for poverty-related and neglected infectious diseases – HIV/AIDS

Specific challenge: Vaccines offer a safe and cost-effective way to protect large populations against infectious diseases, or at least to mitigate the clinical course of these diseases. Yet, many poverty-related and neglected infectious diseases continue to escape attempts to develop effective vaccines against them. Disappointing results of recent clinical trials point to bottlenecks in identifying viable candidate vaccines, which if unaddressed will continue to present significant risks of failure at relatively late stages of the development process. The specific challenge will be to shift this "risk curve" in order to better select successful vaccine candidates (and discard those with a higher risk of failure) at an earlier stage of the vaccine development process.

{Note: this topic will be implemented over three years with focused calls on vaccine development for tuberculosis (2014), HIV/AIDS (2015) and malaria and neglected infectious diseases (2016)}.

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

1. Establishment of a platform for identification of (at least 10) new vaccine candidates for HIV/AIDS, and support to their discovery, pre-clinical and early clinical testing.

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

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

Expected impact:

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

Type of action: Collaborative Project (100%)

Improving diagnosis

PHC 9 - 2014) Development of new diagnostic tools and technologies: *in vitro* devices, assays and platforms

Specific challenge:

- The development of new diagnostics (more sensitive, robust and selective) for improved clinical practice demands the translation of multidisciplinary scientific and technological knowledge from diverse fields into clinical applications.
- Innovation in the diagnostics area relies on the development, translation and uptake of existing, new or evolving and often complex technologies.
- A wide range of multidisciplinary competencies need to be brought together to develop and bring new diagnostics to the patient. This is also a field where many small European companies are active.

Scope:

- Proposals will focus on the development of innovative *in vitro* diagnostic tools and technologies (not novel applications of existing ones). Tools and technologies will improve over state of the art, the performance of diagnosis, prediction, monitoring, intervention or assessment of therapeutic response based on i*n vitro* devices, assays and platforms.
- Additionally, proposals may include approaches based on high-throughput screening, nanotechnologies or microfluidics, data analysis methodology, or point-of-care diagnostics.

Expected impact:

- New *in vitro* diagnostic tools and methods providing more accurate, more reliable and earlier disease diagnosis.
- Growth of the European diagnostics sector, in particular for SMEs

Type of action: Collaborative Project (100%)

PHC 10 - 2015) Development of new diagnostic tools and technologies: *in vivo* medical imaging technologies

Specific challenge:

- The development of new diagnostics (more sensitive, robust and selective) for improved clinical practice demands the translation of multidisciplinary scientific and technological knowledge from diverse fields into clinical applications.
- Innovation in the diagnostics area relies on the development, translation and uptake of existing, new or evolving, and often complex technologies. A wide range of multidisciplinary competencies need to be brought together to develop and bring new diagnostics to the patient. This is also a field where many European companies are active.

Scope: Proposals will focus on the development of innovative *in vivo* tools and technologies (not novel applications of existing ones). Tools and technology should aim at improving diagnosis, prediction, monitoring, image-based intervention or assessment of therapeutic response. Preference will be given to innovations that offer a clear advantage over existing tools and technologies. Development of *In vivo* medical imaging technologies should profit from existing high-tech engineering or physics solutions or innovative ideas and concepts coming from those fields.

Expected impact:

- New *in vivo* diagnostic tools and methods providing more accurate, more reliable and earlier disease diagnosis.
- Growth of the European diagnostics sector, in particular for SMEs

Type of action: Collaborative Project (100%)

PHC 11 – 2014 and 2015) Clinical validation of biomarkers

Specific challenge:

- Biomarkers are used in clinical practice to describe both normal and pathological conditions. They can also have a prognostic or a predictive power. They are therefore increasingly used in medicine and many potential biomarkers are proposed every year.
- Only a few of them are however validated for use in a clinical setting. Such validation implies the demonstration of a link to a pertinent clinical endpoint or process, as well as a robust and appropriate analytical method.
- The clinical validation of biomarkers will be increasingly important for the development of new diagnostics, and this is an area where many small European companies are active.

Scope:

- The clinical validation of existing potential biomarkers (not the identification of new ones) is sought. This validation should provide evidence for: high analytical validity; appropriate sensitivity and specificity; clinical validity/ utility.
- Both *in vivo* and *in vitro* potential biomarkers are eligible. Preference will be given to disease related biomarkers (i.e. diagnostic, susceptibility/risk, monitoring and prognostic biomarkers)

Expected impact:

- Increased clinical availability and exploitation of biomarkers for the benefit of the patient.
- Facilitation of entry of improved diagnostics in the clinic and the market.
- Support for the implementation of the Commission proposal for a revised In vitro diagnostic devices regulation[2].
- Growth of the European diagnostics sector, in particular SMEs

Type of action: SME instrument

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

Innovative treatments and technologies

PHC 12 - 2014) New therapies for chronic non-communicable diseases

Specific challenge:

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

Scope:

- Clinical trial(s) supporting proof of concept in humans to assess the potential clinical efficacy of the novel therapeutic concept(s) / optimisation of available therapies (e.g. drug repurposing). The application may build on pre-existing pre-clinical research.

A concise feasibility assessment justified by available published and preliminary results and supporting data is also to be provided. Considerations of effectiveness / potential clinical benefit (possibly including real world data) should be integrated in the application if relevant.

Expected impact:

- New therapeutic strategies with the highest potential to generate advances in clinical practice for chronic diseases ready for further phase II clinical development.
- Early identification of candidate strategies holding *no/little* promise for successful development and which do not warrant further investment into expensive late-stage clinical development.
- Improved therapeutic outcome of major chronic health issues with significant impact on burden of diseases both for individual patients and for health systems.

Type of action: Collaborative projects (100%)

PHC 13 - 2015) New therapies for rare diseases

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

Specific problems posed for rare diseases include the small and dispersed patient populations, the nature of the therapies proposed which are often highly specialised and novel requiring the engagement of regulatory authorities during development and the small markets for the therapies developed making generally leading to low commercial returns.

Scope:

- Support will be given for development of new or improved therapeutic approaches, for repurposing of existing therapies, as well as for preclinical research, animal model development and GMP production.
- Proposed treatments to be developed may range from small molecule to gene or cell therapy.
- Clinical trials will only be supported in cases where "orphan designation" has been given and where the proposed clinical trial design takes into account recommendations from protocol assistance given by the European Medicines Agency and where a clear patient recruitment strategy is presented. A concise feasibility assessment justified by available published and preliminary results and supporting data is also to be provided. Considerations of effectiveness / potential clinical benefit (possibly including real world data) should be integrated in the application if relevant.
- Selected projects should contribute to the objectives of, and follow the guidelines and policies of the International Rare Diseases Research Consortium, IRDiRC.

Expected impact:

- Advancing the development of new therapeutic options for patients living with rare diseases.
- Contribution to reaching the IRDiRC objective to deliver 200 new therapies for rare diseases by 2020.

Type of action: Collaborative projects (100%)

PHC 14 – 2014/15) Clinical research on regenerative medicine

Specific challenge: Translating basic knowledge on regenerative medicine into the clinic is held up by the difficulty in undertaking 'first in man' studies. Specific research is needed for proving safety, efficacy and repeatability of new treatments. The main players are academic and clinical centres, SME spin-offs and start-ups, and very often iterative dialogue with the authorities is needed before specific regulatory requirements can be established.

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

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

Expected impact:

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

Type of action: Collaborative projects (100%)

PHC 15 – 2015) Tools and technologies for advanced therapies

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

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

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

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

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

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

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

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

Expected impact:

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

Type of action: Collaborative Project (100%)

PHC 16 – 2014) Comparing the effectiveness of existing healthcare interventions in the elderly

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

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

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

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

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

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

Expected impact:

- Evidence base for more effective and safer interventions in the elderly population and the use of health technology assessment methodology in this target group, and in particular:
- Improvement of individual patient outcomes and health outcome predictability through tailoring of interventions
- Contribution to better guidelines development for chronic diseases and comorbidities management
- Support to regulatory guidance in this population and provision of more accurate information to patients and prescribers

Type of action: Collaborative Project (100%)

PHC 17 – 2015) Establishing effectiveness of health care interventions in the paediatric population

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

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

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

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

Expected impact:

- Significantly decreasing treatment related risk in the paediatric population (e.g. by researching adverse drug reactions, etc.)
- Establishing novel and/or improved treatment schemes for healthcare interventions in the paediatric population
- Validating benefits of frequently used health interventions in the paediatric population

Type of action: Collaborative Project (100%)

Advancing active and healthy ageing

PHC 18 – 2014) Advancing active and healthy ageing with ICT: Service robotics within assisted living environments; and ICT solutions for independent living with cognitive impairment

NOTE: ***it is not yet clear whether a single topic can support actions at different reimbursement rates. As this topic currently provides for reimbursement at both 100 and 70%, readers should be aware that the topic may at a later date be split into two parts.***

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

The challenge is to develop new breakthroughs for ICT based assisted living and deploy innovative and user led ICT pilot projects, translating promising results into scalable practice across Europe.

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

i) Service robotics within assisted living environments (Research - 100%)

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

ii) ICT Solutions for independent living with cognitive impairment (Innovation – 70%)

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

Innovation in organisational and business models for service delivery will be supported, as well as standardisation and interoperability work on required ICT platforms, services and data sources. The number of users involved should be sufficient to ensure statistical significance in impact analysis, with a minimum of 4 pilot sites in 4 countries involving in total no fewer than 5000 users.

Expected impact:

For i) service robotics and assisted living environments

- Evidence for the benefits of service robotics developed, based on proof of concept and involvement of relevant stakeholders

- Reduction of admissions and days spent in care institutions, and prolongation of time spent living in own home when ageing with emerging functional impairments.
- Improvement in quality of life of older persons of their care providers.
- Global leadership in advanced solutions supporting active and healthy ageing

For ii) ICT Solutions for independent living with cognitive impairment

- Based on quantitative and qualitative output indicators and impact data, each pilot is expected to demonstrate relevant contributions to the following expected impacts:
    - Clear evidence on return of investment from ICT based solutions for cognitive impairments of older people;
    - Best practice for viable business and financing models which are scalable across Europe;
    - Clear evidence of improvements to quality of life and active ageing for involved users and carers;
    - Contribution to the competitiveness of the European ICT industry in the domain, through enhanced interoperability and scalable markets;
    - Prolongation of active participation in society, avoidance of unnecessary hospitalization and delay institutionalization for as long as possible.

Type of action: For i) service robotics and assisted living environments - Collaborative Project (100%). For ii) ICT Solutions for independent living with cognitive impairment - Collaborative project (70%)

PHC 19 – 2015) Advancing active and healthy ageing with ICT: Early risk detection and intervention

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

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

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

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

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

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

Expected impact:

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

Type of action: Collaborative Project (100%)

PHC 20 – 2015) Promoting mental wellbeing: in the ageing population

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

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

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

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

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

Expected impact:

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

Type of action: Collaborative Project (100%)

Integrated, sustainable, citizen-centred care

PHC 21 - 2014) Developing and comparing new models for safe and efficient, prevention oriented, health and care systems:

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

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

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

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

Models can apply to different levels within the health system (micro – the patient interaction level, meso- the health care organization and community level, and macro - the policy level). They must be compared with alternatives (including existing models), capitalising on the EU's diversity. Views of relevant stakeholders such as policy makers and citizens should be taken into account in the design of these models. Capacity building and awareness raising activities for the adoption and further use of models developed will be included.

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

Expected impact:

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

Type of action: Collaborative project (100%)

PHC 22 - 2015) Piloting personalised medicine in health and care systems

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

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

Scope: Larger scale pilots of new models of care, based on the concept of personalised medicine will be conducted in existing health care environments and will take into account the EU's diversity in health system organisation. Research should be conducted in coordination with national/regional or local authorities engaging in health sector reform, with the design of new models taking into account the views of other relevant stakeholders, including policy makers and citizens.
Evidence for health, economic and social benefit to individual patients, whole or stratified population groups and at the level of health care systems will be demonstrated. The organisational and resource requirements of the piloted models (data, personnel and financing) will be tracked, creating evidence on methods of implementation and benefits of the reform while ensuring safety, equity and cost efficiency. Appropriate measures for knowledge transfer and capacity building should be put in place.

Expected impact: Based on quantitative and qualitative outcome and impact data, evidence on the validity, utility and cost-effectiveness of ‘omics’ based health promotion and disease prevention programs allowing informed decisions on the organisation of health and care systems

Type of action: Collaborative project (100%)

PHC 23 - 2015) Advanced ICT systems and services for Integrated Care

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

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

Scope: To go clearly beyond the current state of art in tele-health and tele-care systems by developing new ICT-based approaches for integrated care. Proposals will address barriers both from technological and organisational points of view:

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

Validation will provide proof-of-concept on the basis of quantitative success measures.

Expected impact:

- Reduced admissions and days spent in care institutions, and improvements in the daily activities of older persons through effective use of ICT and better coordination of care processes.
- Strengthened evidence base on health outcomes, quality of life and care efficiency gains from the use of ICT in integrated care.
- Improved cooperation and secure information exchange among the actors involved in health, social and informal care services.
- Improved interaction between patients and their carers, and more active participation of patients and their relatives in care processes.
- Reinforced medical knowledge with respect to management of co-morbidities.
- Strengthened European industrial position in ICT products and services by measurable indicators such as new business areas, start-ups and protected intellectual property

Type of action: Collaborative Project (100%)

PHC 24 - 2014) Self-management of health and disease: citizen engagement and mHealth

Specific challenge: Empowering citizens to manage their own health and disease will result in more cost-effective healthcare systems by enabling the management of chronic diseases outside institutions, improving health outcomes, and by encouraging healthy citizens to remain so. Several clinical situations would be prevented or better monitored and managed with the participation of the patient him or herself.

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

Support for knowledge infrastructures is also required, as well as the combination of predictive personalised models with personal health systems and other sources of data.

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

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

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

Projects shall enable individuals to become co-managers of their health and wellbeing (including physical and mental wellbeing) with the help of ICT, tools and personalised services. The focus is on the following elements:

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

(ii) mHealth applications for disease management

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

- Knowledge management systems to analyse and compile the data collected by applications on individuals' health and activities in order for such information to be used by the persons themselves, health professionals and public health monitoring authorities.
- Guidance for patients on chronic disease management supported by mHealth.
- Economic aspects of encouraging secondary prevention and addressing avoidable negative health and wellbeing outcomes and
- Public health or health promotion interventions addressed to large sectors of population through mHealth applications.

Expected impact: In both cases

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

For (i)

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

For (ii)

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

Type of action: Collaborative Projects (100%)

PHC 25 - 2015) Self-management of health and disease: decisional support systems and patient empowerment supported by ICT

Specific challenge: Empowering citizens and patients to manage their own health and disease will result in more cost-effective healthcare systems by enabling the management of chronic diseases outside institutions, improving health outcomes, and by encouraging healthy citizens to remain so. Several clinical situations would be prevented or better monitored and managed with the participation of the patient him or herself.

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

Support for knowledge infrastructures is also required, as well as to combine predictive personalised models with personal health systems and other sources of data, and used by the patient or citizen him or herself.

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

(i) decisional support systems

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

(ii) patient empowerment supported by ICT

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

Proposals will aim to empower patients to manage their pre-existing conditions. Health management will be addressed holistically, from healthy lifestyle interlinked with disease management, placing the

patient in the centre and putting increased emphasis on health education, secondary prevention and self-management of individual conditions, including co-morbidities.

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

Expected impact: In both cases

- Improving the participation of the patient in the care process.
- Improving the management of a disease by reducing the number of severe episodes and complications.
- Increasing the level of education and adherence of individuals, patients and care givers related to (i) preventive thinking in health and (ii) application of ICT for personalised care.

For (i)

- Increasing the level of importance of the prevention sector in healthcare using predictive modelling.
- Boosting the development of personal devices used for self-management of health.

For (ii)

Several of the following impacts:

- Improved interaction between patients, their relatives, providers of health-, social- and informal care givers.
- Strengthened evidence base on health outcomes, quality of life, care efficiency gains and economic benefits from the use of ICT in new care models.
- Reinforced medical knowledge with respect to efficient management of comorbidities.
- Increased confidence in decision support systems for disease/patient management.
- Involvement of health care providers/authorities with increased commitment in the deployment of innovative services empowering the patient.

Type of action:

For (i) Collaborative projects (100%)

For (ii) PCP

PHC 26 - 2015) Public procurement of innovative eHealth services

Specific challenge: The sustainability of pilot and demonstration solutions and services is broadly perceived as one of the biggest challenges in streamlining healthcare delivery processes and in improving cost efficiency while maintaining or improving patient safety. The pace of development has been slow and penetration of ICT still has high growth potential in healthcare compared to other public or private sectors.

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

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

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

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

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

Expected impact:

- Contribution to regulatory and legal process development addressing possible barriers to procurement of innovative solutions in healthcare.
- Growing awareness and successful use of public procurement by the procurers to boost innovation in the application of ICT in the sector concerned.

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

Type of action: PPI

PHC 27 – 201x): eHealth Sectoral Prize

Details TBC

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

PHC 28 - 2015) Digital representation of health data to improve diseases' diagnosis and treatment

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

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

They will be used by healthcare professionals for personalised prediction and decision in prevention, diagnosis or treatment and should take into account data protection and ethical considerations. The models should be multi-level and multi-scale and will integrate, when relevant for the targeted clinical situation, the required molecular and cellular data, including genomics and epigenomics data, or data on administration of therapeutics and exposure to environmental factors or link personalised physiology,functional disorders and diseases modelling. Integration of data coming from other technologies and key-enabling technologies is encouraged.

Expected impact:

- Better management of complex clinical situations.
- Enabling use of the same information by the different medical services.
- Better control and inter-service coordination in the management of the patient health.
- Providing a consistent view of a patient's care needs.

Type of action: Collaborative Projects (100%)

PHC 29 - 2014) Foresight for health policy development and regulation

Specific challenge: The complex interactions between multiple determinants of health and wellbeing such as air quality, greenhouse gas emissions, traffic and congestion, ambient noise, built environment, urban sprawl, waste, lifestyle, behaviour, occupation, demographic change, socio-economic factors, and so on are not well understood.

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

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

Scope: Proposals should identify key driving forces (external and internal to the health systems) likely to influence health and wellbeing in Europe beyond 2020. Research should help understand the inter-relationships between these factors; analyse their economic and social impact and suggest alternative policy options to respond to the challenges they pose. Proposals should present a comprehensive, structured and participatory framework of analysis, integrating key factors impacting health and demand for health services.

Use should be made of current techniques for foresight such as scanning, trend monitoring, and expert opinion (to create collective intelligence) and scenario development, back-casting and wildcards (to help define alternative futures).

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

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

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

It will provide guidance for future (public) health research

Type of action: Collaborative projects (100%)

PHC 30 – 2014) Advancing bioinformatics to meet biomedical and clinical needs

Specific challenge: Recent technological advances in molecular biology and biomedical sciences are resulting in a greatly increased rate of data generation and of many different types of data. Furthermore, these new technologies are becoming much less expensive and more accessible to individual laboratories and clinics – thus the rate of data generation at a local level is also set to increase dramatically. Currently available bioinformatics tools and approaches are not up to the task of data collection, storage, organisation, integration, analysis and exploitation in biomedical research and the clinic of such diverse and complex data. It is proposed to promote specific research actions to ensure that bioinformatics capabilities are not only made adequate for the current data challenge but also to meet future biomedical and clinical needs. SME interest in the field is high.

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

Expected impact:

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

Type of action: Collaborative Project (100%)

PHC 31 – 2015) New approaches to improve predictive human safety testing

Specific challenge: Current approaches to assessing and predicting the safety of chemicals in humans and the safety and efficacy of drugs, particularly tests done in animal models, are expensive and time consuming and often not very accurate. New and improved approaches are needed to improve the quality of human safety testing, as well as to speed up and improve efficiency of predictive toxicological testing to meet regulatory requirements. Key areas of toxicological concern for human health include carcinogenicity, reproductive effects, developmental effects, immune system and allergies, neuro- and organ toxicity. Safety testing is of worldwide concern – markets are global – therefore, international cooperation could be an important element in addressing the challenge.

Scope: Proposals should capitalise on advances in research in biology and medicine, together with advances in computational biology and chemistry, high-throughput chemical screening technologies, and systems biology approaches to understand complex biological pathways of pharmacological and toxicological relevance and to identify early markers predictive of toxicological effects with the objective to develop and validate routine, animal-free, toxicity testing approaches. The research could include the development of methodologies for confirmatory testing of mechanistic hypotheses to improve understanding of toxicity mechanisms. Proposals should envisage research collaborations, co-ordination and information exchange between, amongst others, the research & clinical communities, SMEs, industry and regulatory agencies. Co-operation with similar initiatives in the USA, Japan and elsewhere would be highly beneficial from scientific and economic standpoints.

Expected impact:

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

Form of funding: Collaborative Project (100%)

PHC 32 - 2014) eHealth interoperability

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

(i) There is little stakeholder consensus on a common reference information model for eHealth deployment in Europe, and it seems unlikely that international consensus can be reached for common (clinical) reference standards in a reasonable timeframe and budget. It is therefore reasonable to ask whether competing / overlapping standards can co-exist in a common eHealth European interoperability framework; this is of relevance to the MoU on eHealth between the EC and the US department of Health and Human services.

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

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

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

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

eHealth Interoperability Framework should be demonstrated. The successful proposal should support large scale deployments of eHealth services (including cross border) in Europe and contribute to the implementation of the EU-US MoU and roadmap.

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

- unambiguous definition and description of medicinal and pharmaceutical products, including unique identification.
- handling of substitution

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

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

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

(iv) The proposal should build on existing work done by projects such as epSOS and SemanticHealthNet which will have developed key building blocks which will help addressing the challenge. Pilot project epSOS has been piloting two basic use cases (ePrescription and Patient Summary) and successful proposals are expected to identify and agree on a roadmap of use cases that should be deployed on large scale in the future after the epSOS use cases. The successful proposal will demonstrate the value proposition of healthcare providers with regard to interoperability and assess sustainable incitement schemes that would encourage healthcare providers to code health data and provide it in an interoperable way and to invest in interoperable eHealth systems.

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

Expected impact: (i) Convergence in the use of eHealth Standards in Europe and in the world. Contribution to the eHealth Interoperability Framework and to large scale deployment of eHealth Services (including cross border) in Europe. Contribution to the EU-US roadmap

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

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

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

Type of action: CSA (100%)

Call – Co-ordination activities

H2020-HCO-2014/2015

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

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

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

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

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

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

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

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

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

Expected impact:

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

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

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

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

Type of action: CSA (100%)

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

Specific challenge: Following the implementation of the actions foreseen by the Commission's Communication on Joint Programming to tackle Europe's major societal challenges, the Competitiveness Council has welcomed the progress made by EU Member States in Joint Programming Initiatives (JPIs) launched so far. Several Council Conclusions on Joint Programming[3] invite the Commission to support JPIs via Coordination and Support Actions.

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

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

Scope:

- Coordination of exchange on national programmes on demographic change
- Facilitation and management of an effective governance of the JPI
- Monitoring of national research activities in the area
- Support for the implementation of the Strategic Research Agenda of the JPI MYBL[4]
    - Coordination and organisation of potential joint calls
    - Alignment of national research programmes and activities to the JPI's Strategic Research Agenda
    - Harmonization, integration, and enhanced accessibility of national data related to active and healthy ageing, demographics, and statistics, to enable evidence-based policy making and effective cross-policy actions; common usage of databases and infrastructures
    - Investigate novel forms of implementation of SRA such as synchronised calls
- Dissemination and awareness actions
- Liaison with relevant EU level initiatives
- Collaboration with international initiatives and third countries

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

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

Support for the development and dissemination of policy guidelines based on the JPI's outcome

Expected impact:

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

Type of action: CSA (100%)

HCO 3 – 201x) Support for the European Reference Networks: Efficient network modelling and validation

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

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

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

Support is therefore required in facilitating:

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

- The design and validation of a model of Network organisation. That will be based in system modelling research methodologies and will imply building technical foundations and knowledge and integrating these with the organizational, technical, and cultural aspects of a European Reference Network System and the identification of best practices and their effective implantation in several areas related with the mandate of the directive

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

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

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

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

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

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

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

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

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

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

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

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

Type of action: CSA (100%)

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

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

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

The support action should assist the GloPID-R executive committee, notably for the organisation of and reporting on meetings (e.g. *ad hoc* meetings of working groups), support information exchange among all members of the participating bodies, facilitate coordination among relevant research projects and initiatives as well as communicate progress of relevant research funded under Horizon 2020 and by consortium members. This action should also include support activities with relevant stakeholders groups and with the public at large (e.g. development of website, communication materials, etc.)

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

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

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

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

Type of action: CSA (100%)

HCO 5 -201x) Global Alliance for Chronic Diseases: prevention and treatment of type 2 diabetes

Specific challenge: In the past twenty years the global death rate from diabetes has doubled and the World Health Organisation (WHO) is predicting that this will increase by two thirds by 2030. It is currently estimated that 347 million people worldwide suffer from diabetes with more than 80% from low-and middle-income countries. Of those suffering from diabetes, type 2 comprises 90% of this population around the world.

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

Scope: This call for proposals is focused on type 2 diabetes. The aim of this call is to fund projects that will generate new knowledge on interventions and their implementation for the prevention and treatment of type 2 diabetes in low and middle income countries, and in vulnerable populations in high income countries. Studies that aim to evaluate the contribution of public policies to diabetes prevention efforts, or estimate the potential effects of such policies if adopted and implemented, are within the scope of this call. Proposals can address prevention or treatment of specific complications of type 2 diabetes.

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

- lifestyle and behavioural issues through community-wide approaches, environmental supports or other strategies targeting individuals at high-risk.
- structural interventions or policies designed to promote improved health outcomes.
- delivery of health care.
- approaches to improving accessibility or adherence to pharmaceutical, nutritional or other promising or proven interventions.

The outcomes of the proposed intervention studies, whether the focus is on individual or population approaches, should therefore specifically relate to Type 2 diabetes. Projects addressing gestational diabetes are within the scope of this call.

All Projects submitted to this call must :

- focus on research into implementation of prevention and/or treatment strategies derived from existing knowledge and research.
- Develop an improved understanding of the key barriers and facilitators at local and national levels that affect the prevention and treatment of type 2 diabetes.

- Include an assessment of equity and gender gaps in diabetes prevention and treatment.

- Demonstrate a sound understanding of the local health system context.

- Provide evidence of a health economics dimension such as cost effectiveness of the proposed intervention.

- Describe a clear proposed pathway to embedding the intervention into policy and practice after the study which addresses how:

  – Local and/or national policy makers will be engaged both at the start of the project as well as the end.

  – The project outcomes/evidence will be utilised for the scaling up of the intervention on a local, national and international level.

  – Future scaled-up implementations will fit within the local social, cultural and economic context.

  – Identify obstacles such as inequities and equity gaps including gender that will be taken into account in the design of an implementation strategy.

- Be proposed by a multidisciplinary project team, including local researchers as co-investigators where applicable.

- Include local stakeholders such as patient groups or community groups.

- The GACD aims to develop a network of researchers that can enhance the cumulative learning across the individual projects, and work towards understanding how socio-economic, cultural, geopolitical and policy contexts have influenced results and how findings might be adapted and applied in different settings. The funded researchers will meet annually to discuss their research and share information in order to develop approaches to standardise data collection, and wherever feasible to use these standardised approaches in their respective projects. The following types of projects DO NOT fall within the scope of this call:

- Replication of effectiveness studies and clinical trials testing the efficacy or effectiveness of new or established pharmacological agents (or combination of agents) which have wider effects than those relating to type 2 diabetes.

- Aetiological or mechanistic studies of type 2 diabetes.

- Phase I or Phase IIa trials.

<u>Expected impact:</u>

- Reducing health inequalities and inequities, including gender, in the prevention and treatment of type 2 diabetes in both a local and global context.
- Pursuing knowledge translation and exchange approaches that are designed to maximize the public health benefits of research findings within different health contexts.
- Providing evidence to inform local health service providers, policy and decision makers on the effective scaling up of the interventions at the local, national and regional levels.

- Contribute to the Global Alliance for Chronic Diseases.
- Contribute to the WHO Global Action Plan on NCDs (2013-2020).
- Contribute to the United Nations Millennium Development Goals.

Type of action: Collaborative projects (100%).

Another GACD call is expected to be published for the year 2015.

HCO 6 - 2014) ERA-NET - Establishing synergies between the Joint Programming on Neurodegenerative Disease Research and Horizon 2020

Details TBC

HCO 7 - 2014) ERA-NET: Cancer research programmes and activities

Details TBC

HCO 8 - 2014) ERA-NET: Brain related diseases research programmes and activities

Details TBC

HCO 9 - 2014) ERA-NET: Systems medicine for clinical needs research programmes and activities

Details TBC

HCO 10 – 201x) ERA NET: Rare Disease research implementing IRDiRC objectives

Fast track to Innovation – pilot

Fast track to Innovation Topic

Under this Fast Track to Innovation (FTI) pilot, proposals for innovation actions linked to any technology field will be invited, on the basis of a continuously open call (with its first cut-off date in 2015) and a bottom-up-driven logic.

[Any legal entity may participate and proposals may be submitted at any time. The Commission shall initiate three cut-off dates per year to evaluate proposals. Time between a cut-off date and signature of the grant agreement or notification of the grant decision shall not exceed six months. No more than 5 legal entities shall participate in an action. The amount of the grant shall not exceed EUR 3 million.

Proposals shall be ranked according to the impact, quality and efficiency of implementation and excellence, with the criterion of impact given a higher weighting. Factors such as time sensitivity and the international competitive situation shall be taken into sufficient account when evaluating the impact of a proposal, to allow for flexibility according to the various specificities within different fields of applied research.]