SC1 WP 2018 – 2020

Societal Challenge 1 - Health, Demographic Change and Well-being

Topics already mentioned in draft 2020 Calls and New 2020 Topics (numbered CSA 1 to 6 and RIA 1 to 6)

Contents

Call 1. Better Health and care, economic growth and sustainable health systems (DG RTD)

Priority 1.1 Personalised medicine

SC1-BHC-06-2020: Digital diagnostics – developing tools for clinical decisions integrating in vitro and in vivo diagnostics

Specific challenge:

The availability of appropriate decision support tools for healthcare practitioners can promote uptake of personalised medicine in health care. There is a need to carry out research activities aiming to develop and validate such decision tools that would integrate available diagnostic means for the area concerned, enabling increased precision of diagnostics and clinical decision making. The tools will incorporate Artificial Intelligence (AI) solutions resulting in platforms or devices that would allow a highly personalised diagnosis, based on the integration of data available from many sources and offering a detailed health status assessment with a multitude of viewpoints, in a systemic way and easy to use for clinical purposes.

Scope:

Proposals should develop tools or platforms that will use information provided by most relevant diagnostic means for a particular area, resulting in an accurate, detailed, structured, systemic and prioritised assessment of the health status in a patient. The proposed solutions should integrate medical records, *in vitro* and *in vivo* diagnostics and AI systems while taking into account the actual needs of healthcare practitioners, with a view of practical deployment in real-life settings. These tools/platforms should contribute to improving diagnosis and clinical decision, not only integrate existing data. Any medical data relevant for a particular disease (textual data, numerical measurements, recorded signals, images etc.) may be considered. The aim is to steer the development of solutions towards concrete patient and public sector needs, having the citizen and healthcare providers at the centre. Proposals should be aligned with the realisation of the objectives of the International Consortium for Personalised Medicine. Careful attention should be paid to appropriately addressing ethics concerns and ensuring data safety and privacy, in line with existing European and international standards and legislation.

Expected impact:

- Increase EU's capacity to innovate in the area of medical instruments through the development of new diagnostic platforms integrating *in vitro* and *in vivo* data and providing quick, detailed, accurate and highly personalised diagnostics for optimal decision in clinical practice.

- Improve the quality and sustainability of healthcare systems through quicker and more encompassing diagnosis of medical conditions, leading to quicker clinical decisions and timely delivery of personalised treatments, with reduction of errors and delays (and costs associated to them).

- Contribute to the growth of the European diagnostics sector, in particular for SMEs.

- Reinforce EU's role among world leaders in the production of medical diagnostic devices.

Type of action: Research and Innovation action

SC1-HCO-01-2018-2019-2020: Actions in support of the International Consortium for Personalised Medicine

Specific Challenge:

Personalised Medicine is a very broad and multifaceted area where success relies on a well-functioning collaboration between several disciplines and different actors. While great advances have been made in some fields of medicine, in particular in stratification of cancer patients and in addressing rare diseases, most of today's healthcare protocols do not include personalised approaches apart from occasional division into broad age groups (children/adults/elderly), sex or ethnicity. Furthermore the prevention aspect of personalised medicine, i.e. identifying individuals prone to develop certain diseases, is largely isolated from treatment options. As is the case for a relatively nascent field there is a need for standardisation of approaches, including for sampling, data storage, interpretation and data exchange and also for clinical trials design and reimbursement models. European countries with their social model of healthcare along with (in several cases) centralised cost reimbursement, are ideally placed to lead the way for an integrated health management system. Many needs for coordination and support activities have been identified by ICPerMed, which includes representatives from most EU countries along with several other European countries and Canada. Also the wider internationalisation of ICPerMed can be underpinned by coordinating networking activities with third countries.

Scope:

Each action should focus on *one* of the following fields:

- **International aspect**: The action should focus on building links with third countries by analysing the potential and advantages of collaboration in personalised medicine (PM) with those countries, studying areas of interest for Europe in PM collaboration and promoting international standards in the field. In particular the uptake of personalised approaches in health systems and healthcare should be addressed, taking into account social and cultural aspects, health economy issues and equitable healthcare. For the 2020 call, the project should focus on the African Union as a group of countries. The project should have a duration of at least four years and address sustainability beyond that to ensure longer term structuring effect. Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least one international participant from Africa.

- **ICPerMed secretariat**: The project should continue the work done by the secretariat for ICPerMed, organising the meetings of the ICPerMed Executive Committee, convening dedicated workshops and preparing and issuing updates of the ICPerMed Action Plan. Furthermore maintaining the network of policy makers and funders

gathered in ICPerMed and expanding the membership to new interested and complementary partners (2020 call).

For grants awarded under this topic for Coordination and Support Actions it is expected that results could contribute to European or international standards. Therefore, the respective option of Article 28.2 of the Model Grant Agreement will be applied.

The Commission considers that proposals requesting a contribution from the EU of between EUR 1.5 and 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

Contributing to the implementation and reach of the ICPerMed initiative; furthermore:

- **International aspect**: Integrating the country/group of countries into ICPerMed activities. Support wider adoption of standards developed in Europe. Contribute towards the UN Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages.

- **ICPerMed secretariat**: Ensure continuity of the operations of ICPerMed beyond 2020. Increase the visibility of the consortium and provide harmonised vision for the further development of personalised medicine. Contribute to the convergence of members' approaches to personalised medicine and further alignment of research efforts in the field.

Type of Action: Coordination and support action

SC1-HCO-03-2020: ~~Improving EU-13 participation in EU-supported health research programmes~~
New title: Bridging the divide in health research and innovation – boosting return on investment

Specific Challenge:

The Innovation Union Scoreboard reveals significant disparities in terms of research and innovation performance among the different member states and regions within the European Union. The disparities are equally present in health research and innovation which unfortunately also translates into lower participation in the Union's research and innovation framework programme, Horizon 2020.

There are serious efforts deployed at national and European level to help to close the R&I divide. Many instruments provide direct investment to organisations from lagging regions and countries, such as the European Structural and Investment Funds, national grants, the Spreading Excellence and Widening Participation programme of Horizon2020 while others encourage networking such as the COST actions.

These European and national investments yield the most when beneficiaries have the necessary capabilities, adequate governance structure, and suitable science and HR policies. This call aims providing support in the health R&I domain to organisations from lower performing regions that are willing to carry out structural reforms to improve their R&I performance. The call builds on past efforts of the European Commission (especially the HCO-14 2014 and the HCO-08 2017 calls in H2020 SC1).

Scope:

Applicants shall propose actions that would shift benefiting organisations' R&I performance and would eventually increase their participation in EU funded collaborative projects. Proposed activities shall aim to improve governance and managerial practices, increase the organisations' international profile and HR policies to attract and retain talents and create a culture that rewards scientific performance and innovation. Applicants may propose any actions that contribute towards these goals.

Beneficiaries of the activities should be active in the field of health research and innovation and should come from low performing[1] Member States/regions that have identified health R&I as a priority in their Research and Innovation Strategies for Smart Specialisation (RIS3). Applicants shall seek synergies with European Structural and Investment Funds and with European and national research and innovation programmes. Applicants are encouraged to leverage funding of this call with other resources.

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

Expected Impact:

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

An increased number of organisations from low performing Member States/regions among the top international health R&I institute that are able to attract funding and talents and render these resources into scientific excellence and innovation.

Ultimately, increased participation rate of low performing countries in the EU's Research and Innovation Framework Programme.

Type of Action: Coordination and support action

SC1-HCO-14-2020: ERA-NET Place holder 2

CSA 1 - Towards a Health research and innovation Cloud: learning from data sharing initiatives in health research

Specific Challenge:

Technological innovation has triggered an unprecedented increase in data production in health research and healthcare. The need to make EU health research data FAIR (i.e., Findable, Accessible, Interoperable and Re-usable) becomes more pressing than ever before if European health research is to reap the full benefits of this valuable resource. The stakes are high because making optimal use of this health data is expected to both accelerate research discoveries and bring them closer to clinical application for the benefit of EU citizens.

A wide range of challenges needs to be overcome before this vision becomes a reality. To be able to seamlessly integrate and analyse health data coming from different sources and different health sub-disciplines, individual research institutes and/or hospitals would need a potent IT infrastructure and interoperability solutions as well as powerful data analytics tools. Services in the Internet Cloud (i.e., Cloud Services) are a promising starting point to build these systems.

Properly addressing the security and privacy of health research data, and the compliance with various levels of legislations and with different jurisdictions is a critical step for the design of a Health Research and Innovation Cloud (HRIC). These aspects need to be considered so that the collection, sharing, analysis, curation of health research data across different application domains can be achieved in ways that are technologically robust, scientifically reliable, and ethically and legally sound.

Scope:

To appropriately address this specific challenge, the successful project should propose a multidisciplinary network of stakeholders representing data-intensive EU health research projects and EU infrastructures who would design an **implementation roadmap /strategic agenda for** a **FAIR data portal** with all relevant publicly-funded health research databases, registries and infrastructures where projects can deposit or access quality health research data.

The network of stakeholders is expected to build a **community** in order to align strategies, capitalise on existing efforts, and on the work done by major European and international initiatives.

This network of stakeholders should also define and implement **two pilot studies** that link health research data with clinical data and health administrative data, and that are already advanced in data interoperability solutions, to demonstrate the added benefit of data sharing across the healthcare continuum.

Essentially, this multi-stakeholder platform should provide a forum where participants can share experience, learn from each other, and collaborate on data research challenges to ultimately overcome them.

The multi-stakeholder platform should also produce guidance on data modelling, handling, access and preservation for new health research projects that are expected to join the HRIC. The Action should provide recommendations for the professional knowledge, skills and competences corresponding to the needs of health research data-intensive initiatives.

The HRIC should support EU Open Science policies such as the European Open Science Cloud and the collaboration between multiple healthcare and research institutions in compliance with citizens' data privacy, ethics and ownership needs.

The selected project is expected to collaborate with the consortium funded under topic 'INFRAEOSC-06-2019-2020: Enhancing the EOSC portal and connecting thematic clouds.'

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

Expected Impact:

- Better use of health data, which will in turn lead to more effective diagnostic tools and more targeted treatment options for the benefit of EU citizens.
- Effective sharing of data, knowledge and know-how within the EU health research ecosystem and thus accelerate the pace of EU health research discoveries.
- Through the pilot actions, demonstrate the added value of the closer collaboration of health researchers with health professionals and improve the healthcare systems' capacity to take up research results.
- Contribute to the Digital Single Market through piloting IT health research solutions.
- Further the “Open science” and “Open to the world” priorities and contribute to the Health thematic cloud of the European Open Science Cloud.

Type of Action: Coordination and Support Action

CSA 2 - Coordinating and supporting research on the human microbiome in Europe and beyond

Specific Challenge:

Integration and application of metagenomics data from the human microbiome has shown large potential for personalised medicine approaches. Information and details about conditions of healthy citizen and patients can be very helpful to complete the picture i.e. to better understand the health or disease state and to predict its development.

The number of European and international projects and initiatives is increasing but they are largely fragmented and have different underlying methods, standards and operating procedures so that comparing and consolidating results and knowledge is challenging. The International Human Microbiome Consortium (IHMC) aims to share experiences, to facilitate international cooperation and to work for a common set of principles and policies. There is a need for further coordinated action at European and at international level. Strategic multi-actor cooperation could increase coherence and exploit comparability and synergies between countries to finally act on common health challenges and agendas.

Scope:

Proposals should aim at a platform for collaboration and coordination across various research and innovation programmes on the human microbiome, in Europe and worldwide, dealing with a wide range of diseases and health issues at different sites of the human body (not only one organ), including also nutritional and environmental aspects. Proposals should map the progress and the state of play for specific disease and health issues as well as the success and meaningfulness in different countries. They should propose strategic research agendas for future actions on the human microbiome addressing emerging fields and political priorities. In particular, they should support and enhance cooperation in similar activities within Europe and beyond. Participation of relevant partners from outside EU is strongly encouraged.

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

Expected Impact:

- Harmonisation and increased comparability of metagenomics and human microbiome data in Europe and beyond.

- Improved coherence and reduction of overlap between national, EU and other funding in the area of human microbiome research, thus ensuring an efficient use of the available resources.

- Reinforced collaborations and synergies in Europe and beyond, thus creating the basis for the development of joint research programmes and facilitate the alignment of research agendas in Europe and beyond.

- Internationally agreed methods, standards and procedures for the area of human microbiome research.

- Knowledge exchange and enhanced engagement of citizens, scientists and political stakeholders in special areas or for special priority health risks.

- Integration of metagenomics and human microbiome disciplines into other multilateral co-operation areas or personalised medicine approaches.

Type of Action: Coordination and support action

CSA 6 - Guidelines on analytical use cases of real-world data (RWD) for clinical care, health technology assessment and for policy making

Specific challenge:

Patients, doctors and all other actors in the health care system need information about the safety, efficacy and effectiveness of health interventions. Different approaches have been developed to gather this necessary information. Notably randomised controlled clinical trials (RCTs) are a key tool. In recent years, technological developments have made it possible to collect health and wellbeing data at much larger scale than was previously possible. It includes data from electronic health records, registries, biobanks, cohorts, claims databases, administrative data and mHealth solutions that is often referred to as real-world data (RWD).

RWD finds applications in clinical research, clinical decision-making, regulatory decision-making and health technology assessment. RWD offers the possibility to complement the information available from RCTs. An illustration of the potential of gathering RWD is that it may improve the collection of safety data, after a new health intervention has been approved. RWD can also allow reducing the uncertainty on the effectiveness estimated at market launch by providing additional information on the health intervention as it is used in daily practice. It is of particular interest in the case of intervention for which, due to the particular situation (medical condition, health care setting etc.), only limited data may be available at the time of first approving it. Making use of RWD may be especially relevant in the context of stratifying intervention groups and personalising health and care. RWD also supports the development of health economic models and can serve as inputs for outcome-based managed entry agreements.

The use of RWD can benefit different groups of actors in the health systems: healthcare professionals by providing information for clinical decision-making, industry and regulators by providing information to improve market access and surveillance and policy makers by providing information on negotiate prices and reimbursement conditions of health interventions.

Along with the long list of expected benefits of the use of RWD in healthcare systems, as outlined in the "Expected impact" section, several methodological and conceptual challenges lay ahead of the proper exploitation of RWD.

Scope:

To address these challenges, each action should focus on the following:

- Carry out a landscaping exercise of completed and ongoing Horizon2020, IMI and EMA projects and EUnetHTA and GAPP Joint Actions outputs in the field of RWD and derive guidelines for the use of RWD targeting different stakeholders' groups and purposes: healthcare professionals, industry, regulators and policy-makers. These guidelines should be derived from within these stakeholders' fields with input from patients' organisations and academic researchers. The guidelines should cover the entire healthcare continuum, should include guidance on quality and accuracy of RWD by design, guidance on RWD standards and on the curation of real-world databases, guidance for integrating different types of RWD (and RCT data where relevant), methodological guidance for its analysis including quantitative combination of heterogeneous RWD (and RCT data where relevant), and address data privacy issues linked to RWD use.

- Create an EU wide online inventory of existing initiatives and projects on RWD and develop of an IT tool to perform searches.

- Market research by companies is not in the scope of this topic.

The Commission considers that proposals requesting a contribution from the EU of between EUR 1.5 and 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Facilitate the use of different types of RWD by different stakeholders in the EU.

- Reach an agreement between different involved parties (i.e., researchers, clinicians, regulators, policy makers, HTA agencies, industry, insurers, etc.) regarding what RWD is needed, what are the relevant outcomes at which point in time, and for which purpose.

- In the long run, overcome challenges when using different sources of RWD, in particular linked to difference in structure, setup and content of different RWD databases.

- Move towards common standards in the EU for different RWD uses and pre-analytical processing, taking into account stakeholders' needs.

- Move closer to implementation of well-thought-through RWD collection strategies at institutional level (i.e., transparency in the choice of RWD to be collected, clear responsibilities of professionals in charge of the data management, standard operating procedures, etc.).

Type of Action: Coordination and support action

RIA 5 - Real-world data to advance research on complex disease

Specific Challenge:

- Complex chronic disease (CCD) = determined by a number of genetic and environmental factors and involving multiple morbidities.
- Limited success so far on cures or ways to stop disease progression in CCDs; not many solutions, including in personalised disease management.
- Generating and collecting data, for example through cohorts, is complex, time consuming and expensive.
- Huge amount of data are collected daily in clinical practice, also in a fragmented way. Their exploitation is very limited.
- With the development of mobile application even more data are being generated daily.
- Bringing together research data and RWD offers potential for advancing research on CCDs.

Scope:

Proposal should/may:

- Bring together RWD with data acquired from existing sources (such as data collected from cohorts, data from biobanks, genome research initiatives).
- Study disease prevention, early detection, treatment and quality of care, with the aim to improve public health.
- Use real world data for surveillance purposes, including demonstrating of the clinical added value in real settings of the proposed intervention, identifying any adverse reaction to the intervention in real settings, assessing the long term impact of the intervention.
- Ensure that the process put in place for collecting real world data is sustainable and will be made available for future research.

Expected impact:

- New approaches for addressing CCDs
- Improved monitoring of quality of life in real settings
- Sustainable data platform for future research use
- Shorten the life span of research

Type of Action: Research and Innovation Actions, 4-6 million Euro per project

RIA 6 - Implementation research for scaling up patient-centred health services

Specific Challenge:

Research evidence and technological and process improvements and in particular those involving the use of digital tools, present a large opportunity for improving the functioning and sustainability of health systems. However, the uptake of well-researched and proven interventions addressing current challenges is still slow. Implementation research on scaling up evidence-based innovations and good practices interventions should facilitate the transferability of these practices across the borders of Europe and beyond.

Scope:

Innovative solutions for healthcare have the potential to improve patient care in European healthcare setting. Integrated care principles allow care for patients to be better coordinated, and jointly planned by the health and social care professionals across vertically and horizontally relevant preventive and curative services. To respond to changing organisation of care and support the transition of hospital services towards a patient-centred integrated care model, healthcare providers are encouraged to reorganize to make health services more patient-centred, prevention- oriented, responsive, safe, effective, and efficient. Its stated impact should be broad, addressing economic and social benefits and its effect on reducing inequalities.

Based on the concept of implementation research, the proposed projects should identify the facilitators of and barriers to scaling-up comprehensive interventions in the field health services, including context-specific factors and differing social and health systems environments in Europe.

The interventions researched should be innovative, based on the use of digital solutions, well researched and supported by sufficient documented evidence. The topic does not cover micro-level interventions, e.g. to promote a specific therapeutic regimen for a single disease.

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

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

Synergies with multiple sources of funding (e.g. ESIF2, SRSP3, Health for Growth4, national health/research programmes, European5 or national investment schemes and procurement6

[2] European Structural and Investment Funds, European Commission ESIF
[3] Structural Reform Support Programme, European Commission SRSS
[4] Health for Growth programme, European Commission SANTE
[5] European Fund for Strategic Investments, European Commission EFSI

instruments) for the various multiple facets of the intervention being implemented are encouraged/sought. In that case, each of the multiple requests for funding will be evaluated separately in the respective funding scheme[7].

Selected projects should contribute to the third pillar of Digicare Communication on "Digital tools for citizens empowerment and person-centred care.

The Commission considers that proposals requesting a contribution from the EU Horizon 2020 research programme of EUR 4 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- A larger group of citizens benefits from the studied health services intervention. The intervention should lead to improving the functioning and sustainability of health systems, put emphasis on prevention, greater health equity and additional societal benefits.

- A validated framework and strategy for a large-scale implementation of an effective and safe evidence-based health systems intervention will be available to healthcare providers and policy makers that will facilitate the transferability of these practices.

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

Type of Action: Research and Innovation action

[6] Pre-Commercial Procurement /Public Procurement of Innovative solutions, European Commission PCP/PPI
[7] https://ec.europa.eu/digital-single-market/en/news/staff-working-document-enabling-digital-transformation-health-and-care-digital-single-market

Priority 1.2 Innovative health and care industry

SC1-BHC-08-2020: New therapies for Non Communicable Diseases

Specific challenge:

Non-communicable diseases represent a significant burden on individuals and healthcare systems, accounting for 86 % of all deaths in Europe. Innovative and effective therapeutic interventions are required to find a cure or provide best quality of care when prevention strategies fail. While considerable knowledge has been generated by biomedical research, therapeutic interventions often do not reach patients as a consequence of considerable attrition rates in clinical trials. This is due to a variety of reasons, including lack of robust preclinical data, lack of effective predictive means, inappropriate timing of the intervention and inadequate stratification of patients.

Scope:

Proposals should conduct clinical trial(s) of novel or refined therapies[8] for patients suffering from non-communicable diseases[9]. The clinical trial(s) should be supported by proof-of-concept[10] of clinical safety and efficacy[11] of the therapy and may be investigator initiated. Preclinical research must be completed before submission of the proposal. Applicants should present a sound feasibility assessment, including appropriate patient selection for the intervention and realistic recruitment plans, justified by publications or preliminary results. Proposal should demonstrate the potential clinical benefit including through patient-reported outcomes. Sex, gender, age and other stratification criteria[12] could be considered whenever relevant. Where appropriate, patients and carers should be involved and their views should be reflected in the research activities.

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

Expected impact:

- Therapeutic strategies with the highest potential to generate meaningful advances in clinical practice and care for patients with non-communicable diseases.

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

Type of action: Research and innovation actions

[8] Applicants may address any mono- or combinatorial, pharmacological and non-pharmacological intervention, including drug repurposing, medical devices, surgery, chemoprevention, lifestyle interventions, etc.
[9] Rare diseases and regenerative medicine are not within the scope of this topic.
[10] Comparative effectiveness studies are not within the scope of this topic.
[11] Phase 3 and phase 4 clinical trials are excluded.
[12] Clinical and molecular features of the patient and/or the disease

SC1-BHC-11-2020: ~~New, animal-free regulatory test methods for human safety testing at the horizon of 2030~~
New Title: Advancing the safety assessment of chemicals without the use of animal testing

Specific Challenge:

Despite considerable progress in the development and application of animal-free approaches to toxicological profiling of chemicals in support of chemical safety assessment, significant challenges remain regarding the provision of viable solutions to address complex systemic health effects potentially linked to chronic exposure to chemicals across a variety of regulated sectors. Consequently, efforts are needed to further progress on the development, validation and translation of scientifically sound methods that not only reduce the reliance on animal testing but which also deliver more relevant, reliable and cost-effective means to facilitate decision-making to support regulation, innovation and competiveness.

Scope:

Proposals should consider integrative approaches that build on advances in all relevant fields of science and technology, including elements such as novel *in vitro* and *in silico* tools and the understanding of human biology and related toxicity pathways, with the aim of proposing and demonstrating scientifically valid means for comprehensive safety assessment of chemical substances without resorting to animal testing. Exploitation of information and knowhow from clinical, epidemiological, exposure and biomonitoring studies is strongly encouraged to inform research strategies and to establish the scientific credibility of the approaches proposed for a variety of relevant decision-making contexts. In addition, attention should be given to establishing and pursuing concrete measures to seek acceptance and uptake by end-users striving to address safety assessment challenges in support of product development and addressing regulatory information requirements.

Proposals should involve, amongst others, academic research communities, industry, SMEs, and regulatory bodies as appropriate.

Cooperation with complementary initiatives outside the EU is strongly encouraged as a way to coordinate international research efforts and to accelerate the harmonisation, acceptance and promotion of new approaches worldwide.

Proposals could consider the involvement of the European Commission's Joint Research Centre (JRC) to provide add-value regarding such aspects as supporting validation of emerging approaches, promotion of research results, and the interfacing with the regulatory community. In this respect, the JRC is open to collaborate with any successful proposal.

Applicants are encouraged to seek during the life-time of the project additional support and cooperation from various industry sectors in order to facilitate and accelerate progress. Equally, collaboration should be sought with complementary publically-funded projects and initiatives being pursued at EU and Member State level.

The Commission considers that proposals requesting a contribution from the EU of between EUR 10 and 30 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Scientifically sound, practicably implementable non-animal solutions readily deployable to inform safety assessment of chemicals across a variety of sectors.
- Deployment of proposed non-animal methods and safety assessment approaches that aid industry in meaningful safety assessment decision contexts.
- Recognition from regulatory bodies and their engagement to translate results, methods and solutions into safety assessment practice.
- Commercial exploitation of the developed safety assessment approaches, products and services.
- Reduced use of laboratory animals in safety testing.

Type of Action: Research and Innovation action

~~SC1-BHC-12-2020: Boosting the translation of results of health research into validated, innovative applications~~

CSA 3 - Clinical investigation and evaluation of high-risk medical devices - developing methodological approaches adapted to their specificities

Specific challenge:

- Medical devices have specificities compared to medicinal products that make the conduct of double-blind randomised controlled clinical investigations difficult. Taking into account these specificities, there is a need for methodologies that enable to generate improved clinical evidence. Furthermore, new developments in medical technologies such as mHealth, artificial intelligence, and combined products, pose additional challenges on developers[13] to generate high-quality clinical evidence.

- In May 2017, a new Regulation on medical devices, Regulation (EU) 2017/745[14] entered into force that will come into effect in spring 2020. This new Regulation sets forth reinforced rules for the generation of clinical evidence, in particular for the highest-risk devices for which clinical investigation [15] will be compulsory [16]. In addition to the before mentioned, the clinical evaluation[17] of such a medical device has to be updated throughout its lifetime in a continuous process involving proactive collection of data and synthesis of all available data.

- Owing to rapid scientific progress and lack of knowledge on the regulatory frameworks among the scientific community, there is a need to raise awareness on new regulatory requirements in terms of clinical evidence. It is important to inform stakeholders involved in the clinical evaluation of high-risk medical devices (e.g. academic researchers, clinicians, manufacturers, notified bodies, contract research organisations) about the new regulatory framework and the evidence required for conformity assessment.

Research can help to address these challenges by developing and promoting methodological approaches, including alternative statistical methodologies, adapted to the specificities of high-risk medical devices. These methodological approaches will improve the robustness of clinical data needed at different phases of the product's lifetime, such as conformity assessment, post-market clinical follow-up and post-market surveillance.

Scope:

To address these challenges, the proposed research should focus on i) methods to generate clinical data both within the context of a clinical investigation and in daily practice (i.e. real-world data) so that robust clinical evidence is available for high-risk medical devices, and ii) synthesis methods that will allow to make optimal use of all available data taking into account its heterogeneity. Proposals should in particular:

[13] Developers include manufacturers and other entities active in the development of medical devices

[14] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[15] As defined in Article 2 (44) of the Regulation (EU) 2017/745

[16] as provided for in Article 61.4 of the Regulation (EU) 2017/745 : implantable and class III devices with the exceptions listed in Article 61.5 and 61.6. Those devices are referred to as "high-risk" devices in the text.

[17] As defined in Article 2 (45) of the Regulation (EU) 2017/745

- Analyse the specificities of high-risk medical devices and the potential associated issues in terms of clinical evaluation, carry out a review of the currently used clinical investigation designs for the evaluation of such devices, provide a hierarchy of these approaches, identify gaps to be filled (in particular in view of new developments like e.g. mHealth, artificial intelligence, and combined products) and derive recommendations for the choice of clinical investigation methodology to obtain sufficient evidence.

- Develop methodologies for generating clinical data on existing and novel high-risk medical devices enabling to collect and use sound data for providing clinical evidence evaluated during conformity assessment in accordance with the new Regulation and throughout the entire lifetime of the device. Proposals should take into account the various specificities of high-risk medical devices and clinical fields if relevant.

- Contribute to the exchange of best practices among notified bodies with regard to the assessment of clinical data as provided by developers of high-risk medical devices.

- Support networking activities among developers and in particular academic centres with regard to regulatory requirements for assessing high-risk medical devices and foster a pool of scientific expertise on clinical evaluation of high-risk medical devices.

Applicant consortia should bring together partners with relevant expertise from e.g. academia, competent national authorities, centres of expertise for clinical research and care, scientific and medical learned societies. The consortium should also seek input from relevant stakeholders such as patients, technology developers, and healthcare providers. The composition of the consortium should ensure a broad geographical representation of European countries. Gender equality aspects should be taken into account in carrying out the relevant research objectives and activities.

Proposals should complement or build on existing work, including results of EU-funded research projects and Joint Actions in the field of medical devices evaluation.

The Commission considers that proposals requesting a contribution from the EU of between EUR 1 and 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amount.

Expected impact:

- Improved evidence on safety and efficacy of high-risk medical devices for the benefit of the patient

- Higher quality and reliability of clinical data needed for conformity assessment and continuous market access

- Improved knowledge of relevant legislative frameworks and regulatory requirements among all stakeholders involved in the development of high-risk medical devices

Type of Action: Coordination and Support Action

CSA 4 - Reliable and accessible information on future therapies in regenerative medicine

Specific Challenge:

Regenerative therapies have the potential to treat many debilitating diseases however the pace of their clinical development does not meet public expectations. Advanced therapies face difficulties reaching patients because *inter alia* the complexity and costs of product development, regulatory hurdles and the non-harmonized procedures for reimbursements. With the onset of unauthorised uses of advanced therapies, regulators have issued warnings about unproven practices and concerns for patient safety[18] [19]. There is a need to provide a reliable, transparent, accessible resource for patients to make informed decisions, for citizens to have access to scientifically viable information on novel therapies as well as provide researchers with a practical aid for efficient product and therapy development.

Scope:

Proposals should offer well-structured and detailed strategies to convey accurate and up-to-date information on advanced therapies using multiple contemporary modalities, including a website. The consortium should consist of diverse actors and could include science communicators, patients' representatives, industry and academic researchers as well as the major European learned societies in the field. They must provide expertise across the field of stem cells, regenerative medicine, genome editing and gene therapy. All communication material/information should be in English as well as several other EU languages. The website should be user-friendly and should contain tailored sections dedicated to at least researchers, patients, and the public. Proposals should provide state-of-the-art strategies to engage the public and foresee regular evaluation of whether they reach the targeted audiences. In addition, a series of communication events should be organised, also open to the public, where innovative technologies could be presented and discussed. Resources should be allocated for supporting the research community in speeding up the development of new therapies, including a survey aimed at identifying bottlenecks and proposing actions. The proposals must consider the involvement of the European Medicines Agency (EMA[20]), the Heads of Medicines Agencies (HMA[21]) network and/or EUnetHTA[22] network and the produced materials should cover all stages of product development such as manufacturing guidelines and requirements, national and international regulations, data and clinical management as well as market approval and acceptability. Sustainability plans for the action must be explored during the project duration so that information gathered is not lost after the end of the project.

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

[18] https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm586343.htm
[19] https://www.tga.gov.au/media-release/regulation-autologous-cell-and-tissue-products
[20] European Medicines Agency: http://www.ema.europa.eu
[21] The Heads of Medicines Agencies is a network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area http://www.hma.eu/
[22] EUnetHTA Joint Action 3 is a European network of national/regional HTA bodies under the EU Third Health Programme http://www.eunethta.eu

Expected impact:

- Communicate to patients and the public objectively, accurately and transparently, the latest developments and actual treatments available in the field in order to avoid misconceptions
- Provide the research community and patients with a high-quality information source for product development
- Ensure benefits for patients and healthcare systems
- Establish or reinforce the networking between advanced therapy-learned societies and the relevant EU national regulatory authorities
- Sustainability ensured for at least 5 years after the end of the project

Type of Action: Coordination and support action

Priority 1.3 Infectious diseases and improving global health

SC1-BHC-17-2020: Global Alliance for Chronic Diseases (GACD) 2

Placeholder - Will be done later, after GACD meeting - To Do

SC1-BHC-20-2020: ~~Using pre-commercial procurements and public procurement of innovative solutions in health care systems to: - reduce the risk of hospital-acquired infections and/or - improve integrated care~~

New Title: Pre-commercial procurement or public procurement of innovative solutions in health care systems to reduce the risk of hospital-acquired infections

Specific Challenge:

Implementation of timely and correct diagnostics for infectious diseases (ID) that will speed up the identification of the causative infectious disease pathogens, resistance and drug susceptibility is crucial for tailoring the antimicrobial treatment, thus ensuring appropriate antimicrobial drug use. In practice however, cost issues hamper the implementation of rapid diagnostics for ID, as innovative rapid diagnostics are currently significantly more expensive than culture-based diagnostics that are widely used since decades. Thus, the uptake of these new rapid tests in hospitals, and especially primary care centres, has been limited.

Scope:

The objective is to respond to this clinical and public health challenge and to facilitate the uptake of innovative rapid diagnostics for infectious diseases into healthcare practice using pre-commercial procurement (PCP) or public procurement of innovative solutions (PPI). This topic will contribute to the EU One Health Action Plan against Antimicrobial Resistance[23].

The detailed scope and the requirements for innovation procurement actions covered by this topic will be developed by the consortium selected in SC1-BHC-12-2018: 'Innovation in healthcare - a CSA towards using pre-commercial procurement and public procurement of innovative solutions in healthcare systems'. Proposals should, however:

- be driven by clearly identified procurement needs of the participating organisations and building on a deep understanding of the needs in the area of ID diagnostics, as well as the needs of the end-users;

- be driven by 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 supply of health and care services;

- demonstrate strong commitment of end-users and relevant communities in the development and implementation process;

[23] https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf

- Specify measures that will ensure the sustainability of solutions beyond the lifespan of the proposed project, notably taking into account levels of acceptance with users and professionals as well as health economics considerations.

- synergies with the Structural |Reform Support Program and the European Structural and Investment Fund are encouraged

Proposals of this topic should follow the specific requirements for innovation procurement PCP/PPI supported by Horizon 2020 grants as set out in General Annex E of the work programme.

The Commission considers that proposals requesting a contribution from the EU of between EUR 9 and 11 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- New rapid diagnostic tests for infectious diseases in hospitals and primary care centres

- Increased and improved advocacy of rapid ID diagnostics in hospitals and primary care centres

- Strengthening of implementation of better targeted antimicrobial treatment, improved clinical decisions and health outcomes for the benefits of patients.

Type of Action: Pre-commercial procurement or public procurement of innovative solutions

SC1-HCO-07-2020: ERA-NET Place holder 1

RIA 1 - Addressing low vaccine uptake

Specific Challenge:

Vaccines are one of the most important medical breakthroughs in the last 100 years. Every year vaccines save millions of people around the world from illness, disability and death, and they continue to be one of the most cost-effective ways for EU Member States to increase the health and wellbeing of their citizens. Despite this, vaccination uptake faces significant challenges across Europe, and these have increased in particular over the past 20 years. Recent studies have shown Europe to be the world region with the most negative views towards the safety and effectiveness of vaccines, and the importance of childhood vaccination[24].

Recent figures on collected by the World Health Organization (WHO) show that the vaccine coverage rates for many vaccines in Europe have been falling year-on-year, and in 2016 one vaccine had a coverage rate of over 95% in Europe.[25] Seasonal influenza vaccination also remains significantly below the 75% coverage target for older age groups.[26]

As a result of these reductions in vaccine coverage, several EU Member States have faced considerable outbreaks of vaccine-preventable diseases in recent years. More than 14,000 cases of measles were reported across the EU in 2017[27], which is more than three times the number of cases reported in 2016. During the same period 50 people in the EU died due to measles[28].

These figures highlighted the urgent need to get to grips with vaccine uptake issues, whether uptake of existing or new vaccines. Research has an essential role to play in understanding the underlying causes of poor vaccine uptake, including vaccine hesitancy, and to develop strategies and guidelines to help Member States increase vaccination coverage.

Scope:

Proposals should work to increase understanding of the determinants of low vaccine uptake in specific contexts situated in the WHO Europe Region, and should develop strategies to increase vaccination rates of essential vaccines within these contexts. From this work, proposals should aim to develop a series of recommendations that national and regional public health authorities in Europe could implement in order to increase vaccine coverage. Proposals should build on existing research and findings in this domain, as well as existing guidelines and recommendations from public health authorities, including those from WHO and the European Centre for Disease Prevention and Control.

The approach taken should include either a detailed examination of the causes of reduced vaccine uptake, or the design and testing of one or more interventions to improve vaccine uptake, or a combination of both. Factors influencing vaccine uptake such as access, inequality, social/cultural influences and vaccine/vaccination-specific issues in specific population(s) that are identified as having lower than average vaccination coverage should be

[24] http://www.ebiomedicine.com/article/S2352-3964(16)30398-X/fulltext
[25] http://www.who.int/immunization/monitoring_surveillance/data/gs_eurprofile.pdf
[26] http://ecdc.europa.eu/en/publications/Publications/Seasonal-influenza-vaccination-antiviral-use-europe.pdf
[27] https://ecdc.europa.eu/sites/portal/files/documents/Monthly%20measles%20and%20rubella%20monitoring%20report%20-%20JAN%202018.pdf
[28] https://ecdc.europa.eu/en/news-events/measles-cases-eu-treble-2017-outbreaks-still-ongoing

examined. Interventions to improve vaccine uptake should be based on existing high-quality research findings, with a sound hypothesis for why the chosen intervention(s) could be effective at increasing vaccine coverage in the target population(s). These interventions could be made in a wide variety of ways, for example online or offline media, educational material, modification of primary healthcare practices, incentivisation, or any other strategies that are supported by a strong hypothesis.

Finally, the findings of the project must be gathered into a clear and coherent set of recommendations that can be readily utilised by public health authorities in Europe to improve vaccine coverage. Proposals should include in their work the development of a strategy to boost the uptake and implementation of these guidelines.

Proposals must take into account the specific contexts of the population(s) that they are studying, including factors such as age, religion, politics, geography, and socio-economic situation. Proposals must include partners from a variety of different social science and public health-related disciplines. Proposals will also be expected to create links with other existing initiatives, both in Europe and internationally. This should include specific budget for networking and travelling to or organising meetings for researchers and other stakeholders that work on vaccine uptake challenges.

The Commission considers that proposals requesting a contribution from the EU of between EUR 2 and 3 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Contribute to increasing vaccine coverage in Europe, in particular in specific populations with low vaccine uptake and in specific contexts.

- Develop practical and readily implementable guidelines to aid national and regional public health authorities in Europe to increase vaccination rates.

- Work towards meeting the goals on vaccination set out in President Juncker's State of the Union address in September 2017[29] and in the Council Recommendation on strengthened cooperation against vaccine preventable diseases[30].

Type of Action: Research and Innovation action

[29] http://europa.eu/rapid/press-release_SPEECH-17-3165_en.htm
[30] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5925775_en (placeholder reference)

RIA 2 - New approaches for clinical management of resistant bacterial infections in high prevalence settings

AMR topic – prudent use/stewardship

Data collected by the European Centre for disease prevention and control (ECDC)[31] shows that nowadays in several European countries prevalence levels of infections that can no longer be treated with last-line classes of antibiotics have reached levels where isolation measures may no longer be feasible.

Type of Action: Research and Innovation action

RIA 3 - Creation of a European wide sustainable network for harmonised large-scale clinical research studies for infectious diseases

Specific Challenge:

Infectious diseases pose a serious threat to human health and there are several many challenges and needs for efficiently protecting citizens across Europe and beyond. There is still a need to understand how antibiotics and other interventions work on patients, how to better assess the effectiveness of vaccines, innovation is needed to overcome the problem of antimicrobial resistance, and in case of emerging epidemics and pandemics, a timely response to a rapidly emerging infectious diseases is significantly challenging and often delayed. There is a need to establish a pan-European clinical research network that has the capacity and capability to directly enrol patients with infectious diseases, and to increase efficiency for testing and developing new diagnostic, preventive and/or therapeutic strategies and therapies. Europe should also contribute to the G7 aim concerning the need to establish a global clinical studies network on drug resistance that provides access to a large clinical research infrastructure for the design, coordination and conducting of clinical trials and studies. It should also respond to the Council Recommendation on strengthen cooperation for vaccine preventable diseases launched in 2018 (add reference) that also calls for the reinforcement and establishment of novel infrastructures to increase the effectiveness and efficiency of EU and national vaccine R&D funding.

Scope:

Proposals should set up a European-wide multidisciplinary network able to provide a platform for a rapid response in the conduction of clinical studies in relation to any severe infection.

The proposed consortium should comprise expertise of stakeholders from academic organizations, SMEs, larger industry, patient organisations, ethics committee, public health bodies and regulators to perform clinical studies and further advance clinical research in the field of infectious diseases. It should develop new, or make use of existing, standardised methodological approaches to rapidly perform large-scale clinical trials with the view of delivering optimal preventive or therapeutic interventions to patients affected by infectious diseases. Applicants should build on successful European collaborative initiatives such as

[31] https://ecdc.europa.eu/en/antimicrobial-resistance

PREPARE[32] and COMBACTE[33]. To ensure the common benefit of the outcomes, it should also work in cooperation with the existing global experts networks and infrastructures such as ECRIN[34] and the European clinical research network (to be) created as response to the CSA call SC1-HCO-08-2018. The network should address all aspects of clinical trial conduct, from study preparation and design, trial management and reporting. It should develop and allow for innovative research approaches and enable flexibility in responding to unpredictable events during its implementation. The sustainability of the network should also be addressed in the proposal. Furthermore, the network should create synergies with global initiatives, enabling quick and smooth interactions and collaboration across the world.

Special attention should be given to EU Member States and Associated Countries with limited capacity to perform clinical trials.

The Commission considers that a proposal requesting an EU contribution between EUR 25 to 30 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amount.

Expected Impact:

- Reduce the cost and time by efficiently implementing clinical trials for diagnosis, prevention and treatment of infections.
- Create and strengthen the operational capacity and the infrastructures for providing real-time evidence for optimal medical intervention and practice.
- Contribute to existing EU policies, including the "Council Recommendation on strengthen cooperation for vaccine preventable diseases" (placeholder for link), the ID COM (placeholder for link) and the Communication "A European one health action plan against Antimicrobial Resistance (AMR)[35]
- To ensure the EU´s worldwide leadership in controlling and responding to infectious diseases.
- Foster links between existing networks in Europe and other countries/regions in the world to optimise a coordinated response to infectious diseases for innovation and delivery of new preventive and therapeutic technologies.

Type of Action: Research and Innovation Action

[32] http://www.prepare-europe.eu/
[33] https://www.combacte.com/
[34] http://www.ecrin.org/
[35] https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf

Priority 1.4 Innovative health and care systems - Integration of care

SC1-BHC-24-2020: Healthcare interventions for the management of the elderly multimorbid patient

Specific challenge:

It is estimated that more than 50 million European citizens suffer from multimorbidity. As the global population continues to grow and age, multimorbidity is increasingly prevalent in elderly patients.

The management of multimorbid patients presents many challenges for Europe. As healthcare systems remain single-disease focussed, the healthcare path for multimorbid patients is very complex. Healthcare costs associated with multimorbidity are high and rising. An estimated 55% of all healthcare costs are due to multimorbidity. Currently, there are limited means to address effectively the complex needs of multimorbid patients and caregivers. There is a lack of best practises. As a result, multimorbid patients suffer from inappropriate interventions, including delays in the care pathway, polypharmacy, adverse drug reactions, or non-adherence to treatments. This leads to a highly negative impact on the quality of life of individuals and is often associated with significant costs, some of which are avoidable.

Scope:

Proposals should focus on interventions for effective, integrated approaches, to improve the management of multimorbid elderly patients. Proposals should support the delivery of best care adapted to multimorbid elderly patients The patient-centred approach should be holistic, inclusive, cross-sectoral and interdisciplinary. Proposals should aim at improving the quality of life of the elderly patient and simplifying the care path of multimorbid patients, including through self-management. Proposals may stratify patients, develop the clinical concept of intrinsic capacity, define quality performance indicators for multimorbidity, strengthen cooperation among health professionals and use social innovation. Aspects of independent living, fragmentation of treatment, polypharmacy, adherence to treatments, sex and gender may also be addressed. Cost effectiveness and inequalities should be addressed.

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

Expected Impact:

One or more of the following points should be included:

- New patient-oriented and stratified healthcare models for multimorbid elderly patients.
- New clinical guidelines and best practices for improved management of elderly multimorbid patients.
- Cost containment in healthcare interventions for multimorbid elderly patients.

- Develop or modify quality key performance indicators of multimorbidity.

Type of Action: Research and Innovation action

CSA 5 - Coordination of clinical research activities of the European Reference Networks

Specific challenge:

European Reference Networks (ERNs) have been established under the Directive on Patients' rights in cross-border health care in view of tackling complex or rare diseases and conditions that require highly specialised diagnostic tools and treatments. ERNs have major research potential due to their network structure bringing together highly specialised multidisciplinary expertise across Europe and access to rare diseases patient populations. Coordination and support is needed to realise this potential..

Scope:

This activity will aim at enhancing research and innovation capacity of the ERNs in view of achieving the goals of the International Rare Diseases Research Consortium (IRDiRC) for bringing new diagnostic tools and therapies more efficiently to the patients. Support will be given to identify research priorities and potential synergies among ERNs and coordinate research and innovation activities to be tackled commonly by ERNs. The project should address fostering collaboration in the field of clinical research among ERNs and other stakeholders, such as research infrastructures, industry and patient organisations, as well as international collaboration with other clinical research networks. To ensure broad geographical representation and participation across ERNs the proposals shall involve participants from several countries and ERNs and aim at engaging all approved ERNs.

The Commission considers that proposals requesting a contribution from the EU of between EUR 1.5 and 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Along the IRDiRC vision to enable all people living with a rare disease to receive an accurate diagnosis, care, and available therapy within one year of coming to medical attention by 2027.

- Contribute to the development of the European ecosystem for rare diseases which brings efficiently results of research and innovation into the benefit of the patients.

Type of Action: Coordination and support action

Priority 1.5 Decoding the role of the environment, including climate change, for health and well-being

SC1-BHC-29-2020: ~~Environment, climate change and health – novel mitigating measures for improving population health~~
New Title: Novel measures for improving urban health - addressing environment, climate and socioeconomic factors

Specific Challenge:

The natural and built[36] environment as well as the social fabric are critical determinants of health and well-being. Three quarters of the European population now live in cities and urbanisation continues at high speed, driven by economic growth and employment opportunities. The related environmental changes e.g. pollution of air and water, transportation problems, reduced social cohesion and stress affect physical as well as mental health. Although health has improved in the EU over the last decades and the population is ageing, large differences in health still exist between and within all countries in the EU. These differences are caused by many factors such as living conditions, health-related behaviour, education, occupation and income, health care. Some of these inequalities are widening[37]. As European cities are growing, they are increasingly taking action and introducing policies to become more sustainable and liveable, investing in a range of smart and innovative solutions such as clean and sustainable transport, higher energy efficiency and stronger social cohesion. Similar initiatives are underway e.g. in Canada as well as in Asia and Africa which could provide valuable knowledge.

At EU level, the Urban Agenda for the EU[38] focuses on improving the life of their citizens for example through the development of digital solutions, reducing urban poverty and better integration of migrants and refugees. The headline targets in the EU2020 strategy aim to turn the EU into a smart, sustainable and inclusive economy delivering high levels of employment, productivity and social cohesion[39].

Improving urban health and reducing health disparities can be achieved by changes in individual behaviour as well as policies such as urban design and sustainable transport, (re)creating green and blue space or improved housing standards. There is need to address public policies across sectors to achieve health benefits, systematically taking into account the health implications of decisions, to seek synergies, and avoid harmful health impacts (health in all policies[40]).

Scope:

European research should engage to build the evidence base of effective policies, developing and testing new initiatives to improve urban health and environment in Europe. Given the variety of national experiences across European countries and regions, there is an important potential to learn from each other's practices and develop novel measures for urban health.

[36] Man-made structures, features, and facilities viewed collectively as an environment in which people live and work (https://en.oxforddictionaries.com/definition/built_environment)
[37] http://www.health-inequalities.eu/about-hi/health-inequalities-in-the-eu/
[38] https://ec.europa.eu/futurium/en/urban-agenda
[39] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF
[40] http://www.who.int/healthpromotion/conferences/8gchp/statement_2013/en/

Proposals should develop and test effective interventions and/or policies for improved urban health, reduced health inequalities and improved environment In Europe. These interventions or policies should also be assessed for cost-effectiveness. Proposals could address physical or mental health, or both. They could address any sector (with priority being on other sectors than health care) or policy area relevant to achieve a lasting health improvement. Proposals should include analysis of gender aspects and address any gender inequities in the design of interventions. Research teams should bring in all appropriate scientific disciplines to design interventions. This includes social scientists not least for their role on behavioural aspects.

In order to link research to practical needs and user demands, teams should include other relevant parties in urban health, building partnership with stakeholders such as policy makers, users, business, and local communities. Proposals should address the need for more systematic data collection on urban health across the EU, to allow better analysis and conclusions. This may include the linking up with or developing relevant population based cohorts.

As urban health is of concern in many regions of the world, proposals should foresee the possibility to link up internationally with other relevant urban health initiatives. Proposals should include in their budgets funds for participation in at least one international meeting gathering urban health initiatives relevant to the research.

The Commission considers that a proposal requesting an EU contribution between EUR 4 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- More robust evidence for policy making on improved urban health in the EU
- Improved population health , physical and mental, in urban areas of the EU
- Reduced health inequalities in urban areas
- Improved environment and reduced climate footprint

Type of Action: Research and innovation action

RIA 4 - Micro- and nano-plastics in our environment: Understanding exposures and impacts on human health

Specific Challenge:

Global plastic production has increased exponentially over the past decades. A significant proportion of the plastic produced is not disposed of properly and persists in the environment, especially the marine environment. When exposed to sunlight, plastic products can be slowly degraded into smaller pieces (micro- or even nanoplastics). Furthermore, microplastics are intentionally added to, for example, toothpaste and beauty products (referred to as microbeads) or are a secondary by-product of rubber from, e.g., tyre wear or artificial turf.

Plastic debris is associated with a "cocktail of contaminants" made up of chemical ingredients present originally in the plastic and chemical pollutants absorbed to the plastic from the environment, including metals and other persistent contaminants such as polychlorinated biphenyls (PCBs) and flame retardants. The debris is filtered into marine species' gastrointestinal tract mechanically or it may look like food to some species, thus entering the food chain.

Risk assessments and reviews carried out in recent years have concluded that there is evidence that humans are exposed to micro- and nano-plastics through their diet or inhalation. However, our understanding of the fate and toxicity of these plastic particles in humans constitutes a major knowledge gap, rendering it difficult to carry out proper science-based risk assessment and management.

Scope:

Proposals should use innovative approaches to provide policy relevant scientific data in support of improved human health risk assessment of micro and/or nano-plastics. The following issues, *inter alia*, could be considered: environmental/food sources for micro-plastics and transmission to humans; methods for identification and quantification of micro and nanoplastics in foods, other media and tissues; exposure levels of humans and methods for human biomonitoring; bioaccumulation and cell uptake; toxicology and uptake of micro/nanoplastics and additives/adsorbed contaminants; fate in the GI tract including immune response; targets in secondary organs.

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

Expected Impact:

- Better understanding of health impacts of exposure to micro/nanoplastics
- Innovation in health risk assessment of micro/nanoplastics.
- Contribution to the health-relevant aims of the European Strategy for Plastics in a Circular Economy[41]

Type of Action: Research and Innovation action

[41] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0028&from=EN

Possible coordinated call between SC1, SC2, SC5 (and nano?)

Call 2. Digital transformation in Health and Care (DG CNECT)

SC1-DTH-02-2020: Personalised early risk prediction, prevention and intervention

Specific Challenge:

The ageing of the population together with the rising burden of chronic conditions and multi-morbidity bring an ever increasing demand to strengthen disease prevention and integrate service delivery around people's needs for health and social care.

It is widely recognised that health systems must put more emphasis on prevention and adopt a person-centred rather than a disease-centred approach. The goal must be to overcome service fragmentation and to move towards integration and coordination of interventions along the continuum of care.

Personalised early risk prediction models, estimating the probability that a specific event occurs in a given individual over a predefined time, can enable earlier and better intervention, prevent negative consequences on a person's quality of life and thus result in improved individual health outcomes.

The challenge is to develop and validate these comprehensive models for prediction, prevention and intervention using multiple available data resources and to integrate them in personalised health and care pathways that empower individuals to actively contribute to risk mitigation, prevention and targeted intervention.

Scope:

Proposals should introduce innovative solutions through data, advanced or novel digital technologies, services, products and organisational changes that lead to more effective health and care systems. These innovative solutions may address one or multiple conditions and explore ways of inducing adequate personalised preventive measures (e.g. behavioural change, diet, interventions, medication, primary prevention) from advanced predictive models. Sustainable behaviour change refers to efforts to change people's personal habits to prevent disease, stimulate healthy people to monitor their health parameters and thus lowering the risk of developing (chronic) conditions.

Proposals should build on the use of data generated by individuals, health professionals and other service providers (including but not limited to data collected through IoT enabled devices, wearables, mobile devices etc. collected outside the controlled environment of clinical trials) by citizens, healthcare professionals, public authorities and industry, with a view to developing personalised early risk prediction, prevention and intervention approaches that meet the needs of individuals and lead to better health outcomes.

Proposals should also include actions aimed at increasing health literacy as well as advancing health and care professionals' proficiency in novel, data-oriented health services through the use of digital solutions to increase knowledge about diseases and help them in the interpretation of symptoms and effects (e.g. with visualisations like dashboards etc.), notably of early warning signs and medical information. Early warning signs relay to either healthy people monitoring several body parameters e.g. to conduct healthy life styles and increase physical activity levels or to the detection of the deterioration of the condition ot already diseased patients.

Proposals are expected to be built on realistic scenarios for new health and care pathways, and should integrate multi-disciplinary research involving behavioural, sociological, medical and other relevant disciplines. Stakeholder engagement should be part of the research design for an agile approach to ensuring that relevant user needs (including gender aspects) are met and solutions find acceptance by users. Full account should be taken of data protection, privacy and data security aspects.

No large-scale piloting or clinical trials are expected in this Research and Innovation Action. However, proposals should include validation and demonstration of feasibility of their respective models, technologies and scenarios.

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

Expected Impact: The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- Evidence of the benefits of personalised risk prediction, prevention and intervention, based on proof of concept and involvement of relevant stakeholders.

- Clear improvements of outcomes for individuals, care systems and wider society from prevention measures and interventions based on personalised early risk prediction in comparison with current practices.

- Usefulness and effectiveness of integration and coordination of interventions in new health and care pathways based on person-centred early risk prediction, prevention and intervention models.

- Realise large-scale collection of user-generated data in compliance with data protection, privacy and security rules and principles.

- Support integration with tools and services under the European Open Science Cloud.

Type of Action: Research and Innovation action

SC1-DTH-04-2020: International cooperation in smart living environments for ageing people

Specific Challenge:

Demographic change and the ageing of the population create new heterogeneous challenges for society and, in particular, for ageing people. On top of the health-related age impairments such as poor health, cognitive impairment and frailty, ageing people are at risk of facing situations leading to potential 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.

Digital solutions can play a key role when addressing these challenges and, within them, those aimed at creating smart living environments for ageing people. For these to be successful, one necessary condition is to ensure users' acceptance, which in turns requires bringing the users to the centre of the design. Moreover, these environments need to provide innovative user-friendly user interfaces such as voice-based interaction.

These challenges are shared by ageing populations beyond the EU and other countries are looking into the potential of digital solutions to address them. In this context, there is a need to explore collaboration and cooperation with international efforts in this domain.

This action aims to address these challenges by developing smart living environments for ageing people, while strengthening relevant international collaboration in the area.

Scope:

Proposals should develop and validate new solutions leading to smart living environments for ageing people, supporting independent active and healthy lifestyles.

The proposed solutions should provide personalised advice, guidance and follow-up for key age related issues in daily life which impact the person's ability to remain active, healthy and independent. These may include amongst others diet, physical activity, risk avoidance, preventive measures, lifestyle and activity management, leisure, social participation and overall wellness. Proposals should pay particular focus to measures aimed at fostering social participation and avoiding social exclusion.

Proposal should convincingly describe the planned progress beyond state of the art in the development and integration of trusted smart living environments for ageing people, which should build upon intelligent ICT environments, access to relevant physiological and behavioural data, emotional computing, open platform and Internet of Things approaches.

Proposals should be based on trans-disciplinary research, involving behavioural, sociological, psychological, medical and other relevant disciplines, including gender and cultural aspects.

Proposed solutions should make use and further develop user interaction, including voice-based, taking into account Artificial Intelligence methods for understanding the users' intentions, knowledge extraction and learning. It is essential that they build on active user engagement in order to ensure the understanding of user needs. They need to safeguard ethics, privacy, security and regulatory aspects and take gender issues into account appropriately. The proposed solutions should be unobtrusive and avoid attention theft.

Proposals should include validation in realistic test sites, such as at home or at care centres, in order to demonstrate the expected benefits and impacts.

The proposed research and innovation actions should address one of the following international collaboration possibilities:

1. Cooperation with Japan

Proposals addressing international collaboration with Japan should ensure the use of generalized infrastructures such as cloud system and open sources.

Without limiting the use of specific applications or hardware systems, platform approaches are required to ensure interoperability as well as contributions to appropriate ongoing or new standardization work.

Proposals should be driven by the needs, interests and lifestyles of older people in order to ensure user acceptance, taking into consideration the relevant cultural aspects.

An amount of EUR 4 million will be reserved for proposals focusing on cooperation with Japan.

2. Collaboration with Canada

[to be further developed]

3. Other possibilities to be defined

The Commission considers that proposals requesting a contribution from the EU of between EUR 3 and 4 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. Participation of SMEs is encouraged.

Expected Impact:

The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- Independent living, and quality of life of older persons compared to current state of the art
- Usefulness and effectiveness of personalized recommendations and follow-up in terms of the goals of preserving physical, cognitive, mental and social well-being for as long as possible
- Evidence of user-centred design and innovation, effective ways of human computer interaction, and user acceptance;
- Fostering social participation and reducing social exclusion's risks
- Validation of non-obtrusive technology for physical, cognitive, social and mental well-being

- Strengthened international cooperation in Research and Innovation on ICT for AHA

Type of Action: Research and Innovation action

SC1-DTH-06-2020: Accelerating the uptake of in-silico clinical trials for testing medicines

Specific Challenge:

The development of a new pharmaceutical product and its introduction into the market is estimated to cost today over 2 billion, from which nearly 75% is spent at the late stages of the drug development process in the various phases of the clinical trials. As biomedical knowledge increases and bioinformatics capability likewise grows, there is hope that greater predictive power may be obtained from in-silico (computer modelling) analyses such as predictive toxicology.

EU research and innovation programmes have already allocated budget for the development and improvement of in-silico methods such as SC1-PM16-2017[42], SC1-PM17-2017[43], SC1-DTH07-2018[44], CSA ICT-2013.5.2-Virtual Physiological Human[4546], IMI1-Call 1-Expert systems for in silico toxicity prediction[4748]. However, the in-silico clinical trials, understood as the use of individualised computer simulations for testing medicines, are still in their starting phase and not integrated yet into the clinic and the market. Adoption of computer models and simulation approaches, their translation into the clinic and penetration on the market of ICT solutions, depend on the trust of users (healthcare professionals and patients), the industry and investors. The users need proofs of validation in the real clinical contexts.

The specific challenge of this call is accelerating the uptake of in-silico clinical trials to become closer to innovation and the market in order to surpass the barriers that prevent their wider adoption, bring together industrial and academic stakeholders to advance further research on this topic, and gain the trust of regulatory bodies for innovation in order to, in collaboration with academic and industrial experts, develop the framework of standards, protocols and shared resources required to evaluate the safety and the efficacy of medicines at the end of the drug development process using in-silico clinical trials for testing.

Scope:

Proposals will develop innovative scientific and technological in-silico clinical trials for testing medicines. The proposed in-silico clinical trials for testing medicines will be the result of a multidisciplinary effort (e.g. within the fields of computational modelling, chemo/bio-informatics, systems biology, pharmacology, -omics (genomics, metabolomics), tissue

[42] http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-pm-16-2017.html
[43] http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-pm-17-2017.html
[44] http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-dth-07-2018.html
[45] https://cordis.europa.eu/project/rcn/110724_en.html
[46] http://avicenna-isct.org/wp-content/uploads/2016/01/AvicennaRoadmapPDF-27-01-16.pdf
[47] https://www.imi.europa.eu/apply-funding/closed-calls/imi1-call-1
[48] https://www.imi.europa.eu/projects-results/project-factsheets/etox

mechanics, biology, pharmaceutics, medicine, physiology, toxicology) and must also explore and inform of the reasons for failure should the drug be found not efficient or safe and will suggest improvements. To help adopt such in-silico methods for testing medicines, measures for validation (human trials, animal studies, validation in cell cultures) of the in-silico results must also be included in the proposed projects. The benefit for human health, environment and animal welfare must be analysed and quantified. Engagement with regulators and consideration of the regulatory framework issues for in silico clinical trials are mandatory.

Expected Impact:

The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- Accelerate the adoption of in-silico clinical trials for testing medicines, their translation into the clinic and the market.
- Increase the trust of users (healthcare professionals and patients), investors and stakeholders at industry and academia to adopt in-silico clinical trials for testing medicines as a substitution or complement of current clinical trials when appropriate.
- Redesign current drug clinical trials by integrating in-silico methods for testing medicines and create a unique, digitised, personalised testing environment.
- Engagement with regulators and consideration of the regulatory framework for in silico clinical trials.
- Reducing the size and the duration of the human clinical trials.
- Alternative and complement for animal and human clinical trials in order to increase efficacy, patient safety and significant reduction in animal testing.
- Lower development costs and/or shorter time-to-market for new drugs.
- Setting standards for in-silico clinical trials for testing.
- Contribution to the European Cloud Initiative, notably by providing open, reusable data and in silico models for clinical trials.

Type of Action: Research and Innovation action

SC1-DTH-10-2019-2020: Digital health and care services

Specific Challenge:

Digital solutions supporting a continuum of care across a range of health and care services can relieve the pressure on governments to provide more cost-effective health and care systems by improving the use of healthcare and health outcomes. In this context the challenges are to network, lead and facilitate health systems research, innovation and digitisation in view of addressing key areas of interventions in health and care services including health promotion and disease prevention.

Scope:

Support the health and care service provider to procure the development of digital services that can facilitate the transition to integrated care models across health and social services and country-specific cross-institutional set-ups, including decentralised procurement environments and collaboration across institutions. Key challenges that could be addressed are patient empowerment, self-management, patient safety, patient involvement, chronic disease management, diagnosing, hospital logistics, skills and independent living. These challenges could be addressed by ICT-based solutions such as, e-Health, telemedicine, and mHealth, to be defined through the market consultation process. This should result in early adoption and demonstration of the potential for scaling-up the services and positive impact with evidence of appropriate incentives of various actors.

Proposals should deliver and:

- be driven by clearly identified user needs guiding the procurers of the buyers group[49];
- be driven by 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 supply of health and care services;
- demonstrate strong commitment of end-users and their communities in the co-creation process;
- as applicable contribute to the use of interoperable solutions based on open platforms and take into account existing best practices and standardisation initiatives;
- provide robust safeguards to ensure compliance with ethical standards and privacy protection;
- include clear time-lines, a well-structured work-plan aligned to the objectives of the different phases and according particular importance to the role played by the preparatory phase; (templates[50] made available by the Commission are strongly recommended to be used in particular as concerns the call for tender) and;
- address training aspects, digital health literacy and new collaborative innovation principles and practises, management, and retention of healthcare staff under this topic.

[49] Proposals are encouraged to follow the principles of Green Public Procurement as appropriate, see http://ec.europa.eu/environment/gpp/index_en.htm

[50] Reference to template to be added

The procurers, hospital clusters, care services providers and other parts of the regional ecosystems should share knowledge, test results and needs to better coordinate the primary and community care, and stimulate local responsibility for care services, monitoring and rehabilitation. This may include aspects such as organisational processes, digital health literacy, workforce training, financing and business models, hospital and telemedicine services, home care, patient centeredness, development of shared open source IT-based platforms, data integration, standards and regulatory issues, management and retention of healthcare staff.

The service innovation should facilitate the early adoption and transferability (to other local contexts) of successful solutions addressing the innovation gap. Multi-policy/strategy collaboration across institutions (hospitals and institutions under the responsibility of municipalities), industries, academia and user communities capable of establishing dedicated operational programmes are necessary to safeguard both the service and business performance metrics and the growth potential in the innovation chain.

The proposals should include the methodology foreseen to measure progress and validation process applicable in the tendering phase, towards the key performance areas of quality of care, sustainability and economic value within the selected key area of intervention, see e.g. MAFEIP[51]. Sufficient travel allowances for regular information days concerning the procedures and thematic networking events (e.g. related to relevant co-ordination and support actions including SC1-HCC-04-2018[52]) should be foreseen. A plan to implement the services should be included. In that context investigation of complementary procurement approaches (see e.g.[53]) including value based procurement are encouraged.

The Commission considers that proposals requesting a contribution from the EU of around €5-6M would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Proposals for this topic should follow the specific requirements for pre-commercial procurement (PCP) supported by Horizon 2020 grants as set out in Annex E of the WP.

Expected Impact:

The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- Established path to innovation, evidence of benefits of disruptive technologies that can support the development of sustainable business models, improved user and market engagement, strengthened procurement community, evidence of healthy innovation ecosystem including researchers, users, eHealth and other solution providers and procurers. Evidence in key performance areas i.e., quality in health and care, sustainability of the delivery system and economic value.

[51] Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing – MAFEIP: http://mafeip.eu

[52] EC Horizon 2020 SC1-HCC-04-2018: Digital health and care services – support for strategy and (early) adoption, pp. 95-98, http://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-health_en.pdf

[53] Targeted consultation on the draft Guidance on Public Procurement of Innovation, https://ec.europa.eu/growth/content/targeted-consultation-draft-guidance-public-procurement-innovation_en, EC DG GROW, 04/10/2017

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

Type of Action: Pre-Commercial Procurement

SC1-HCC-06-2020: Coordination and Support to better data and secure cross-border digital infrastructures building on European capacities for personalised medicine (previous title: Support to eHealth Innovation ecosystems in Europe)

Type of Action: Coordination and support action

SC1-HCC-07-2020: Support for European eHealth Interoperability roadmap for deployment

Specific Challenge:

Large amounts of valuable health data are generated and recorded concerning EU citizens. This includes clinical and medical data that are collected at times of treatments or data generated by the citizens themselves on health and care, fitness and wellbeing. Opportunities to use these data for better health, to make contributions to personalised or precision medicine, better prevention approaches and innovative services are often missed because data do not become available and are not interoperable and portable to the extent necessary. Interoperability of digital platforms and solutions, making data accessible in an actionable form for exchange and portability is required to pave the way for better health outcomes and treatments. Efforts have been and are still invested in standardisation and harmonisation (including common clinical models, tools and agreed approaches), privacy and security (including data access and data integrity) and communication (towards citizens, patients and healthcare providers) to allow citizen/patient empowerment, advance medical science and improve health for everyone.

Scope:

The focus is to support deployment and monitoring of eHealth interoperability meaning real life interoperable digital platforms and solutions for use by citizens , by health services and the workforce across borders in the EU Digital Single Market. The support should comprise a coherent package of activities that will improve the deployment of interoperable eHealth solutions and platforms, with a significant number of citizens in several Member States accessing and providing their own health data in platforms. The deployment should consider interoperability of (electronic) Health Records across national borders, the empowered

European citizen, compliance with the General Data Protection Regulation[54], the Network and Information Systems Directive[55] and the operation in a European digital single market. The deployment should be guided by strong and systemic contributions for better data and better computational approaches to advance disease prevention and personalised medicine. Emphasis should be given to specific fields of high societal relevance and high prevalence. Omics type of information associated to health datasets use and exchange should be strongly considered with special regard to analysis and corresponding further health-related data.

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

Expected Impact:

The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- Citizen-centred secure electronic health data use across Europe for citizens managing own health data,
- Specific contributions made for improved health conditions, healthy working conditions and quality of life;
- Improved efficiency in terms of health economics and occupational health such as on timeliness of intervention or prevention approaches;
- Extended EU citizens' management of own healthy life continuum across borders, actors and confinements;
- Improved level of accessibility and portability of citizens' health data;
- Open, extensible and harmonisation-based citizen health records solution for service and app developers;
- Easy and safe for citizens to provide and donate their health data for research;
- Support integration with tools and services under the Digital Service Infrastructure supported by the Connecting Europe Facility.

Type of Action: Coordination and support action

[54] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation): http://eur-lex.europa.eu/eli/reg/2016/679/oj

[55] Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union: http://eur-lex.europa.eu/eli/dir/2016/1148/oj

SC1-HCC-08-2020: Scaling up innovation for active and healthy ageing

Specific Challenge:

The European Commission has promoted scaling up of digital innovation for active and healthy ageing both with research and innovation funding under Horizon 2020 and previous Framework Programmes and with its support for stakeholder partnerships like the European Innovation Partnership on Active and Healthy Ageing with its Regional Reference Sites.

In its Communication on "enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society" (COM/2018/233 final) the Commission sets out a number of measures for the large-scale use of digital tools for citizen empowerment and person-centred care which are of high relevance for active and healthy ageing. These measures depend on active contributions from local and regional ecosystems, stakeholder groups and organisations including industry, civil society, academia and public administration.

The specific challenge is to facilitate active contributions (in the form of institutional, technological and behavioural change) from all stakeholders to continue on a path towards large-scale deployment of innovative solutions for active and healthy ageing.

Scope:

Proposals are expected to define mechanisms to facilitate further uptake by actively involving partners from the European Innovation Partnership on Active and Healthy ageing as well as other relevant stakeholder groups (e.g. Joint Programming Initiative on More Years Better Lives and the Active and Assisted Living programme), and research and innovation projects, at European, national and regional levels.

The work will build on previous actions and have a clear focus on the successful support to supply and demand sides in implementing scaling up strategies for innovative solutions (technology, integration of health and social care, systemic change). In particular, complementarity and consistency must be ensured with the outcomes, guidelines and strategies delivered in projects funded from SC1-HCO-17-2017 ("Support for large scale uptake of Digital Innovation for Active and Healthy Ageing"), SC1-HCC-01-2018 ("Supporting investment in smart living environments for ageing well through certification") and SC1-HCC-05-2018 ("Support to a Digital Health and Care Innovation initiative in the context of Digital Single Market strategy").

A particular focus must be on the development and implementation of a long-term investment strategy, which would leverage and blend funding sources, from European, national and/or regional programmes/promotional banks as well as private investments, and involve new players and partners.

Financial support for upscaling measures and large-scale deployment should be considered in the tasks to be defined for the Coordination and Support Action. These should include twinning programmes and capacity building for local and regional authorities.

Proposals are also expected to set up a cooperation mechanism facilitating regular exchanges between the demand (both public and private procurers) and supply (including SMEs and start-ups) sides to identify the difficulties innovators may experience in scaling up solutions

across borders in the EU and define measures to improve cross-border deployment of these solutions.

The Action is expected to develop and apply strategies for implementation of transformative solutions and change management, in particular in the following fields:

- mHealth solutions for active and healthy ageing
- smart age-friendly homes and independent living
- chronic disease management

[add Reference to General Annex K – financial contribution to third parties]

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

Expected Impact:

The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- Accelerated progress on scaling-up digital innovation for active and healthy ageing across the EU.
- Contribution of the policy activities to i) The Quality of Life of the EU population, ii) The Sustainability of Health and Care delivery and iii) Economic growth and job-creation in the EU.
- Increased levels of investment by public authorities and private investors in digital innovation for health and active ageing that result from policy activities.
- Wider commitment to investment leading to successful and cost-effective implementation of digitally-enabled, person-centred care solutions
- Enhanced market conditions that can facilitate economies of scale for the suppliers of technology and services

Type of Action: Coordination and support action

SC1-HCC-09-2020: Supporting deployment of eHealth in low and lower middle income countries in Africa for better health outcomes

Specific Challenge:

E-Health can contribute to better, more accessible and more efficient health and care services, in particular to remote populations and underserved communities. E-Health and mHealth technologies can only be successful, if they are supported by national governments, who have established e-Health policies and strategies and demonstrate strong ownership of the national e-Health programme. E-Health programmes will only achieve their objectives, if they are adapted to country needs, are citizen-centered and sustainable through sound public finance management. These pre-requisites will impact on the quality and accessibility of such e-Health services and their sustainability, usability, data security and interoperability, privacy and ethics issues.

Access to one's own health data and high-quality mHealth services in real-life environment are still a challenge because of a lack of government ownership, e-Health policies including enabling regulations, a sustainable and trustable infrastructure, and digital literacy.

Coordination and support is needed for taking stock of and further developing strategic partnerships on E-Health deployment together with low and middle income countries and regions in Africa with the aim to improve the health of the citizens.

Scope:

The aim is to support the coordination of a registry of relevant existing e-Health solutions describing their services and potential for low and lower middle income African countries[56] or regions together with a roadmap and strategic implementation plans building on the requirements of end-user communities and policy makers in the target countries. The action should take into account national and regional policies and (best) practices regarding health and care services and health infrastructures and also include lessons learned from existing eHealth policies and programmes at all levels of the health system.

It should identify and build on and identify relevant existing and emerging initiatives and capacities in Europe and Africa which can form the basis for future cooperation and deployment.

The action should make use of and contribute to standardisation[57] as appropriate. Proposals should comply with and contribute to the development of the relevant legislation, in particular

[56] Low and lower middle income countries as defined by the World Bank in September 2016 (https://datahelpdesk.worldbank.org/knowledgebase/articles/906519):
Low income countries: Benin, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Eritrea, Gambia, Guinea (Conakry), Guinea (Bissau), Madagascar, Malawi, Mali, Mozambique, Niger, Rwanda, Senegal, Sierra Leone, Somalia, South Sudan, Tanzania, Togo, Uganda, Zimbabwe
Lower middle income countries: Cabo Verde, Cameroon, Congo (Brazzaville), Cote d'Ivoire, Djibouti, Egypt, Ghana, Kenya, Lesotho, Mauritania, Mauritius, Morocco, Nigeria, Sao Tome and Principe, Sudan, eSwatini (Swaziland), Tunisia, Zambia

[57] refer to DG DEVCO Staff Working Document on Digitalisation for Development (Council regulation November 2017) and the relevant WHO guidelines on eHealth

on ethics and data protection of health data. Socio-economic and gender issues should be addressed appropriately.

The action should also ensure that relevant stakeholders including end-users are engaged during the process through national, regional and international workshops and a set of communication and dissemination actions, aligned to national policies, to support the deployment of e-Health services in low and lower middle income countries in Africa. The action should provide an added value, to the facilitation of the cooperation between European and low and middle income countries in Africa for a better health for all.

The Commission considers that proposals requesting a contribution from the EU of up to EUR 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. [add specific details about funding for African partners]

Expected Impact:

The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- Higher level of international cooperation and networking in eHealth programmes and policies between European countries or regions and low and middle income African countries, focusing on areas that are beneficial to the target countries / regions and their citizens in eHealth

- Increased opportunities for e-health innovators, patients, medical staff and health system stakeholders in Europe and Africa

- Better accessibility of eHealth Services

Type of Action: Coordination and support action

Call 3. Trusted digital solutions and Cybersecurity in Health and Care

DT-ICT-12-2020: The smart hospital of the future

Type of Action: Innovation action

DT-TDS-04-2020: Demonstrating the potential and benefits of a European Digital Health Infrastructure for Personalised Medicine

Type of Action: Research and Innovation action