ENAnnex 11Horizon 2020Work Programme 2018 - 2020

8. Health, demographic change and well-being

Important notice on the Horizon 2020 Work Programme covering 2018, 2019 and 2020.

The parts of the Work Programme that relate to 2019 and 2020 (topics, dates, budget) are provided at this stage on an indicative basis. Such Work Programme parts will be decided during 2018 and 2019

(European Commission Decision C(2017)XXXX of XX October 2017)

*“THIS DRAFT IS FOR DISCUSSION ONLY – BUDGETS & CONTENT WILL VARY AS IT IS DISCUSSED WITHIN COMMISSION & WITH MEMBER STATES”*

*For 2020 only topic titles and instrument are given.*

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Introduction

The headline goal of the 'Health, demographic change and well-being' societal challenge 1 (SC1) is better health and well-being for all, acknowledging the role research and innovation have in preserving the health of citizens and promoting wealth. Its main policy objectives are in line with several Commission priorities and with the [3 O strategy](https://ec.europa.eu/digital-single-market/en/news/open-innovation-open-science-open-world-vision-europe). Beyond its importance for human well-being, health is also considered with its dimension of social policies and socio-economic sustainability.

Europe faces rising and potentially unsustainable health and care costs, mainly due to the increasing prevalence of chronic diseases, to an ageing population requiring more diversified care and to increasing societal demands. Health research and innovation also face new challenges as a result of new research paradigms and methodologies in line with increasingly complex medical and health challenges, including increasing awareness of the influence of external environmental factors, and in view of worldwide competition. The world, including Europe, is confronted with migration, climate change and new threats of emerging infectious diseases influencing health and well-being. Furthermore, health inequalities and access to health and care also constitute major challenges for our societies. Europe needs smart, scalable and sustainable solutions building on innovation opportunities in order to overcome these challenges, and must grasp every opportunity for leadership. Technology and innovation continue to offer new opportunities at an accelerating pace.

In order to address these objectives and respond to these challenges, SC1 implements a comprehensive strategy covering the whole innovation cycle. SC1 supports multidisciplinary and translational approaches, aiming at the integration of new knowledge generated in pre-clinical, clinical and public health settings. It takes advantage of all Horizon 2020 instruments: Research and Innovation Actions (RIA), Innovation Actions (IA) and Coordination and Support Actions (CSA), Innovation Procurement (Pre-Commercial Procurement, PCP, and Public Procurement of Innovative Solutions, PPI), SME instrument, public-public partnerships (ERA-NET Cofund, European Joint Programme Cofund), and prizes. It also builds strong links and synergies with Joint Programming Initiatives (JPIs), with activities undertaken by the Innovative Medicines Initiative 2[[1]](#footnote-1) (IMI2), the European and Developing Countries Clinical Trials Partnership 2[[2]](#footnote-2) (EDCTP2) and the Active and Assisted Living Joint Programme 2[[3]](#footnote-3) (AAL2). Topics in this work programme also respond to the priorities of the European Innovation Partnership on Active and Healthy Ageing[[4]](#footnote-4) (EIP-AHA).

Diseases do not respect borders and need to be addressed at global level. Therefore the many SC1 research priorities include an international dimension, mainly through multi-lateral initiatives (such as in the areas of rare diseases, chronic diseases and infectious diseases).

PUBLIC HEALTH EMERGENCY In this regard, recent infectious diseases outbreaks such as Ebola, Zika, SARS and MERS-CoV demonstrated that cross-border epidemics are a major threat for the health security and prosperity. Human and socio-economic consequences resulting from infectious diseases outbreaks are significant. Threats need to be swiftly identified and at a much earlier stage, before becoming a public health emergency (PHE). Under WP 2018-2020, research investment in measures that better detect and foresee these potential epidemics will be stepped up so that preparedness and surveillance can further improve. This includes the swift mobilisation of research funds to address a public health emergency independently recognised by the Commission[[5]](#footnote-5).

Social sciences and humanities research is employed, and sex differences and gender aspects are also addressed where relevant. SC1 integrates the principle of responsible research and innovation, including ethics, in all its activities.

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

Furthermore, the programme should allow for further building of clinical research infrastructure and evidence with regard to efficient and validated models of organisation of complex networks such as European Reference Networks of healthcare providers established by Article 12 of Directive 2011/24/EU[[6]](#footnote-6).

Finally, beneficiaries in actions funded under this work programme might in the future benefit from additional (follow-up) funding.

Contribution to Focus Area Digitisation: EUR XXX million

Contribution to Focus Area Security Union: EUR XXX million

Call 1. "Better Health and care, economic growth and sustainable health systems"

H2020-SC1- BHC -2018-2020

***Overall mission statement:***

This call will aim at reconciling better health and healthy ageing with the need to develop sustainable health and care systems and growth opportunities for the health and care related industries. The scope of the call may range from prevention, diagnosis, stratified approaches, predictive toxicology, the development of novel and repurposed therapeutic approaches, including medical technologies and advanced therapies, cohorts and registries-based research, to integration of care and systemic digital solutions for health and ageing well. It aims to translate new knowledge into innovative applications and accelerate large-scale uptake and deployment in different health and care settings, making health and care systems and services more accessible, responsive and efficient in Europe and beyond.

Research areas to be addressed under this priority will implement and provide the evidence base for global and EU policies, including the [2030 Agenda for Sustainable Development and its Sustainable Development Goals](https://sustainabledevelopment.un.org/post2015/transformingourworld) (SDGs, in particular the SDG3 on 'Good Health and Well-being'), the implementation of the declaration of the [Sixth Ministerial Conference on Environment and Health](http://www.euro.who.int/en/media-centre/events/events/2017/06/sixth-ministerial-conference-on-environment-and-health), the [cross-border healthcare directive](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011L0024) (and its support to the European Reference Networks), the [Commission Communication on upgrading the single market](https://ec.europa.eu/transparency/regdoc/rep/1/2015/EN/1-2015-550-EN-F1-1.PDF) (and its proposed health technology assessments initiative), the [Council Conclusions on Personalised Medicine](http://data.consilium.europa.eu/doc/document/ST-15054-2015-INIT/en/pdf) and [on Pharmaceuticals](http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/), and the [Digital Single Market](https://ec.europa.eu/commission/priorities/digital-single-market_en).

This Call will be implemented through 5 main priorities:

1. Personalised medicine
2. Innovative health and care industry
3. Infectious diseases and improving global health
4. Innovative health and care systems - Integration of care
5. Decoding the role of the environment for health and well-being

1.1 Personalised medicine

***Mission statement:***

This priority will aim at generating and translating knowledge on disease aetiology and technological innovation into personalised health and care solutions. Areas of application include chronic, rare and communicable diseases. Targeted populations include children and the ageing population, as well as adolescents and young adults, adults, minorities, and high-risk groups, all of whom face potential barriers to timely access to quality health and care services. Relevant links with the [European Open Science Cloud](https://ec.europa.eu/digital-single-market/en/european-open-science-cloud) initiative and the [European Reference Networks](https://ec.europa.eu/health/ern/policy_en) will be sought. Research under this priority will also attempt to develop an understanding on the economic impact and the health system transformation potential of personalised medicine.

The expected impact of this priority is to: (i) establish Europe as a global leader in personalised medicine research; (ii) support the personalised medicine science base through a coordinated approach to research; (iii) provide evidence to policy makers of the benefit of personalised medicine to citizens and healthcare systems. The International Consortium on Personalised Medicine will be instrumental to achieve these aims.

Proposals are invited against the following topic(s):

SC1-BHC-01-2019 (ex-1): Understanding causative mechanisms in co-morbidities

Specific challenge:

The increasing number of individuals with co-morbidities poses an urgent need to improve management of patients with multiple co-existing diseases. A better understanding of their causative mechanisms is needed to develop early diagnosis, efficient prevention and monitoring, and better treatments adapted to co-morbid patients throughout their life course. Furthermore, there are many different etiological models of comorbid conditions (e.g., direct causation model or a consequence of treatment). In this context, capturing and measuring patient's complexity in the context of comorbidities is crucial for adequate management of these conditions and requires innovative approaches.

Scope:

Proposals should identify causative mechanisms combining mental and physical disorders through the integration of basic, pre-clinical and/or clinical research. Applicants should prove the relevance of the identified mechanisms for co-morbid development. Where pertinent, development of biomarkers for diagnosis and monitoring of comorbid conditions in patients is encouraged. A purposeful exploitation of existing data, biobanks, registries and cohorts is expected[[7]](#footnote-7). Sex and gender aspects, age, socio-economic factors and any other non-health related individual attributes should be taken into consideration.

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

Expected impact:

* New directions for clinical research to improve prevention, diagnosis, therapy development, and management of comorbidities
* Whenever relevant identified biomarkers for more accurate and earlier diagnosis as well as monitoring of patients' condition.

Type of Action: Research and Innovation action

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

SC1-BHC-02-2019 (ex-4): Systems approaches for the discovery of combinatorial therapies

Specific Challenge:

Many complex disorders pose a challenge to identify the most effective therapeutic interventions because current therapies often target specific aspects of a disease, without achieving complete control or the best possible results for patients. Due to the multiple causes of such diseases and the heterogeneity between patients, approaches directed at single targets have had limited efficacy, overlooking important factors involved in disease pathophysiology. Hence, a promising therapeutic approach to meet this challenge is to combine different therapies, while increasing therapeutic efficacy in a cost-effective manner.

Scope:

Projects should focus on marketed therapeutic interventions and/or on products currently in the final stages of clinical development\*. Research should aim to understand at systems level the pathophysiology of a disorder in groups of patients responding well or poorly to particular therapeutic interventions. This knowledge should be the foundation of further studies to discover and develop combinatorial therapies tailored to the needs of individuals or stratified patient groups.

Projects should have access to standardized biobank samples derived from retrospective or currently running clinical studies. These patient samples should be re-analysed with modern high-throughput technologies. The existing and newly produced data should be integrated using systems approaches, which could combine sub-cellular/cellular and/or organ level *in-silico* models and network analysis as appropriate, and used to build more sophisticated computational frameworks to predict patient responses to combinatorial therapies. These predictions should be validated in pre-clinical and clinical studies taking into account sex and gender differences.

Applicants should include a thorough data management plan for transnational data sharing to enable the computational analysis and it is strongly recommended to adhere to the state-of-the-art international standards and to the FAIR principles.

The topic invites proposals in complex disorders of high prevalence and of a high economic burden (rare diseases are excluded). Proposals should include a cost-effectiveness analysis of the new therapeutic approach(es) in comparison to already established practice. SME participation is encouraged.

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.

Impact:

* New concepts of combinatorial therapies for complex disorders tailored to the needs of individuals or stratified patient groups
* Improved efficacy and cost-effectiveness in comparison to established therapeutic interventions
* Enable the development of personalised medicine
* Increased research & innovation opportunities in this industry intensive field, particularly for SMEs

Type of Action: Research and Innovation action

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

SC1-BHC-03-2018 (ex-5): Exploiting research results and potential of the human microbiome for personalised prediction and prevention of disease

Specific Challenge:

The human microbiome has been discovered as playing an important role for a stable state of health, for determinants of resilience and for dynamic responses to disturbances. Many different projectsin 'metagenomics' and epidemiological research in recent years have delivered new knowledge on associations between the microbiome and a wide range of (*gastrointestinal, oncologic, neurologic, respiratory, dermatologic, metabolic, cardiovascular, inflammatory, infectious, mental, etc.*) diseases. International initiatives such as the International Human Microbiome Consortium (IHMC) have generated high quality comprehensive large scale data catalogues and maps. These research efforts were first of all made to identify host-microbe-interactions and microbiome-mediated potential causalities and mechanisms of diseases. The long-term vision and challenge beyond that is to define balanced healthy conditions and to predict and prevent diseases through the development of novel personalised approaches and clinical tools.

The novel clinical means for predicting and preventing diseases should bring benefit and provide opportunities but they need to be validated and efficiently integrated into personalised medicine. The challenge is to build on the existing high quality data deposited in relevant databases and to combine these data and knowledge with endogenous and exogenous factors, lifestyle, ageing, dietary data, environmental data, mental disorders and/or any other comorbidity. This should accelerate the translation of data and knowledge into novel, personalised approaches and clinical tools to predict and prevent diseases. Building on existing data it is necessary to produce also new data with the aim to make the research more comprehensive and to achieve more valuable clinical tools.

These objectives cannot be accomplished on an individual country level which calls for broad transnational collaboration.

*This topic will focus on the clinical aspects of prevention and be developed in collaboration with Societal Challenge 2 where the food/nutrition aspects of prevention will be addressed, the topic may be complemented by topics funded under the IMI2 JU.*

Scope:

The aim is to achieve understanding of balanced healthy conditions and on that basis to deliver personalised approaches and clinical tools predicting and preventing diseases. Proposals should integrate and use high quality microbiome and other -omics data produced by large scale international initiatives. They should combine these data with disease-oriented functional analysis, innovative imaging, functional, structural and lifestyle, ageing, dietary and/or environmental data.

Proposals must build on data from existing microbiome projects and, as appropriate, on data from other international initiatives. Production of new data should make it more comprehensive with the aim to deliver more valuable clinical tools. Proposals should address relevant ethical implications, take into account sex and gender differences and include a section on research data management. International cooperation is requested.

Proposals addressing rare diseases are not in scope of this action.

The Commission considers that proposals requesting a contribution from the EU of between EUR 13 and 14 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:

* Personalised medicine approaches for the prediction and prevention of diseases through exploitation, integration and combination of data from existing microbiome projects and appropriate other international -omics studies.
* More valuable clinical tools built on existing data and new complementary data in relevant repositories.
* Identification and validation of microbial functionalities; robust healthy conditions and determinants of resilience for defined populations at specific body sites.
* Better prediction and prevention of diseases through validated novel clinical tools that are helpful for end-users.
* More intensive collaboration and strategic synergies between scientists across disciplines, sectors and around the globe (in line with the Union's strategy for international cooperation in research and innovation).

Type of Action: Research and Innovation action

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

SC1-BHC-04-2018 (ex-10): Rare Disease Joint Programme Co-Fund

Specific Challenge:

Despite the advances on biomedical research most of the estimated 6000 to 8000 rare diseases lack means for specific diagnosis and therapy. Small and dispersed patient populations, fragmented expertise and research resources make rare diseases a prime area for EU-level collaboration. Substantial funding from the EU Framework Programmes for Research and Innovation has had an integrating effect in the field, and three consecutive ERA-NETs have built the base for closer research collaboration between Member States. European Reference Networks (ERNs) established under the Directive on Patients' Rights in Cross-Border Healthcare will bring a major structuring effect on research and care by linking thematic expert centres across the EU.

There is a need to more efficiently bring the results of rare diseases research and innovation to the patients in terms of new and optimised treatment options, diagnostic tools and integrated care, making sure that patients maximally benefit from the research and investments done at the EU and Member States levels.

Scope:

The overall objective is to implement a European Joint Programme COFUND for Rare Diseases which would create a research and innovation pipeline "from bench to bedside" ensuring rapid translation of research results into clinical applications and uptake in health care for the benefit of patients. The initiative should follow the policies and contribute to the objectives of the International Rare Diseases Research Consortium (IRDiRC).

The specific objectives of the EJP COFUND are to improve the integration, the efficacy, the production and the social impact of research on rare diseases through the development, demonstration and promotion of sharing of research and clinical data, materials, processes, knowledge and know-how, and to implement and further develop an efficient model of financial support for research on rare diseases including basic, clinical, epidemiological, social, economic, and health service research.

The EJP COFUND should be implemented through a joint programme of activities ranging from research to coordination and networking activities, including training, demonstration and dissemination activities, to be structured along the four main components:

* Research and innovation programme to be funded through transnational calls for proposals or cascade funding based on the annual work plans of the EJP COFUND;
* Development of a virtual platform for rare diseases information, research data, samples, tools and standards to support and accelerate rare diseases research;
* Capacity building to improve the research and innovation potential of key stakeholders and enhance uptake of research results;
* Strategic coordination and management.

The research and innovation programme should encompass the following aspects of rare diseases: development of new diagnostic means, improved annotation and interpretation of genetic variants, functional analysis of candidate variants, animal and cellular models for human conditions, natural history studies with improved, scalable and participants-centred registries, preclinical research for new therapies, development of new methods for clinical trials, clinical trials for new and/or repurposed therapies including advanced therapies, discovery and validation of robust biomarkers, basic research into pathomechanisms and molecular pathways, socio-economic and health care oriented studies including burden of illness studies, and health services research to improve patient outcomes and health care systems.

The development of the virtual platform for rare diseases information, research data, samples, tools and standards should build on the existing resources, link directly with the funded research projects and establish new connections across the rare diseases community in particular with European Reference Networks (ERNs). Pilot actions involving funded research projects, ERNs, or relevant national or regional research and care institutions should be launched to ensure the usefulness of the developed tools to be followed by upscaling in a progressive manner.

Capacity building activities should include training and support activities focussing on areas such as research data management, product development, HTA processes, translational research and defining and sharing best practice guidelines and involve large groups of stakeholders including patient organisations.

Strategic coordination and management should encompass annual programming including gap-analysis and identification of research needs and policy questions in demand for evidence generation. Appropriate considerations of the relevant ethical, legal and societal aspects should be included. Close linkage with IRDiRC would be ensured by integration of the IRDiRC Secretariat in the EJP COFUND.

Participation of patient organisation should be encouraged in relevant activities of the EJP COFUND.

The Commission considers that proposals requesting a contribution from the EU of approximately EUR 50 million would allow these challenges to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

* Improve lives of rare disease patients by providing new and optimised treatment options and diagnostic tools for these diseases
* Decrease fragmentation of rare diseases expertise and research resources
* Increase EU's capacity to innovate in the field of rare diseases
* Improve health care systems' capacity to uptake research results
* Reinforce EU's role as a global actor for rare diseases

Type of action: COFUND (European Joint Programme)

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

SC1-BHC-05-2018 (ex-25): International flagship collaboration with Canada for human data storage, integration and sharing for developing personalised medicine approaches

Specific challenge:

The EU has ample experience in building and running data repositories to support biomedical research. Notable initiatives are ELIXIR[[8]](#footnote-8), the Pan-European infrastructure for life sciences data and the European Genome-phenome Archive[[9]](#footnote-9), storing many types of data up to the population-wide level. Similar expertise exists in Canada notably via IHEC (International Human Epigenome Consortium[[10]](#footnote-10)) and its Data Portal[[11]](#footnote-11) maintained at the Montreal Neurological Institute as well as PhenomeCentral, a repository for clinicians and scientists working on human rare disorders[[12]](#footnote-12).

There is a recognised need for tools that allow researchers to manage, exchange and preserve their data efficiently. Immense quantities of high-value information have been deposited in numerous data repositories, but these are scattered around the world and often don’t use compatible data standards. There is a pressing need for better integration of public repositories, coordinated data sharing and sustainable storage of high value data. Apart from hardware and maintenance costs, the cost of data curation, a necessary element to foster progress in biology and medicine, also needs to be considered.

Scope:

To build a collaboration of stakeholders in Europe and Canada in the domain of repositories storing and sharing human –omics data that will create a framework for long-term cooperation. In order to do so, this program aims to enhance and standardise data deposition, curation and exchange procedures thus ensuring better data reuse and increased benefit to the scientific communities worldwide. The selected projects should build on the data quality metrics, standards and access policy developed by major international initiatives (e.g., IHEC, ICGC[[13]](#footnote-13), IHMC[[14]](#footnote-14), MME[[15]](#footnote-15)).

Considering the existing data policies, projects should develop approaches that integrate data from disparate sources and include one or more of the following elements:

* Data models that guarantee the interoperability of human health research data from different repositories and integrate different types of –omics data and, where relevant, clinical research and lifestyle data. The projects should build on existing research infrastructures such as -omics repositories, biobanks and registries.
* Reference architecture for data and process interoperability.
* Technologies and methodologies for data harvesting, data discovery, data transfers, and archiving complex datasets.
* Bioinformatics toolbox to support the analysis and the management of data on diseases from a personalised medicine standpoint.
* International ethical and legal governance model for a research data management and storage infrastructure and an associated data management plan compliant with the required level of data security and privacy that is aligned with the recent recommendations of the OECD Council on Health Data Governance[[16]](#footnote-16).

This topic raises important issues of data sharing, privacy protection, informational right to self-determination and data security, which should be addressed from a legal, ethical as well as a social sciences perspective. It is important that proposals enable sustainable, collaborative projects and ensure cross-references with existing infrastructures (e.g., BBMRI-ERIC) and other on-going initiatives (e.g., International Consortium for Personalised Medicine, European Open Science Cloud, Rare Diseases European Joint Programme Co-fund). The proposals should take stock of the BBMRI-ERIC Code of Conduct for using personal data in health research. A multidisciplinary approach, i.e., involving clinicians, biologists, bioinformaticians, etc., is considered a key aspect of successful proposals.

Proposals to request a maximum budget of approximately EUR 6 million over 4 years will be considered as allowing this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals to request smaller amounts. In addition to the EU and Canada, the proposed project consortia may involve other international partners. Finally, the selected projects are expected to coordinate actions.

Expected Impact:

* Intensified sharing, reuse, collaboration and knowledge discovery in the health field.
* Integration of various health and disease data in data-intensive fields such as personalised medicine.
* More efficient research through reduced duplication of experimentation.
* A network of research infrastructures and databases in the EU and Canada that build synergies between ongoing activities, contributing to delivering the backbone for new discoveries that address the Societal Challenges delineated in Horizon 2020[[17]](#footnote-17).
* Strengthened position of the EU's and Canada's in science and more collaboration between academia and industry resulting in more innovation, jobs and growth.
* Contribute to the Digital Single Market through piloting IT health research solutions.
* Further the “Open science” and “Open to the world” priorities.

Type of Action: Research and Innovation action

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

SC1-HCO-01-2018-2019-2020 (ex-CSA1): 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 today's healthcare protocols do not include personalised approaches apart from occasional division into broad age groups (children/adults/elderly), gender 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 IC PerMed, which includes representatives from most EU countries along with several other European countries and Canada. Also the wider internationalisation of IC PerMed 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 certain 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 health economy issues and equitable healthcare. For the 2018 call, the project should focus on CELAC as a group of countries, and for the 2019 call on China. Participants from the relevant countries should be actively involved.
* Regional aspect: The action should establish and support networking between regions in different European countries, in particular linking remote or sparsely populated regions with regions harbouring critical mass of medical and PM expertise. The focus of the action can include aspects of genomic analysis, me-Health (mobile and electronic Health), telemedicine etc. but should aim at structuring PM application at regional level, e.g. for improving remote care for the elderly. (2018 call)
* Healthcare- and pharma-economic models for personalised medicine, interlinking European public health approaches with medical practice and financing. The action should carry out studies in support of research in and development of new health- and pharma economic models for PM, including prevention, to capture value and to develop relevant health financing models. Analysing mid- and long-term impacts of innovative products designated for sub-sets of patient populations on the patients themselves and on public health systems. Assessing the benefits of personalised medicines development while ensuring patient access, equity, solidarity and financial sustainability of public health systems in the EU. The action should involve several different stakeholders and the results of the studies and workshops should be actively disseminated to a wider audience, including relevant authorities, professionals and the wider public. (2018 call)
* Standardisation for clinical trials design. Development of new clinical trials design methodology for PM, including guidelines for research and reflection papers to inform regulatory and reimbursement authorities. The results of the studies and workshops should be actively disseminated to a wider audience, including relevant authorities, industry, researchers and other professionals. (2019 call)

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 IC PerMed initiative; furthermore:

* Integrating the country/group of countries into IC PerMed 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.
* Strengthened links between European regions setting up or planning centralised personalised medicine healthcare approaches. Aligning research funding with ongoing and foreseen investments e.g. from Structural Funds. Recommendations on best practice in implementing PM at regional level.
* Increased understanding of individualised medicine perspectives on how to capture value and design relevant payment models. Recommendations for faster translation from discovery to patients'/citizens' access. Contributing to understanding of trends and dynamics in the pharmaceutical markets in relation to increased emphasis of research and development efforts on PM. Suggestions on how savings through prevention can be included in payment and reward models and contribute to the sustainability of public health systems in the EU. Improved knowledge and understanding among healthcare professionals and the wider public of potential benefits of PM approaches.
* Contribute to standardisation of PM clinical trials design. Demonstrate feasibility and importance of PM approaches. Underpin accelerated market uptake. Improved knowledge and understanding among healthcare professionals, regulatory authorities and industry how best to adapt clinical trials designs to stratified patient populations.

Type of Action:Coordination and Support Action

*For 2020: Open CsA would give flexibility to address needs as they are (being) defined*

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

SC1-HCO-02-2018 (ex-CSA9): Data integration and data-driven in-silico models for enabling personalised medicine - a European standardization framework

Specific Challenge:

Big data relevant to personalised medicine encompasses many different, heterogeneous and complex data sets. The challenge is to harness and understand this abundance and diversity of data to produce medical benefits tailored to the individual or stratified patient groups.

To meet this challenge it is necessary that best practices are defined and widely adopted when using new technologies. For example, health research data production should be compliant with community-based quality standards, coupled with interoperable approaches for data integration and appropriate in-silico models to make sense of the data and produce results of medical relevance. Computational/in-silico models can be used to predict disease evolution, treatment response, and ultimately enable the personalisation of medical interventions

Standards, standard operating procedures or harmonisation strategies are part of the knowledge economy that facilitates innovation and the broader adoption of new technologies by European industry and by the regulatory authorities when approving new medicinal products and/or medical devices. Standards are key elements to facilitate competitiveness of European industry and the success of clinical research.

Scope:

The project should establish a forum for in-silico methodologies applied in translational and clinical research, where different transnational initiatives should meet and debate on their standardisation strategies. The project should evaluate the data integration and data-driven in silico models strategies and identify best practices for integrating and modelling heterogeneous human disease data transnationally. The project should focus on those heterogeneous types of human data which are best structured and thus pose fewer technical challenges for transnational sharing of data. Such data could be in principle biological and clinical data and the models should comprise of several computational models e.g. systems biology, physiological modelling, network analysis etc.

The project should deliver recommendations for flexible/adaptable standardisation guidelines for European collaborative research for heterogeneous data integration and data-driven in-silico models with predictive capability to interpret the human disease data while respecting legal and ethical requirements for data protection. In addition to the research standards the project should also ensure that the standardisation guidelines delivered address the regulatory needs in terms of data-driven in-silico models. Such guidelines should be based on open access principles and on interoperable solutions to those standards existing in the industry and used by the regulatory authorities. Inclusion of regulatory authorities could lead to an increased impact of the research proposed, and this will be considered in the evaluation of the proposal.

The action should also aim to organise awareness workshops during which scientists and policy makers and regulatory authorities would debate on future developments of in-silico models in health research.

The proposal should adhere to the FAIR[[18]](#footnote-18) principles, include partners from DG-RTD, DG-CONNECT relevant initiatives and create a collaboration with the relevant ESFRI European infrastructures and IMI projects and the relevant standardisation bodies e.g. CENELEC.

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:

* Harmonisation of health disease data integration and data-driven in silico models in Europe
* Accelerate the use of academic research data in clinical research and the broader adaptation by research, regulatory authorities and industry community
* Contribution to the sustainability of health research by using the power of health data
* Growth of the European data-driven economy

Type of Action: Coordination and Support Action

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

SC1-HCO-04-2018 (ex-NEW CSA12): ERA-NET to support the Joint Programming in Neurodegenerative Diseases strategic plan (JPND)

Specific challenge:

The EU Joint Programming Initiative on Neurodegenerative Diseases Research, in particular Alzheimer's (JPND), was established in 2009 as the pilot of the Member State-led Joint Programming Initiatives and enables the participating EU Member States to work together on the challenge of age-related neurodegenerative diseases. JPND allows the establishment, alignment and building on of national research programmes to increase the effectiveness and impact of research efforts.

Building on earlier successes of the JPND Research Strategy in scaling-up and establishing synergies with Horizon 2020, there is a need to continue previous efforts to consolidate the JPND successes in defragmentation, better coordination and alignment amongst the countries participating in the JPND.

Scope:

Proposals should coordinate national and regional programmes for research in the area of neurodegenerative diseases research by implementing a transnational call with EU co-funding resulting in grants to third parties, with a view to scale-up the implementation of the JPND Research Strategy.

Proposals should also promote the strategic alignment of research activities related to neurodegenerative diseases across Europe, such as developing and aligning national research plans and strategies, making data bases more accessible and interoperable, harmonisation of measurements and methodologies, networking of already existing structures and studies, training etc.

Proposals should demonstrate the expected impact on national and transnational programmes as well as the leverage effect on European research and competitiveness, and should plan the development of key indicators for supporting this.

Proposal should implement other joint activities including training and additional joint calls without EU co-funding.

The specific focus of this call will *be further developed by the Member States’*.

The Commission considers that proposals requesting a contribution from the EU of between EUR 5 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:

* Funding of research proposals on a topic identified by the JPND implementation plan or by their action groups, which needs to be addressed at European level and which is complementary to topics of the EC work programmes;
* Leverage transnational excellent research with EU-added value in the area of neurodegenerative diseases;
* Increased commitment of participating countries to the implementation of the JPND SRA;
* Establishment and alignment of national and regional plans and initiatives on neurodegenerative diseases;
* Strengthened exchange and better interoperability between existing European infrastructures and data bases;
* Enhancement and/or better exploitation of national or EC-supported activities.

Type of Action: ERA-NET Cofund

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

1.2 Innovative health and care industry

***Mission statement:***

This priority will focus on translating innovative knowledge and technologies into practical applications benefiting citizens, healthcare systems and businesses. It will support the most innovative stakeholders in Europe in the area of healthcare and ageing/well-being research. Areas of research will include innovative diagnostics and therapeutics, including advanced therapies. SMEs will be an important component and target of this priority. Actions under this priority are expected to demonstrate clear exploitation potential and socioeconomic benefits for patients and sustainable health systems. This priority will be complementary to the activities undertaken under the [SME instrument](https://ec.europa.eu/programmes/horizon2020/en/h2020-section/sme-instrument), the [Fast Track to Innovation](http://ec.europa.eu/programmes/horizon2020/en/h2020-section/fast-track-innovation-pilot) and the [Innovative Medicines Initiative (IMI)](http://www.imi.europa.eu/).

The expected impacts of this priority are to: (i) deliver applications and innovative products and services in the area of health; (ii) exploit the potential of the European healthcare and ageing/well-being industry and contribute to growth, competitiveness and jobs in this sector.

Proposals are invited against the following topic(s):

SC1-BHC-07-2019 (ex-3): Regenerative medicine: from new insights to new applications

Specific Challenge:

Regenerative medicine offers hope for untreatable disease and the ageing population, improved quality of life and reduced medical costs. However, so far, regenerative medicine has not yet proved itself in the clinic beyond rare diseases or conditions of limited public health importance. With recent scientific discoveries opening up new approaches to regenerative medicine, the challenge is to use these to extend the regenerative approach to major diseases and conditions.

Scope:

Regenerative medicine replaces or regenerates human cells, tissue or organs, to restore or establish normal function. Projects should focus on innovative translational research to develop regenerative processes towards the ultimate clinical goal of addressing unmet clinical needs of large patient groups. Proposals shall be based on approaches such as genome editing or gene therapy, transdifferentiation or in vivo reprogramming, cell therapy and transplantation, organoids or use of combined products (non-exhaustive list for illustrative purposes only). Projects focussing on more traditional treatments based on conventional pharmaceuticals, biologics or devices alone are excluded. In all cases, proposals should explain in what way their approach is regenerative. Research on improved methods of tissue and organ transplantation is included on the condition that there is a clear regenerative step in the process. The project may focus from early testing and characterization of regenerative mechanisms to preclinical research, proof of concept or first-in-man trial. Projects should include a section on the proposed therapy's exploitation potential, regulatory and commercialisation strategy and how it would be made available and delivered to patients.

The Commission considers that proposals requesting a contribution from the EU of between EUR 6 and 8 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:

* Potential new regenerative therapies to address unmet clinical needs of large patient groups identified
* Europe's position in translational regenerative medicine strengthened
* New therapies for major human diseases and conditions, and new approaches for therapy taken further in the development pipeline

Type of Action:Research and Innovation action

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

SC1-BHC-09-2018 (ex-17): Innovation platforms for advanced therapies of the future

Specific Challenge:

Advanced therapies are based on gene, cell or tissue-engineered products which are defined and placed on the market according to the terms of Regulation 1394/2007. So far, only a small number of these products have been placed on the market, and of these, most are for rare diseases. However, in recent years, important discoveries and developments, some unprecedented, have been made in molecular and cell biology and in cell technology, which offer improved opportunities for advanced therapies development. The challenge is to use the new knowledge and new technologies to introduce greater innovation into the advanced therapy development chain as a basis for tackling diseases and conditions affecting large patient groups.

Scope:

Building on European strengths and using the definition set out in Regulation (EC) 1394/2007[[19]](#footnote-19), projects should create knowledge and exploitation platforms around innovative concepts for advanced therapy development. Platforms should comprise the components and expertise necessary to create a solid foundation on which to build possible new therapeutic approaches or overcome development bottlenecks. These components would include studying the basic biology of the potential therapy and investigating its mode of action, proof of concept in animal models or first-in–man studies, safety, efficacy, characterisation, refinement and manufacturing of the product. Projects should also propose a business model for exploiting results and carry out appropriate outreach and public information activities. Examples of issues that have been identified as holding back the field include gene delivery to cells, reducing off-target effects in gene therapy, immunogenicity of potential new therapies, cell homing and tracking, or responding to regulatory concerns, such as potency assays, product characterization, or bank-to-bank variability (non-exhaustive list for illustrative purposes only).

The Commission considers that proposals requesting a contribution from the EU of between EUR 12 and 15 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

* Strengthened competitive position of European advanced therapy research and development
* Improved perspectives for treating diseases and conditions in large patient groups with advanced therapies
* Technological progress in the advanced therapy field

Type of Action:Research and Innovation action

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

SC1-BHC-10-2019 (ex-27): Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

Specific Challenge:

We observe a progressive shift in routine diagnostics, and more particularly in personalised medicine practice, from a growing number of molecular tests to a next generation sequencing approach (NGS). NGS can provide insights on a person’s genetic susceptibility to disease, diagnostic information, and predictive indications about treatment outcome. It also allows to embrace simultaneously different molecular pathways of disease evolution and to identify actionable mutations in a patient for medical decision and further research. In addition, it requires less sample material than multiple tests and therefore reduces risk and disagreements for patients. However, the introduction of NGS in clinical practice is hampered by its cost, the availability of proper NGS tests, and diagnostic errors resulting from insufficient quality assurance, technological bias and complex interpretation of data.

Scope:

The objective is to implement NGS in routine diagnostics for personalised medicine and scale up demand-driven innovation for health care systems. This includes organisational, economical, technical and clinical aspects. It should lead to NGS tests, clinically validated procedures, quality assurance schemes, tools and methods for data collection, management, analysis and interpretation, with a view to assist clinical decision-making and foster medical research and innovation. Transferability and cloud based NGS data analyses should be considered, as appropriate.

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 NGS platforms and use of NGS tests in routine diagnostics for personalised medicine;
* Accepted new European standards and quality assurance schemes with respect to NGS;
* Strengthening of implementation of personalised medicine and improved clinical decisions and health outcomes for the benefits of patients;
* Contribution to the sustainability of health care systems;
* Growth and benefit to the European industry, in particular SMEs.

Type of Action: Pre-Commercial Procurement

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

SC1-HCO-05-2018 (ex-CSA5): Strengthen Regulatory Sciences and support for successful regulatory Scientific Advice

Specific Challenge: A large proportion of EC and nationally funded projects in biomedical clinical research is focusing either on the development of novel active substances or on the optimisation of pharmacological treatments, such as exploring novel indications or new treatment/dosing schemes for generic, already registered pharmaceutical products.

To achieve full impact, marketing authorisations or corresponding changes of the regulatory labelling are required to bring the improvements from academic research in the clinical practice. However, in a majority of cases, the clinical results produced researchers in academia do not fulfil regulatory requirements and thus, innovations do not reach the patients in a timely and efficient manner. Insufficient time and know-how are available to develop strategies for successful regulatory Scientific Advice procedures. This is partly because regulatory sciences are well addressed in medical teaching and training programmes.

Scope: Proposals should; (i) establish a comprehensive inventory of existing support activities for regulatory Scientific Advice and Protocol Assistance in Europe; (ii) develop a strategy for training programmes to strengthen Regulatory Sciences and improve support for successful regulatory Scientific Advice and Protocol Assistance based on identified best practices; (iii) deliver corresponding training programmes in an efficient and collaborative manner, and (iv) assess the need for and possibly propose additional mechanisms to support academic groups in regulatory Scientific Advice and Protocol Assistance procedures.

A crucial objective is to coordinate and/or harmonise efforts among Member States and at European level in order to support the target group: Academic clinical scientists. The aim is to reach groups very early in the planning process for relevant potential grant applications. A further aim is to strengthen regulatory knowledge in general by reaching clinical scientists during qualifications and professional training.

The relevant stakeholders must be involved, in particular regulatory authorities alongside academic and industry partners and associations, in order to ensure (i) the comprehensiveness and validity of analyses, (ii) the feasibility and effectiveness of implemented and implementable activities and (iii) the impact of the whole project.

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:

* Improved knowledge of Regulatory Sciences among academic clinical researchers.
* Improved success in regulatory Scientific Advice and Protocol Assistance procedures
* Improved direct (regulatory) impact of results from academic clinical research to ensure that innovations reach patients rapidly

Type of Action: Coordination and Support Action

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

1.3 Infectious diseases and improving global health

***Mission statement:***

This priority will address communicable and chronic diseases affecting global health, including through preparedness. Taking a 'One Health'- and a more personalised approach, it will target the improvement of risk assessment and surveillance tools, and the development of innovative medical countermeasures addressing in particular antimicrobial resistance, emerging and re-emerging infectious diseases (public health emergencies) and poverty-related and neglected diseases. Also relevant to this priority are maternal and newborn health, global research collaboration on dementia, up-scaling interventions in specific diseases to populations in low-and middle-income countries and in vulnerable populations of high-income countries and the connection between global health and extensive migration waves. This priority links to the [EDCTP](http://www.edctp.org/), the [EU](http://ec.europa.eu/dgs/health_food-safety/amr/action_eu/index_en.htm) and [WHO (World Health Organisation) Global AMR action plan](http://www.who.int/drugresistance/global_action_plan/en/)s, the global coordination of emerging infectious diseases research, the [Council Conclusions](http://ec.europa.eu/health/major_chronic_diseases/docs/councilconclusions_1505515_en.pdf) and the [WHO Global Action Against Dementia](WHO%20Global%20Action%20Against%20Dementia), and further multi-lateral research initiatives.

The expected impacts of this priority are: (i) to position the EU as a leading partner in the promotion of global health and the fight against infectious diseases; (ii) to contribute to the SDG3, in particular by supporting research preparedness for epidemics and development of vaccines and medicines for communicable and non-communicable diseases; (iii) to implement the [GloPID-R](http://www.glopid-r.org/) (Global Research Collaboration for Infectious Disease Preparedness) and [GACD (Global Alliance for Chronic Diseases)](http://www.gacd.org/) agendas as well as the related G7 and WHO actions; (iii) to provide evidence for addressing migration-related health issues.

Proposals are invited against the following topic(s):

SC1-BHC-13-2019 (ex-6): Preparedness research for (Re-) Emerging Infectious Diseases

Specific challenge:

A range of factors is responsible for the (re-)emergence of infectious diseases, altering the epidemiology and spread of disease in a changing global environment. People are the principal contributor to this change, through population growth, unplanned urbanisation and high mobility, but also through animal husbandry or intensive farming practices. Other contributors such as climate change and associated environmental impacts also play an important role. Many of these drivers of the (re-)emergence of infectious diseases are interconnected and may interact in complex and unpredictable ways.

At the same time, tools for infectious disease diagnostics and surveillance are evolving rapidly, allowing for ever more accurate diagnosis in ever shorter time. Next generation sequencing combined with surveillance data and data from informal/non-traditional sources (e.g. social media) holds promise for improving the health of individuals and population health. This technology is enabling the rapid and personalised treatment of infected patients, as well as bolstering the detection, tracking and control of infectious disease outbreaks.

If the signal of a potential infectious disease threat is identified, preparedness and response could be significantly improved through the timely analysis of a selection of relevant, pooled data. Such comprehensive analyses, covering the spectrum from pre- to post-outbreak, should allow for a better understanding of the risk of (re-)emergence of infectious diseases, ensure the earlier detection of potential outbreaks, and enable faster implementation of the appropriate public health response to limit the spread of infection. The data required for these analyses will differ according to several factors including, for example, the (suspected) transmission mode of the disease threat (e.g. vaccine-preventable versus vector-borne disease), and whether it is of known or unknown origin.

Scope:

This topic aims to promote preparedness research, i.e. research that contributes to better preparedness of the health sector to the threat posed by (re-)emerging infectious diseases, through the optimal use of available data from different sources. It is expected that proposals develop both 1) the technology to allow the pooling, accessing and analysis of the data in accordance with national or European-level needs, and 2) the innovative modelling methodologies and tools that enable early warning, risk assessment and forecasting of (re-)emerging infectious diseases threats, ensuring an appropriate public health response. The technology and tools that are developed should remain available for public use at the end of the project.

Integrating different information systems and sources for surveillance and early warning, the project should be transdisciplinary and ensure an integrated One Health approach, linking data from a wide range of sources, including human and animal health surveillance, microbial and viral genomic data (including next generation sequencing), pathogen resistance data and environmental data, as well as data from informal/non-traditional sources. Data may be pooled at many different geographic levels, ranging from individual hospital or laboratory level to province, state or country level. The pooling of data should be done in a structured manner, and solutions for gaps in existing data should be proposed.

Solutions for interoperability between different data sources should be addressed and integrated. The data shared should be made available in accordance with the FAIR principles.[[20]](#footnote-20) Appropriate governance mechanisms, taking into account data privacy and data security aspects, for the different types of national or European stakeholders providing and analysing the data need to be foreseen, considering also the different stages of sharing, i.e. in regard to existing data, newly generated data, re-use of data, as well as results generated from the use of data.

The technology and tools developed should be functional outside of outbreaks (i.e. in "peace time"), so that all stakeholders involved develop a routine use of them. At the same time, flexibility is needed to enable adaptation to different outbreak contexts and situations, allowing for the possibility to add new types of data, either from surveillance or research. In so far as possible, the project should build on and further develop already existing relevant European initiatives.

As the pooling is likely to involve large datasets from different sources, the use of advanced IT technologies like high performance computing is anticipated. The use of European health research infrastructures (including e-infrastructures) is encouraged where relevant. Proposals should ensure synergies between scientists across disciplines and sectors, as well as with related European and global initiatives in this area; if more than one proposal is selected they are expected to collaborate. The successful proposal(s) should foresee to consult with the end-users at both national (e.g. public health institutes) and European (e.g. ECDC, EFSA) level at key milestones of the project's timeline. In addition, coordination will be needed with the selected proposal from the Horizon 2020 call topic SFS-36-2017 on the establishment of a European Joint Programme on One Health.

The Commission considers that proposals requesting a contribution from the EU of between EUR 12-15 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

* Strengthened EU's preparedness to address threats from (re-)emerging infectious diseases, by making available the appropriate technology and tools for an increased capacity to detect threats early, estimate their immediate and anticipated risk for public health, and support an appropriate public health response;
* Contribution to achieving Sustainable Development Goal (SDG) 3 by: 1) combating epidemics, and 2) strengthening capacity for early warning and response to health risks. Contribution to achieving of SDG 13 by: 1) integrating climate change measures in policies, and 2) improving awareness-raising on climate change mitigation and early warning.

Instrument: RIA

SC1-BHC-14-2019 (ex-11): Stratified host-directed approaches to improve prevention and/or treatment of infectious diseases

Specific Challenge:

Despite major advances in development of new drugs and vaccines against infectious diseases, many of the therapies and preventive measures do not result in the expected favourable health outcomes for various reasons. The pathogen might be resistant to the treatment, or a required immune response might not be provoked to contain the infection; the used drug might not reach the pathogen, or the pathogen might escape the host defence mechanisms. In addition, each individual might be responding differently to the intervention, making it difficult to make one intervention fit all patients. A promising avenue to overcome treatment failure in infectious diseases is to develop novel therapeutic or preventive approaches on the basis of specific factors identified in the host or the host-pathogen interaction. This approach provides the basis for stratification of individuals based on these characteristics and tailor the treatment or the preventive measure accordingly.

Scope:

Proposals should test emerging concepts in drug and/or vaccine development in order to address the problem of antimicrobial drug resistance and to optimize treatment or preventive measures against infectious diseases of major concern for Europe. Proposals should capitalize on knowledge of the role of host factors, immune-modulators or of host-pathogen interactions influencing disease outcome that can be utilized to strengthen the response to treatment or prevention measures. This should lead to new enhanced therapies and/or preventive measures. Differences in factors such as age, gender and genetic variation among the human population should be taken into consideration.

The proposals should focus on late pre-clinical or clinical research, supporting proof of concept and selecting relevant biomarkers for clinical validation. They should take advantage of existing or newly established cohorts to help identify factors for predicting the course of the disease and its response to the intervention in stratified patients.

The downstream constraints for the uptake of the intervention by national health systems, also in poorly resourced ones, should be taken into account. The suitability, acceptability and adaptability of the interventions to be developed should be addressed and assessed for different population groups, including those living in poorly resourced settings and conditions.

The development of vaccines against HIV, tuberculosis is not in the scope of this topic.

The Commission considers that proposals requesting a contribution from the EU of between EUR 6 and 10 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

* Increase Europe's capacity to control infectious diseases;
* Enriched product development pipelines with novel, potentially more effective, targeted treatments and/or preventive measures for infectious diseases;
* Validated biomarkers with potential for rapid uptake into clinical practice;
* Reduced burden of major infectious diseases;
* Help achieving the Sustainable Development Goal 3, ensure health and well-being for all, at every stage of life.

Instrument: RIA.

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

SC1-BHC-15-2018 (ex-12): New anti-infective agents for prevention and/or treatment of neglected infectious diseases (NID)

***To be implemented by lump sum payments***

Specific Challenge:

Neglected Infectious Diseases (NIDs) diseases are responsible for a significant health and socioeconomic burden in large parts of the world, particularly in resource-poor countries, however some (e.g. leishmaniasis, Chagas disease) are increasingly becoming a concern for Europe too. Despite a significant effort to develop new drugs to treat these diseases over the past 10 years, existing therapies suffer from various shortcomings, namely, a high degree of toxicity and unwanted effects, as well as treatment regimens often lengthy or parenteral that discourage compliance and increase the emergence of resistance. Vaccines can also be a major tool for the control of NIDs, particularly given the limitations of mass drug administration strategies, but currently the only major NIDs for which licensed vaccines exist are rabies and dengue. Development of new, more effective, safe and affordable treatments and vaccines for NIDs is therefore an urgent need.

In the last few years, increased awareness and funding for NIDs has resulted in the identification and preclinical development of several treatment and vaccine candidates against various NIDs. However, the typical NIDs 'market failure' (i.e. high risk and low potential return) discourages the uptake and costly further development of these candidates by pharmaceutical and biotechnology companies. Targeted public funding is therefore necessary to bridge the gap between preclinical and clinical development, and help advance existing candidates along the development pipeline.

Scope:

The topic bridges the gap between preclinical and early clinical development of drugs and/or vaccines against neglected bacterial and parasitic diseases[[21]](#footnote-21). Therefore, the proposed actions should focus on late preclinical (e.g. validation in animal models, toxicology, GMP production, preparation of Investigational Medicinal Product Dossier) and early clinical (up to phase 1) development of already existing lead drug and vaccine candidates. Multidisciplinary platforms bringing together academic and industry research teams, from European and disease-endemic countries, with the capacity to exploit existing experience and propose innovative solutions addressing several relevant pathogens are particularly encouraged.

The downstream constraints of candidates for the effective deployment and uptake by limited-resources public health systems should be taken into account by the proposed action:

* It should address the following key element of the target-product profile (TPP): suitability, acceptability and adaptability of the intervention to be developed for different population groups living in poorly resourced conditions, including particularly vulnerable ones (e.g. children).
* It should also address issues that permeate and often impede access such as: optimal route and dosing or immunization regime, up-scaling of manufacturing, registration and pre-qualification, distribution and field-deployment logistics (e.g. storing temperatures), and the predicted cost per patient of the final product.
* Ultimately, the proposed action should include a clear pathway through the different necessary steps (research, manufacturing, regulatory approvals and licensing, IP management, pricing etc.) in order to ensure appropriate access to people in limited-resource settings.

The proposals should have the participation of at least one (or more) organisation(s) from disease-endemic countries, in particular LAC and Africa.

The Commission considers that proposals requesting a contribution from the EU of between EUR 5 and 10 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

* Increased number and quality of treatment and vaccine candidates for neglected infectious diseases available to proceed into further development and clinical testing and, if appropriate, within the context of the European and Developing Countries Clinical Trials Partnership (EDCTP2).
* Ultimately this will lead to novel treatments or vaccines for NIDs appropriate for limited-resources health systems, therefore reducing the disease burden and its social and economic consequences, and thus contribute to achieving the United Nation's Sustainable Development Goals 1 (No Poverty), 3 (Good Health and Well-being), 5 (Gender Equality), 10 (Reduced Inequalities) and 13 (Climate Change).

Type of Action: Research and Innovation action

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

SC1-BHC-16-2018 (ex-14): Global Alliance for Chronic Diseases (GACD) 1

***For 2018 (depending on GACD Board decision)***

Rationale/justification: Subject to be agreed by GACD Funders.

Intervention scaling up:

* Reaching the SDG goals for NCDs will request the application of successful interventions at large scale.
* Scaling up successful local interventions has proven extremely difficult, especially due to the variety and heterogeneity of local systems and contexts.
* Successful local interventions must be tailored/adapted to those contexts including during the scaling up phase.
* Focus likely to be on hypertension.
* Possibility to target the call to one country only, pending discussions with funders.

Type of Action: Research and Innovation action

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

SC1-BHC-18-2019 (ex-18bis): EU-CELAC collaboration for research on non-communicable diseases

Specific Challenge:

The prevalence and incidence of non-communicable chronic diseases (NCD) has raised sharply in both EU and LAC countries during the last decades and they are by far the leading cause of mortality representing 60% of all deaths worldwide. Furthermore, 70% to 80% of healthcare costs are spent on chronic diseases. With the creation of the Common Research Area, cooperation with CELAC countries is currently intensifying. The 2015 EU-CELAC Summit outlined the importance to contribute to the objectives of the EU-CELAC "Knowledge Area". In particular, cooperation between EU and CELAC on health research would further develop the actions undertaken with the new EU-CELAC Joint Initiative for Research and Innovation.

Scope:

*Placeholder (subject to discussions with MS and LAC)*

To support EU-CELAC research networks addressing common healthcare challenges and supporting data sharing and capacity building, in the area of non-communicable diseases.

Depending on pending discussions with CELAC countries, the EC might explore the possibility to fund all CELAC countries, including Brazil, Mexico, and Trinidad and Tobago.

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

* Contribution to the SDG goals for non-communicable diseases
* *To be further determined*

Type of action: Research and Innovation action

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

SC1-BHC-19-2019 (ex-37): Implementation research for maternal and child health

Specific challenge:

In 2015, an estimated 216 women died per 100,000 live births, and 45% of total deaths among children under five occurred in the first month of life. Leading causes of death in under-five children are preterm birth complications, pneumonia, birth asphyxia, diarrhoea and malaria; about 45% of all child deaths are linked to malnutrition. Lifestyle related conditions such as obesity, diabetes or hypertensive disorders may negatively influence pregnancy and child development.

Each year, an estimated 210 million women become pregnant and 140 million newborn babies are delivered. However, many of the women and children receive care that is below evidence-based standards, others suffer from over-medicalisation. Access to quality care, before, during and after pregnancy, is essential to ensure good maternal health and the favourable early development of the child. In Europe, social and health inequities cause important gaps in access to care in particular for vulnerable groups; in 2013 an estimated 1900 maternal deaths occurred in Europe.[[22]](#footnote-22) In addition, important differences between Member States are noted: in the most recent available European Perinatal Health Report (2010), neonatal mortality ranged between 1.2 and 5.5 deaths per 1000 live births, whereas infant mortality ranged between 2.3 and 9.8 deaths per 1000 live births.[[23]](#footnote-23) In 2013, UNICEF reported neonatal mortality to be highest in Sub-Saharan-Africa and Southern Asia, reporting 31 and 30 deaths per 1000 live births respectively, corresponding to 34% and 54% of all under-five deaths in the respective regions.[[24]](#footnote-24)

Although there is a consolidated evidence base of what works in tackling poor maternal and newborn health, the "knowledge-do" gap has not been bridged and evidence based guidelines are insufficiently implemented. Therefore, more implementation research is needed.

Scope:

Applications are expected to propose implementation research[[25]](#footnote-25) for improving maternal and child (until two years of age) health in Europe and/or globally, valuing the health of the mother before and during pregnancy, and the interdependent relationship between mother and child; particular attention may be given to the neonatal period up to 28 days. The implementation research may cover:

* new or improved health service delivery interventions that strengthen maternal and child health; or
* the scaling up and/or adapting of existing interventions to new contexts.

The introduction of new and innovative technologies and interventions, already approved by relevant regulatory authorities, and which are expected to improve the health service delivery or the adherence to guidelines, can be considered; in contrast, neither pre-clinical research nor clinical trials in the context of product development are within the scope of this call.

The research should take into account the specificities of different contexts and situations; the integration of social sciences is encouraged. In addition, particular attention should be given to equity issues. The research should be integrated from different perspectives, e.g. recognising the interdependent relationship between mother and child; addressing prevention, health promotion and treatment; allowing for the specific needs of vulnerable groups (e.g. preterm infants, adolescents, migrants); addressing different concurrent pathologies, etc. Research may cover physical and/or mental health, as well as communicable and non-communicable diseases or nutrition.

Part and parcel of the implementation research is the collection and use of good quality data, covering delivery, content of care and outcomes. Research is expected to be carried out in continuous partnership, in particular with the end-users, i.e. the concerned women, the fathers, and their community, in addition to policy makers, politicians, development partners, and the media, to ensure that evidence is properly translated into policy and practice. The use of multiple (quantitative and qualitative) research methods is encouraged.

The Commission considers that a proposal requesting an EU contribution between EUR 2 to 4 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

* Improved lives of pregnant women, mothers and children, including the most vulnerable groups in Europe and/or LMICs
* Decreased morbidity or mortality rates of pregnant women, mothers and children in Europe and/or LMICs
* Increased evidence-base and guidelines for policy-makers on the optimal guidance for ensuring that all pregnant women, preterm infants, neonates and children receive as a matter of routine, the best quality of appropriate care and nutrition, adapted to their needs and to the context they live in; this both from a prevention and a treatment perspective
* Contribution to the SDGs 2 on improved nutrition (target 2), Goal 3 on health (targets 1 and 2 on maternal and child health) and Goal 5 on gender equality (targets 1 and 6)

*Applicants may be interested in a separate but connected call topic on "Food systems Africa" under Societal Challenge 2.*

Instrument: Research and Innovation Action.

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

SC1-BHC-21-2018 (ex-NEW 41): Research on HIV and/or tuberculosis in patients with mono-, co-infections or comorbidities in the contest of fostering the collaboration with (alt. widening the participants to) Russia and other countries in the Central- and Eastern European region

Challenge:

ECDC (European Centre for Disease Control) and WHO-Europe (World Health Organisation) report high number of cases for HIV and TB infections (both in incidence and prevalence) in the European regions and in recent years the epidemic situation has deteriorated in Eastern Europe[[26]](#footnote-26),[[27]](#footnote-27).

For TB, in particular diagnosis and treatment of multidrug-resistant TB (MDR-TB) poses a major challenge. In Eastern European countries and Russian Federation there is still high burden of TB and HIV and their comorbid forms. Additionally, a significant proportion of the infected patients are also affected by co-infections and comorbidities that may adversely affect their prognosis, which is a global challenge in healthcare and in particular refers to TB/HIV cases.

Several issues in the current epidemiological situation are still to be addressed to reduce the cases of new infections and deaths, including investigation of reasons underlying fast spread of M/XDR-TB and HIV/AIDS in some regions, development of rapid tools for an accurate detection of TB infections and management of HIV and TB drug resistance. Adverse effects of treatments and the requirement for strict adherence to antiretroviral treatment further complicate management of these diseases.

Given the dynamics of the epidemics and the need to contain them, there is a commitment from the European Union and from the Russian Federation to support joint research and further strengthen the collaboration between research and healthcare centres in the EU and in Russia to address the issues outlined above.

Scope:

Proposals should build research collaborations between Western and Eastern European countries, in particular Russia, and address one of more of the following subtopics:

**1a -TB:** To investigate biomarkers or new diagnostic tests for early screening of TB risk groups for TB infection. The proposed research can include activities such as epidemiological monitoring of M/XDR-TB, bioinformatic analysis of data aimed at the identification of candidate biomarkers, evaluation of infection activity, monitoring treatment efficacy, monitoring disease status and relapse.

The research should lead to better diagnosis of new TB cases, better understanding of progression of the disease and treatment failure, or better prognosis of cases of relapse.

**2a-HIV**: To investigate the susceptibility to HIV and/or disease progression rate after infection and the development of genetically defined adverse effects (AE) during antiretroviral therapy (ART).

**2b-HIV**: To characterise the different HIV subtypes and investigate the links with comorbidities in HIV+patients.

**3a-TB-HIV**: To analyse TB as an immune reconstitution inflammatory syndrome (IRIS) and risk factors in HIV and TB co-infected patients for the optimisation of their combined treatment.

**3b-TB, HIV and/or TB/HIV**: To develop a population-level mathematical model of TB, HIV and/or TB/HIV spread and control of the epidemics. The model should take into account drug-resistance and vulnerable population groups (socioeconomic subgroups with increased HIV or TB risk) and, being fitted to the available routine epidemiological data, permit to predict the dynamics of both infections, including co-infection, under various control and socioeconomic scenarios.

Implementation of the aforementioned subtopics should aim at visible technological advancements, such as novel biomarkers or tools for the prevention and spread of the epidemics.

In performing the research agenda to address one (or more) of the listed subtopics, the applicants might make use of already established European cohort networks or establish new collaborations thus widening their geographical scope and include both HIV/AIDS, TB mono or co-infected individuals and perform retrospective or prospective studies. Comorbidities of HIV or TB infections with non-communicable diseases (NCDs) should be considered by the applicants. Proposed actions should take into consideration vulnerable groups and target populations, which may include, but not limited to: ageing subject, drug users and other social risk groups.

The Commission considers that a proposal requesting an EU contribution between EUR XX to YY 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:

* Improvement of coordination and integration between Western and Eastern European, in particular Russian, clinical and research centres dealing with HIV and TB infected patients
* Produce scientific evidence leading in the long-term to the reduction of the burden of these infection diseases.
* Produce scientific evidence and contribute to the optimisation (and personalisation) of diagnosis, treatments and improvement of quality of life of patients affected by HIV and TB infections (mono or co-infections) and comorbidities.
* Contribute to the EU impact towards the achievement of the Sustainable Development Goal 3: Ensure Healthy lives and promote wellbeing for all at all ages and the WHO's end TB strategy.

Instrument: Research and Innovation Action.

Timing: Duration of the action: maximum 24 months. One or more projects to be funded.

*\*\*\* Add paragraph on specific conditions for international cooperation call*.

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

SC1-HCO-06-2018 (NEW CSA): Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), Establishment of an International Network of Research Centres on Global Governance for Infectious Disease Preparedness

***For 2018 (depending on GloPID-R members' final decision)***

Rationale/justification: Topic details will be developed in line with the timetable of the GloPID-R priority setting process and will be provided during the course of 2017.

International Network of Research Centres

Infectious disease outbreaks such as the Severe Acute Respiratory Syndrome (SARS), H1N1 influenza, Middle East Respiratory Syndrome (MERS), and Ebola, as well as antimicrobial resistance, all underscore the current deficiencies in global governance arrangements and highlight how such deficiencies can lead to sub-optimal health outcomes for people everywhere.

The proposed network of social scientists would have four main priorities:

1. Strengthen research capacity and catalyse social science researchers to generate and apply new knowledge about effective global governance arrangements for infectious disease preparedness and system response mechanisms.
2. Foster cross-country research collaborations to better connect researchers currently working in isolation and to support bigger, more robust research on global infectious disease governance.
3. Facilitate ongoing engagement among researchers and global policymakers to institutionalize the use of research evidence in global and national decision-making on governance arrangements for infectious disease preparedness.
4. Enable better preparedness for infectious diseases through the application of knowledge, sharing of lessons learned, and creation of improved governance arrangements.

The network would require the involvement of multiple countries and support by several funding agencies, and so coordination with GloPID-R funders is foreseen to build the network.

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

Type of Action: Coordination and support action

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

~~SC1-HCO-07-2018 (ex-CSA2): Preparing for data sharing in infectious disease~~

SC1-HCO-08-2019 (ex-CSA3): Creation of a European wide sustainable clinical research networks for infectious diseases

***In the context of widening***

Specific Challenge:

Infectious diseases pose a serious threat to global health. Emerging epidemics, pandemics and rising levels of antimicrobial resistance require a strong and coordinated response to protect citizens in Europe and beyond. There is a need to establish a clinical research network across Europe that has the capacity and capability to directly enrol patients with infectious diseases, to increase efficiency for testing and developing new diagnostic, preventive and/or therapeutic strategies and therapies. This should allow generating rigorous evidence to improve the diagnosis, prevention and treatment of infections and to better respond to infectious disease threats, and 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 in cooperation with the existing global experts networks to ensure the common benefit of the outcomes[[28]](#footnote-28).

Scope:

Proposals should build on successful European collaborative initiatives and further advance clinical research in the field of infectious disease by supporting the establishment of a European wide multidisciplinary clinical research network. Such a network should be capable of performing all clinical trial aspects encompassing study design, execution and reporting. It should develop and allow for innovative research approaches and enable flexibility in responding to unpredictable events and signals. The network should provide clear and direct access for stakeholders including academic organizations, SMEs and larger industry to perform clinical studies. The proposal should develop a business plan to ensure the sustainability of the network. The network should actively disseminate information and contribute to awareness rising. Furthermore, it should also create synergies with global initiatives, enabling quick and smooth interactions and collaboration across the world.

The Commission considers that a proposal requesting an EU contribution between EUR 2 to 3 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 of clinical trials for diagnosis, prevention and treatment of infections
* Attract industry back to invest in the development of anti-infectives
* Strengthen the operational capacity and the required infrastructures for clinical research
* Increase information exchange between sectors and scientific disciplines
* Maintain Europe's leading role in combating AMR and controlling infectious diseases

Type of Action: Coordination and support action

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

SC1-HCO-09-2018 (ex-CSA6): Building international efforts on cohorts

Specific Challenge:

Cohorts are invaluable resources to obtain detailed description of individual biological variations in connection with a variety of environmental, pathogenic, occupational, societal, and lifestyle determinants that influence the onset and evolution of diseases. Europe currently has some of the most valuable population and patient cohorts, including well annotated clinical trial cohorts. Several large cohorts have also been developed in various parts of the world. Despite recent efforts to network cohorts, the level of integration need to be escalated in order to optimise the exploitation of these resources, essential to underpin and facilitate the development of stratified and personalised medicine.

Scope:

Building on existing cohorts, proposals should establish a strategy for the development of the next generation of integrated cohorts, including:

* Map the cohort landscape in Europe.
* Identify best strategies for integration.
* Harmonize past and future data collection.
* Enhance innovative tools for maximising results of clinical relevance for understanding mechanisms, predictive models.
* Develop models for merging population and patients cohorts.
* Contribute to define an international strategic agenda for better coordination of cohorts globally.

The Commission considers that a proposal requesting an EU contribution between EUR 1.5 to 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:

Coordination of large cohorts at EU and global level would:

* Maximise the use of cohorts in defining/improving clinical practice and public health policy and bringing innovations to patients.
* Accelerate the development of personalised medicine

Type of Action: Coordination and Support Action

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

SC1-HCO-10-2018 (ex-CSA7): Coordinating European brain research and developing global initiatives

Specific challenge:

The EU and its Member States have made considerable investments in brain research. For instance, the European Commission has invested about EUR 4.2 billion over the past 10 years. While scientific research has generated a considerable amount of knowledge and innovative approaches, the development of new health interventions is below expectations and needs. At the same time, many large research initiatives have been initiated in recent years such as the Human Brain Project (HBP), The Joint Programming on Neurodegenerative Diseases (JPND), the ERA-Net NEURON and other initiatives.

In many areas of brain research, there is a particular need for better networking and coordination of efforts as well as more access and holistic analysis of available knowledge and data in line with Open science policy. This has the potential to create synergies and open new avenues and to foster understanding of diseases, innovation and accelerate the development of new diagnosis, prevention and treatment options in areas of high and unmet medical needs.

Scope:

Proposals should:

* Identify areas of neurosciences where the need for enhanced coordination of research communities into active clusters is particularly acute;
* Support the emergence of these clusters, facilitate links with research infrastructures and other major initiatives, in coordination with European Commission services, with the aim of sharing results, fostering new collaborations and identifying future research objectives;
* Identify and develop tools and support activities implemented by EU funded initiatives and infra-structures suitable to enhance the Open Science policy in neurosciences, such as sharing clinical data via IT platforms;
* Explore possibilities for broader scale cooperation by fostering dialogue with researchers outside Europe in coordination with research funders around the world.

The relevant stakeholders must be involved, in particular learned societies, large research initiatives and infrastructures as well as relevant funding bodies to ensure the feasibility and effectiveness of the implementation and the impact of the whole project.

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

Expected Impact:

* Reduce fragmentation and duplication of research efforts and foster synergies through enhanced coordination of research in neuroscience at EU and at global level.
* Improve access to and optimise the use of research infrastructures and data sources by the neurosciences research community, thus ensuring better exploitation of large investments in brain research Achieve critical mass and economies of scale by initiating and fostering new global research initiatives.
* Enable and accelerate breakthroughs in brain research.

Type of Action: Coordination and Support Action

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

SC1-HCO-11-2018 (ex-CSA11): Strategic collaboration in healthcare research and innovation between EU and China

Specific challenge:

Compared to its size and increasing weight on the R&I international scene, China's participation and cooperation to the Horizon 2020 SC1 programmes is low. This is a lost opportunity because most of the major health challenges are global, and cooperation with China on specific strategic health challenge can contribute to provide more evidence-based solutions and to avoid duplication.

Scope:

The objective of this action is to support networking between European and Chinese policy makers, programme owners and funders, with the following goals:

1. To develop a sustainable platform between EU and China that will facilitate a constant dialogue on addressing common health R&I challenges.
2. To identify health challenges, commonly shared, whose solution may benefit from close bi-lateral and/or multi-lateral cooperation between EU and China.

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

Expected impact:

* Increased bi-lateral and multi-lateral cooperation on health research strategic items between EU and China
* Higher participation of Chinese researchers in SC1 and of European researchers in Chinese health research programmes

Type of Action:Coordination and Support Action

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

1.4. Innovative health and care systems - Integration of care

***Mission statement:***

This priority will aim at developing new models for effective, accessible and sustainable health interventions and integrated care systems. This aim is particularly relevant in the context of personalised medicine, management of chronic diseases and health promotion. It includes the further development of health technology assessment methods, and the evaluation of community- and population-based intervention strategies, both retrospectively and prospectively. It addresses also the important dimensions of organisational change, workforce skills, associated investment, new financing and business models, all of which will require contributions from the disciplines of social sciences and humanities. This priority includes the integration of the care dimension, by the promotion of health literacy, and by better coordinating primary and community care with the specific needs of the patient.

The expected impact of this priority is to provide better evidence for the development of more sustainable and resilient health systems, including through better and more coordinated health technology assessment, resulting in increased access to quality care for everyone and better health promotion. It should also provide a path to implementation of integrated care programmes, and to strengthen the procurement communities and the links between the demand (care authorities) and supply (technology providers) sides.

Proposals are invited against the following topic(s):

SC1-BHC-22-2019 (ex-7): Mental health in the workplace

Specific Challenge:

In most European countries, absences from work and early retirement due to mental illness have increased in recent years[[29]](#footnote-29). Mental health conditions such as depression, anxiety and stress represent large financial costs for employers and employees, as well as a significant loss for society at large. Mental illness is an important cause of absence from work but it is also linked to high levels of presenteeism, where an employee remains at work despite experiencing symptoms resulting in lower productivity. An EU-level estimate of the overall costs, direct health costs and lost productivity is more than 450 billion EUR per year. The impact of work-related stress has received more attention in recent decades, notably the effects of psychosocial hazards[[30]](#footnote-30). In the EU, the Joint Action on Mental Health and Wellbeing has addressed the issue and developed an EU-Compass for Action on Mental Health to monitor and share information on policy and stakeholder activities in mental health[[31]](#footnote-31)**.**

Reviews of the academic literature provide evidence of a number of risk- and protective factors that may contribute to the level of mental health in the workplace[[32]](#footnote-32). There are many examples of initiatives at the level of the workplace and organisation, such as adapting job design, stress management or specific mental health interventions which are not published in academic journals. There is a need for further study of risk factors, stressors and relationships with common mental disorders to better understand the association between job demands and risks of mental health problems. The impact of presenteeism, which is less studied so far than absenteeism, would merit further study[[33]](#footnote-33). In order to progress, more knowledge is needed about effective interventions by employers to promote mental health, and about the barriers to effective implementation of such interventions, in particular for smaller enterprises and public agencies with less resources and knowledge to manage these health issues.

Scope:

The proposals should aim to develop and demonstrate the effectiveness of actions that an employer can take to promote mental health and prevent mental illness in the workplace. Proposals should focus on important challenges to mental health in the workplace in the EU (such as reducing absenteeism and presentism due to mental illness), e.g. by comparing interventions and studying barriers to effectively implementing such programs in the workplace. This research should build on available scientific knowledge, grey literature and practical experience in workplace mental health. Research should be multidisciplinary, including social sciences. Mixed-methods research[[34]](#footnote-34) is encouraged. Co-morbidities in mental and/or physical health should be addressed, given the associations between them, and the importance of preventing and treating both. The stigma attached to mental ill health is important to consider, as well as other social and cultural factors, which may be relevant to improving the working environment. The important gender aspects including the gender equality dimension should receive attention. The interventions should be assessed in terms of health outcomes, economic effectiveness, including effects on the workplace such as working environment, productivity.

It should contribute to a better evidence base on which to further build policy and action.

Proposals should involve key partners, such as employers and employees in the private and public sector, policy makers, insurers, social partners and civil society in developing initiatives.

The Commission considers that proposals requesting a contribution from the EU of between EUR 2 to 4 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

* Improved policies on mental health in the workplace policies, based on the broader evidence base on risk and protective factors and effective interventions
* Improved mental health and reduced sickness absence in the EU working population.
* Positive impact on productivity and economic results of workplaces by improved policies and action to promote mental health.

Type of Action: Research and Innovation action

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

SC1-BHC-23-2018 (ex-13): Novel patient-centred approaches for survivorship, palliation and end-of-life care

Health conditions linked to end-of-life issues, life-threatening non-communicable diseases, late or long term side effects and consequences of diseases and their treatments impact quality of life and pose an immense societal and economic burden. Palliative[[35]](#footnote-35) and survivorship care benefits patients with malignant and non-malignant chronic health conditions, providing relief from their symptoms and improving their quality of life. From 38% to 74.0% of affected population[[36]](#footnote-36) is estimated to be in need of palliative care. While a variety of interventions are in use, these are often not adequately validated or adapted to the specific needs of patients affected with a specific chronic disease or with multimorbidities. Therefore a need exists to strengthen the evidence base for available effective interventions improving quality of life in the domains of palliative, end-of-life and survivorship care.

Scope:

Proposals should demonstrate, based on preliminary results, the effectiveness of new, improved or specifically adapted interventions to relieve symptoms and suffering caused by life-threatening non-communicable diseases, serious late and long-term side effects of disease treatments in patients and survivors, or symptoms that occur at the end of life. Randomised clinical trials or observational studies of new or improved patient-centred[[37]](#footnote-37) interventions, targeting children[[38]](#footnote-38) and/or adults, should be considered for this topic.

Proposals should prove the feasibility of integrating the proposed interventions in current palliative and/or survivorship care regimes and healthcare systems across Europe.

The proposals should address sex, gender, age and socio-economic factors in health and any other factors (e.g. ethical, familial, cultural differences, beliefs, etc.) that could affect health equity.

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.

Impact:

* Reduced suffering or improved well-being of patients in need for palliative, end-of-life or survivorship care.
* Improved clinical guidelines and policy recommendations with respect to palliative, end-of-life or survivorship care of patients with life-threatening non-communicable diseases or afflicted by late and long term side-effects of treatments.
* Improved quality, effectiveness and cost-effectiveness of palliative, end-of-life or survivorship care services as well as access to care.
* Reduced economic and wider societal burden arising from increased numbers of patients in need of palliative, end-of-life or survivorship care.

Type of Action: Research and Innovation action

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

SC1-BHC-25-2019 (ex-35): Demonstration pilots for implementation of Personalised Medicine in health care

Specific challenge:

Personalised medicine (PM) has the potential to respond to, among others, the increasing burden of co-morbidities and thus enhance the sustainability of health and care systems. With the increasing number of scientific approaches available, it is crucial to demonstrate the benefit of large scale employment of personalised medicine to citizens and healthcare systems. This was also one of the conclusions of Personalised Medicine Conference 2016 (<http://ec.europa.eu/research/conferences/2016/permed2016/index.cfm>).

Scope

The pilots should demonstrate the technical feasibility and economic viability of personalised medicine in real life healthcare settings. The pilots should be tailored to the needs of citizens, making use of a wide variety of data and proposing prediction, prevention or treatment solutions, focussing on major diseases with high burden to the society and including multi-morbidity conditions if relevant. The selected project(s) can build on results of projects on patient stratification funded under EU framework programmes (including from IMI and the SME instrument). The use of big data approaches and high performance computing is encouraged. The applicants should ensure coordination with national, regional or local authorities engaging in health care environments and should aim at linking different institutions (hospitals, other healthcare facilities, public health authorities, payers etc.). The pilots should engage partners in regions or cities having adopted or that are in advanced planning for introducing PM approaches, with partners in less advanced locations. Furthermore, EU 13 partners as well as patient representatives should be involved. The applicants should address the health economic, ethical, legal and societal aspects of the proposed action. Clinical trials as well as projects with primary focus on cancer or rare diseases are excluded from the scope of this topic.

The Commission considers that proposals requesting a contribution from the EU of between EUR 15 and 20 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact

* Evidence for a PM-based model of care that can be used as a basis for the delivery of new ways of care organisation.
* Demonstration of the viability and feasibility of PM approaches at a large scale.

Type of Action: Research and innovation action

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

SC1-BHC-26-2018 (ex-36): HTA research to support evidence-based healthcare

Specific challenge:

Health technology assessment (HTA) is gaining increasing importance across Europe and the world as a tool to support evidence-based decision-making in healthcare. HTA aims to assess the added clinical/therapeutic value of a new health technology compared to the existing standard of care, under the usual circumstances of healthcare practice (relative effectiveness assessment). HTA can also assess additional aspects of added value (e.g. economic or organisational), depending on the specific context in which it is used.

European collaboration on HTA has increased in recent years, notably in the context of EU-funded projects[[39]](#footnote-39), including work towards shared methodologies and the joint production of relative effective assessments. Despite recent progress, a number of methodological challenges remain in the field of HTA. This includes a need for methodologies that address the specificities of particular types of health technologies[[40]](#footnote-40) and their increasingly combined use in healthcare. Better methodological agreement is also needed in particular therapeutic areas, including on important aspects of relative effectiveness assessment such as health outcome measures. Moreover, there is a need to resolve methodological issues related to the use of "real-world" data, to inform the assessment of effectiveness under the usual circumstances of healthcare practice.

Thus the challenge is toaddress these complex issues and needs, by bringing together methodological expertise from across the various relevant research communities. Such a collaborative effort should draw on the best available expertise and latest evidence, in order to develop methodological approaches that are scientifically sound, fit for purpose and fit for the future. Increased methodological collaboration across Europe should also strengthen synergies between HTA, evidence generation and clinical guideline development, promoting the common objective of evidence-based healthcare.

Scope:

Proposals should develop new or improved methodological approaches and frameworks, and foster methodological consensus-building, to address all of the following areas:

* Specific types or groups of health technologies: Help adapt existing HTA frameworks to reflect the specificities of particular types of health technologies2 for which HTA is currently less established but gaining importance. Particular consideration should be given to the increasing role of combinations of technologies, co-dependent technologies (e.g. companion diagnostics) and personalised medicine[[41]](#footnote-41)in healthcare.
* Selected therapeutic areas: The focus should be on therapeutic/disease areas where new products frequently face challenges in HTA, but a high unmet medical need persists. Methodological work and consensus-building should be aimed at key issues for relative effectiveness assessment, such as patient-relevant health outcomes, appropriate outcome measures, clinically relevant patient subgroups, and the current evidence-based standard of care. With regard to patient-relevant health outcomes, patient preferences and patient-reported outcome measures (PROMs) should be taken into account. Particular consideration should be given to strengthening synergies between HTA and clinical guideline development, with a view to more consistent reporting on the clinical/therapeutic value of health technologies.
* Use of real-world data: Methodological work should address current concerns and uncertainties around the quality and suitability of real-world data (e.g. from diseases-specific registries and routine healthcare databases) for relative effectiveness assessment in HTA, including considerations for data collection and analysis[[42]](#footnote-42).
* Implementation: In all of the above areas, part of the efforts should be directed at implementation of methodological work, using e.g. case studies or pilots. Involvement of HTA bodies in all of the above areas should ensure that the needs of HTA practitioners are addressed and uptake in HTA practice is facilitated.

The proposed consortium should bring together partners with the relevant expertise for addressing the above-mentioned areas. This includes researchers from e.g. academia, HTA bodies, regulators, centres of expertise for clinical research and care[[43]](#footnote-43), scientific and medical learned societies, and organisations involved in developing evidence-based clinical guidelines and systematic reviews in healthcare. The consortium should also seek input from relevant stakeholders such as patients, technology developers, healthcare providers and payers.

Proposals should complement or build on existing work, including results of EU-funded projects in the field of HTA1. The consortium should closely liaise with EUnetHTA[[44]](#footnote-44) and create synergies with ongoing EUnetHTA activities.

The Commission considers that a proposal requesting an EU contribution between EUR 8 to 10 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. Should more than one proposal be selected, applicants are expected to collaborate and this should be indicated in the proposal.

Expected Impact:

* New or improved methodological approaches, frameworks and consensus-building mechanisms to address the above-mentioned challenges for particular types and groups of technologies, therapeutic areas and real-world data use in HTA
* Strengthened methodological quality of HTA by input of specialist expertise from the broader scientific, clinical research and evidence-based healthcare community
* Improved methodological agreement between HTA researchers across Europe, increasing the impact of HTA on evidence generation, clinical guideline development and evidence-based healthcare
* Contribute to strengthening EU cooperation on HTA

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

SC1-HCO-12-2018 (ex-CSA4): Innovation in health care - towards using pre-commercial procurement and public procurement of innovative solutions in health care systems

Specific Challenge:

Implementation of timely and correct *diagnostics for infectious diseases* that will speed up the identification of the causative infectious disease pathogens, resistance and drug susceptibility is crucial for tailoring the antimicrobial treatment to ensure appropriate antimicrobial drug use and to reduce unnecessary prescriptions. As innovative rapid diagnostics are significantly more expensive than culture-based diagnostics that are widely used since decades, the uptake of these new tests in hospitals and especially primary care centres has been limited. To respond to this clinical and public health need and facilitate the uptake of innovative rapid diagnostics for infectious diseases into healthcare practice, contracting authorities can act together to create demand for such innovations through public joint procurement.

Other types of innovative solutions for health care have the potential to improve patient care in European health care setting. Integrated care[[45]](#footnote-45) 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 join forces and create demand for such innovations through public joint procurement, serving the triple aim of healthcare: better care experience, better care outcomes, and more efficient care.

However, before joint innovation procurement can be undertaken, first the cross-border cooperation between interested healthcare procurers must be established to counter fragmentation of delivering innovative diagnostics in healthcare settings.

Scope:

The objective of this action is to create a European-wide consortium of health care providers and public procurers in the healthcare sector that define together unmet procurement needs to implement innovative solutions in health care.

The consortium should prepare procurement topics to conduct:

* A PPI to implement rapid diagnostic tools for infectious diseases in clinical practise (at least 1 topic). To assure the compatibility and interoperability between infectious disease diagnostics and avoid technological standardisation issues, public health sector procurers that participate in this CSA should also develop specifications that are suitable for European wide deployment of the innovative diagnostics.
* One or more PCPs to drive the shift towards health systems reform. Clinicians, patients, public procurers in health care systems, health care facility managers, and health insurers/payers should work jointly to identify the gaps and needs that will lead to the development of new innovative solutions for patient-centred integrated health care.

Activities supported by this CSA should include primarily the preparation of innovation procurement topics. Further activities should include the organisation of an open market consultation, consultation with relevant stakeholders (diagnostic companies, clinicians, hospital lab personnel), performance of a market analysis, to gather all input needed to prepare the procurement topics. Interaction with HTA/Reimbursement bodies is also recommended to prepare the ground for a future market uptake of the solutions.

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

The proposal for a CSA should follow the specific requirements for innovation procurement (PCP/PPI) supported by Horizon 2020 grants as set out in Annex E of the WP.

Expected Impact:

* Improved networking of health care providers and public procurers in health care systems to identify stakeholders and specifications for a strategy to launch procurement for innovative diagnostics for infectious diseases, and for innovative solutions in integrated care.
* Optimised procurement strategy for innovative infectious disease diagnostics and for innovative solutions in integrated care.

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

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

1.5 Decoding the role of the environment for health and well-being

***Mission statement:***

This priority will assess how factors external to the human body and to health and healthcare systems impact human health and well-being, including the related socio-economic impacts. This priority will address three main items: (i) the development of the 'human exposome', allowing the assessment of the totality of the life-long environmental influences that individuals are exposed to and their health impacts; (ii) the development of new testing and screening methods to identify endocrine disrupting chemicals; (iii) the assessment of how global environmental changes, including climate change, may affect health, health and care systems. This priority contributes to the implementation of the SDG, in particular SDG3, [the Ostrava declaration on environment and health](http://www.euro.who.int/en/media-centre/events/events/2017/06/sixth-ministerial-conference-on-environment-and-health), EU chemical policies and global efforts to combat climate change. Where appropriate, this priority will create links to the [European Human Biomonitoring Initiative (HBM4EUI)](https://ec.europa.eu/research/conferences/2016/hbm4eu/index.cfm).

The expected impact of this priority is to reinforce health and wellbeing as a strong driver for societal and political changes needed in support of a sustainable society. This priority will provide tools and evidence enabling new approaches to estimation of environmental burden of disease through actions cutting across different policy areas. In addition, it will reinforce the evidence base for preventive actions through new knowledge about the influence of environmental factors, including endocrine disrupters, on human health.

Proposals are invited against the following topic(s):

SC1-BHC-27-2018 (ex-2): Endocrine disrupters – research for better regulation and improved understanding of health effects

Specific Challenge:

There are a variety of natural and anthropogenic chemicals that can produce adverse effects via a disruption of the body's endocrine (hormone) system, referred to as endocrine disrupters (EDs)[[46]](#footnote-46). EDs are of increasing importance in chemical regulations in the European Union, and draft criteria to identify EDs have recently been proposed for two pieces of EU legislation (Biocidal Product Regulation and Plant Protection Products Regulation)[[47]](#footnote-47).

In the EU, the legislation regulating chemical substances often includes their screening and testing according to the EU test methods regulation[[48]](#footnote-48), which predominantly contains test methods developed under the OECD[[49]](#footnote-49). Despite the progress achieved on the development of methods for evaluating EDs, gaps and weaknesses are still found in the current approaches to screening and testing. The current testing tools, either regulatory in vivo tests or novel in vitro assays, do not appropriately identify effects related to certain less studied endocrine-mediated pathways or health outcomes, in which EDs have been implicated. Moreover, the proposed new ED criteria require research into both the adverse effects and the way in which the adverse effect arises which can be described via the adverse outcome pathways (AOPs). New and improved approaches are needed to increase the quality and efficiency of existing methods to meet demanding and evolving regulatory requirements worldwide. Information is also needed as regards how epidemiological and field monitoring data, which are also to be considered as data sources in a regulatory context, can be used to support associations between levels of exposure to specific chemicals and ED-related effects.

Scope:

In consultation with relevant regulatory bodies, research should improve and harmonise screening and testing protocols/strategies and hazard/risk assessments with better and faster tools, methods or models, including high-throughput and *in silico* methods combined with research on adverse outcomes pathways. Focus should be on the most urgent regulatory needs, e.g., methods addressing the thyroid axis, female reproduction, non-genotoxic carcinogens and developmental neurotoxicity. Proposals should involve, in addition to academic researchers, regulatory agencies and other actors as appropriate. International cooperation is essential. Proposals are required to describe how they will contribute to ongoing international ED related activities (e.g. OECD work, EU level databases), including decision schemes under development. To speed up regulatory uptake of test results, validation is an essential step to be considered.

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

An overall coordination mechanism between the projects funded will be required and will be added at the grant preparation stage to all selected proposals as a common work package.

Proposals could consider the involvement of the European Commission Joint Research Centre (JRC) as an added value in order to provide an effective interface between the research activities and regulatory aspects and/or to translate the research results into validated test methods and strategies fit for regulatory purpose. In that respect, the JRC will collaborate with any successful proposal.

Expected Impact:

* Improved hazard and risk assessment of EDs, including in the workplace
* Novel ED assay candidates for regulatory use
* Enhanced international cooperation and support for the OECD work on testing and assessing chemicals for ED activity
* Contribution to the development of an international strategy and guidelines for testing EDs and assessing associated hazard

Type of Action: Research and Innovation action

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

SC1-BHC-28-2019 (ex-9): The Human Exposome Project: a toolbox for assessing and addressing the impact of environment and climate change on health

Specific Challenge:

Despite the general acknowledgement by the scientific community that *'Genetics load the gun but environment pulls the trigger*'[[50]](#footnote-50) when it comes to the causation of major non-communicable diseases (NCDs) such as obesity, diabetes, diseases of the cardiovascular and nervous systems and cancer[[51]](#footnote-51)**,** there is persistent uncertainty as to the global burden of disease attributable to environmental (including life-style) factors. Healthcare costs and negative economic impact attributable to environmental influences are large based on current estimates by WHO[[52]](#footnote-52) and others. Deciphering the human exposome is a novel way of addressing the challenge to improve health and reduce the overall burden of disease. This will require improved knowledge of health risks, including combinations of several risk factors and the mechanisms in which they affect health at different stages throughout the life course. Effective preventive action will need to be designed, building on knowledge of various risk factors including individual behaviour and the social context, taking into account gender issues.

Applying the exposome[[53]](#footnote-53) concept to environmental health research would present a fundamental shift in looking at health, by moving research away from ‘one exposure, one disease’ understanding to a more complex picture upon which to build solid, cost-effective preventive actions and policies in the future. It would respond to the need for more complete and accurate individual-level exposure data in order to estimate the largely unknown environmental component of NCDs.

Scope:

Taking into account ongoing pilot actions, applicants will develop an ambitious multi-component Human Exposome Project. The project will innovate environmental health sciences in the next decade by forcing a paradigm shift beyond the understanding of the genome, to decipher the role played by the multitude of external exposures we are confronted with in our daily life. It will take advantage of the last decade's rapid technological advances which have opened up new opportunities to collect, combine and analyse large data sets offering new possibilities to understand the contribution of environmental factors to the global health burden of common chronic diseases. Proposals should apply science-based innovation to the systematic and agnostic identification of the most important environmental risk factors for the development of major NCDs across the life course, leading to preventive interventions at the individual, group or population level and contribute to sustainable health care. Well-designed epidemiological studies combining retrospective and prospective studies (e.g., European-wide exposomics cohort and biobank if required), integrating behavioural and socio-economic factors and linking to clinical records and archived biopsies, can be included.

The project will advance our knowledge on the human exposome project by pursuing two tracks in parallel, open in two consecutive years.

In 2019 developing a toolboxof innovative approaches, technologies and methods to develop exposomes across the life course, including: Agnostic evaluation of the role of multiple and unknown exposures; Improved assessment of individual exposure to multiple environmental stressors; Enhancement of sensors that combine external exposure and health data measurements; Integration of external exposome data with cross-omics responses and (epi)genetic data across multiple (including already existing) studies; Systematic evaluation and simulations of the health impacts of the multiple exposures contained in the exposome; Socio-economic modelling and econometric analysis; Better data mining tools, including statistical analysis and high-performance/high throughput computing and storage; a long-term host and a single shared data infrastructure, ensuring open access to data generated.

Innovation and connection with industry are expected in the areas of sensor development (external exposome), omics technology and novel biomarker development (internal exposome), bioinformatics, and data processing and management. Proposals are expected to respond to a persistent or long-standing policy/regulatory need where the exposome approach would be useful to solve a scientific issue to underpin better regulation now or in the future (examples: indoor air quality, waste).

The Commission considers that a proposal requesting an EU contribution between EUR 8 to 12 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:

* Innovation in environmental health sciences, in particular for external and internal exposure assessments and data management;
* Enable researchers and policy makers to continuously include new knowledge in the policy making processes by using the toolbox to generate data and information.
* Better prediction of disease risk by acquisition of new knowledge on the influence of external exposures on biological pathways at different life-stages and identification of early signs of health damage caused by environmental factors;

Type of Action: Research and Innovation action

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

SC1-HCO-13-2018 (ex-CSA8): Setting the Priorities for the European Environment and Health Agenda

Specific Challenge:

Environment and health research is wide in scope and multidisciplinary, and the related policies and regulations are spread across different sectors and organisational structures. In Europe, in addition to the specific policies in sectors such as air and water quality, noise or chemicals, there are currently two overarching policy programmes governing environment and health: the Seventh Environment Action Programme to 2020 and the WHO-led European Environment and Health Process taking place in the context of the United Nations Agenda 2030 for Sustainable Development[[54]](#footnote-54). The next milestone as regards these programmes will be the meeting of the Environment and Health Ministers of the WHO European region in June 2017 (Ostrava, Czech Republic), setting out the policy and research priorities for years to come[[55]](#footnote-55). In order to respond to the new and continuing challenges in environment and health in the next decade, identified in these and other policy programmes, increased coordination and cross-fertilisation of ideas between sectors is required, which would raise the visibility of the work undertaken, introduce a more strategic approach and thereby optimise and add value to the H2020 and the next framework contribution to the European environment and health process and policy activities.

Scope:

The aim is to establish a research/policy coordination group consisting of relevant science and policy actors in environment and health from H2020-funded activities and national/EU regulatory bodies as well as main international actors such as WHO and OECD. The objective is to identify proactively key policy areas requiring scientific support for environment and health related issues in the next decade and develop a European medium-term research and innovation strategy and agenda covering key strategic research and policy aspects – from causality research and new technologies and approaches to evaluation of socio-economic impacts of environment and health problems and preventive actions. The strategy is to be accompanied by a set of guidelines, agreed by the stakeholder community, reflecting the current state-of-art for health impact and risk assessment of environmental factors applicable across key sectors. The action is invited to structure its work in an inclusive way ensuring the engagement of all stakeholders including from European countries with less developed environment and health research and policy. The proposal should contain a clear work plan for 3 years, but be open for modifications required to meet the needs of the relevant policy processes (e.g. development of the next framework programme, WHO environment and health process).

The Commission considers that proposals requesting a 3 years duration and requesting an EU contribution between EUR 1.5 to 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts

Expected impact:

* Development of a research and innovation agenda for the environment and health nexus as input to the next framework programme
* Contribution to the European WHO environment and health process and the implementation plan resulting from the Ostrava Ministerial Declaration
* Increased coordination between environment and health projects supported across H2020 sectors and development of a cross-cutting stakeholder community
* A set of guidelines for evaluating the socio-economic impact of environmental influences on health and wellbeing recognised by the international community

Type of Action: Coordination and Support Action

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

Conditions for the Call – "Better Health and care, economic growth and sustainable health systems"

Opening date(s), deadline(s), indicative budget(s):[[56]](#footnote-56)

|  |  |  |
| --- | --- | --- |
| Topics (Type of Action) | Budgets (EUR million) | Deadlines |
| 2018 | 2019 | 2020 |
| Opening: 01 Feb 2018 |
| SC1-BHC-03-2018 (RIA) | 50.00 |  |  | 01 Oct 2018 |
| SC1-BHC-04-2018 (EJP) | 50.00 |  |  |  |
| SC1-BHC-05-2018 (RIA) | 40.00 |  |  |  |
| SC1-HCO-01-2018-2019-2020 (CSA) | 6.00 |  |  |  |
| SC1-HCO-02-2018 (CSA) | 2.00 |  |  |  |
| SC1-HCO-04-2018 (ERA-NET-Co-Fund) | 5.00 |  |  |  |
| SC1-BHC-09-2018 (RIA) | 50.00 |  |  |  |
| SC1-HCO-05-2018 (CSA) | 2.00 |  |  |  |
| SC1-BHC-15-2018 (RIA) | 45.00 |  |  |  |
| SC1-BHC-16-2018 (RIA) | 25.00 |  |  |  |
| SC1-BHC-21-2018 (RIA) | 10.00 |  |  |  |
| SC1-HCO-06-2018 (CSA) | 1.00 |  |  |  |
| SC1-HCO-09-2018 (CSA) | 2.00 |  |  |  |
| SC1-HCO-10-2018 (CSA) | 2.00 |  |  |  |
| SC1-HCO-11-2018 (CSA) | 2.00 |  |  |  |
| SC1-BHC-23-2018 (RIA) | 40.00 |  |  |  |
| SC1-BHC-26-2018 (RIA) | 10.00 |  |  |  |
| SC1-HCO-12-2018 (CSA) | 2.00 |  |  |  |
| SC1-BHC-27-2018 (RIA) | 50.00 |  |  |  |
| SC1-HCO-13-2018 (CSA) | 2.00 |  |  |  |
| Opening: 01 Feb 2019 |
| SC1-BHC-01-2019 (RIA) |  | 70.00 |  | 01 Oct 2019 |
| SC1-BHC-02-2019 (RIA) |  | 50.00 |  |  |
| SC1-HCO-01-2018-2019-2020 (CSA) |  | 4.00 |  |  |
| SC1-BHC-07-2019 (RIA) |  | 50.00 |  |  |
| SC1-BHC-10-2019 (PCP/PPI) |  | 40.00 |  |  |
| SC1-BHC-13-2019 (RIA) |  | 30.00 |  |  |
| SC1-BHC-14-2019 (RIA) |  | 95.00 |  |  |
| SC1-BHC-18-2019 (RIA) |  | 10.00 |  |  |
| SC1-BHC-19-2019 (RIA) |  | 25.00 |  |  |
| SC1-HCO-08-2019 (CSA) |  | 3.00 |  |  |
| SC1-BHC-22-2019 (RIA) |  | 30.00 |  |  |
| SC1-BHC-25-2019 (RIA) |  | 60.00 |  |  |
| SC1-BHC-28-2019-2020 (RIA) |  | 50.00 |  |  |
| Opening: 01 Feb 2020 |
| SC1-HCO-01-2018-2019-2020 (CSA) |  |  | xx.xx | 01 Oct 2020 |
| Overall indicative maximum budget | 396.00 | 517.00 | 10.00 |  |

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

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

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

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

Evaluation Procedure: The procedure for setting a priority order for proposals with the same score is given in General Annex H of the work programme.

The full evaluation procedure is described in the relevant [guide](http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/submit-proposals_en.htm) published on the Participant Portal.

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

Call 2. – Digital transformation in Health and Care

H2020-SC1-DTH-2018-2020

***Mission statement:***

This call aims at supporting the management of health and wellbeing while empowering the participation of citizens and facilitating the transformation of health and care services to more person-centred and community-based care models, thereby enabling better access to healthcare and the sustainability of health and care systems. It is relevant to the Commission priorities 'A new boost for jobs, growth and investment' and 'A connected Digital Single Market', as well as to the European Cloud Initiative and the European Free Flow of Data Initiative. It will contribute to maximising the potential of the digital economy in the health and care sectors. This call will address eHealth, mobile health (mHealth) and Information and Communication Technologies (ICT) for Active and Healthy Ageing.

Proposals are invited against the following topic(s):

SC1-DTH-01-2019 (ex-18): Big data and Artificial Intelligence for monitoring health status and quality of life after the cancer treatment

Specific Challenge:

Currently available methods and strategies for diagnosis and treatment of cancer help clinicians continuously improve quality of care and prevent cancer deaths in the population. Accurate risk assessment, availability of genetic tests, timely diagnosis and effective treatment has created understanding of cancer as a chronic disease that can be cured. However, often rather aggressive treatment, psychological stress (anxiety and depression) can cause physical and psychological problems that may cause long-term after-cure consequences such as similar or other types of cancer, other types of (chronic) diseases and affect the quality of life of a patient. Therefore, the importance of addressing and, if possible, preventing long-term effects of cancer treatment is growing. In addition to patient-reported outcomes such as functional status, symptoms intensity and frequency, multiple domains of well-being and overall satisfaction with life, the use of big data can bring valuable information for monitoring health status and quality of life after the cancer treatment. Information can be collected from traditional sources of health data (comprehensive electronic health records incl. genetic data, validated biomarkers for remission), from rather new sources of health data (mobile health apps and wearables) and from sources that are usually created for other purposes such as environmental data. Big Data can provide new opportunities to define statistical and clinical significance, but present also challenges as it requires specific analytical approaches. It is important to assure ethical aspects of data, confidentiality, anonymity of data transfer and engagement of those who collect / code such data in its analysis and interpretation, in order to avoid misinterpretation and inappropriate conclusions. Involvement of those who work within healthcare systems, patients, family and relatives, and the general public is needed.

Scope:

Proposals should focus and deliver on how to better acquire, manage, share, model, process and exploit big data to effectively monitor health status of individual patients, provide overall actionable insights at the point of care and improve quality of life after the cancer treatment. Relevant solutions include for example systems for determining and monitoring the combined effects of cancer treatment, environment, lifestyle and genetics on the quality of life, enabling early identification of effects that can cause development of new medical conditions and/or impair the quality of life. Proposals are expected to address relevant health economic issues. Integrated solutions should include suitable approaches towards security and privacy issues. The Commission considers that proposals requesting a contribution from the EU of between EUR 3 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

* Mapped comprehensive big data in a reachable and manageable way by applying principles for sharing and reusability, creating a network of knowledge by linking heterogeneous data sources for monitoring health status and quality of life after the cancer treatment;
* Emerging data driven analytics and advanced simulation methods to study causal mechanisms and improve forecasts of ill-health, identification of disease trajectories and relapse;
* Better and faster means of high quality response to prevent or timely address development of new medical conditions and/or improve the quality of life;
* Better knowledge for improved patient counselling as well as to improve follow-up of patients;
* Novel information on health maintenance, onset and course of medical conditions with a view to optimise prevention and treatment;
* Evidence base for the development of policy strategies for prevention, early diagnosis, therapies as well as addressing health inequalities, support to patient registries at national level;
* Improved quality of life after cancer treatment, strengthening personal confidence and enhancing employability;
* Preventative strategies are established which have a real effect of reducing the occurrence of health disorders and co-morbidities associated with cancer treatment.

Type of Action: Research and Innovation action

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

SC1-DTH-03-2018 (ex 21): Adaptive smart working and living environments supporting active and healthy ageing

Specific Challenge:

Demographic change and the ageing of the population create new heterogeneous challenges for age-friendly living and working environments such as a shrinking workforce and increasing numbers of workers with functional impairments, chronic conditions, care duties or re-integration in the labour market.

Digital solutions can support older individuals in being and staying actively involved in professional life for longer by designing fit for purpose working environments and by enabling flexible management of job-, leisure- and health-related activities considering their needs at the workplace, at home and on the move, with a particular focus on social inclusion, health needs and job retention.

Scope:

Proposals should develop and validate digitally enabled adaptive services and solutions leading to smart work environments for older adults, supporting them to remain actively involved in professional life and support independent active and healthy lifestyles while taking into account reduced capabilities due to age-related health risks and conditions.

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

Proposals should convincingly describe the planned progress beyond state of the art in development and integration of unobtrusive, adaptive solutions for age-friendly living and working environments, addressing the needs of employees in specific and various sectors and workplaces[[57]](#footnote-57).

Proposals should build on active user engagement in order to ensure the understanding of user needs, safeguarding ethics, privacy, security and regulatory aspects.

Concepts must aim at realistic and verifiable benefits for flexible and sustainable job longevity measures and the consortium should include the necessary stakeholders to validate all relevant issues. The validation should take place in real settings (at workplaces and at home as required). The approach should demonstrate improvements in quality of life and/or improved health and safety for older adults, better management of aging workforce leading to a win-win for employers and employees, health and social system efficiency gains, business and financing models and organisational changes required for service delivery.

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

Expected Impact:

Proposals should present methodologies and metrics as appropriate for measuring progress with significance towards the expected impact in:

* Independent living and quality of life of older persons compared to current state of the art, enabling older persons to stay actively involved in work life for longer;
* Enhanced health and safety working conditions and quality of life of older persons at work compared to the current situation, enabling older persons to be able to contribute at an appropriate level for a longer period of time;
* Evidence of user-centred design and innovation, new intuitive ways of human-computer interaction, and user acceptance;
* Potential cost-effectiveness due to enhanced self-care, life-style, age-friendly work environments and socio-economic benefits;
* Competitive advantage for European industry through flexible and sustainable work arrangements for an ageing workforce
* Global leadership in ICT based innovation for active and healthy ageing.

Type of Action: Research and Innovation action

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

SC1-DTH-05-2019 (ex 23): Large scale implementation of digital innovation for health and care in an ageing society

Specific Challenge:

An ageing population is increasing demand-side pressures on public health and social care providers across Europe. These pressures undermine the long-term sustainability of existing models for delivering care services to the ageing population.

The challenge is to scale up outcome-based innovative digital health and care solutions across EU borders through joining up actions in procurement of innovation. Digital health and social care solutions which have been tested and have demonstrated success in smaller scale settings are rarely deployed on a large scale across EU borders. There is a lack of collaborative efforts in public purchasing of innovative ICT-based solutions for active and healthy ageing and successfully engaging demand and supply sides in scaling up innovation. This is the case in particular for digital solutions integrating health, social or community care and informal care, IoT enabled independent living solutions that allow the citizens to live safely and independently at home therefore avoiding institutionalisation, or tele-care solutions and tools supporting for self-care and person-centred care. Moreover, take-up of these ICT-based solutions by both public care providers as well as people in need for care is a crucial factor in successfully alleviating the demand-side pressures on public health and care provision.

Scope:

This topic will contribute to the Scaling-Up Strategy[[58]](#footnote-58) of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) and will support the EIP on AHA Reference Sites contribution to the Digital Single Market Strategy. The actions supported will target large-scale deployment of digital health and care solutions at large scale across different regions in Europe. In line with the priority actions of the Scaling-up Strategy, the scope of the PPI pilot(s) is to specify, purchase and deploy ICT based solutions (made up of services and ICT products to enable the provision of services) for active and healthy ageing through a common supply and demand side dialogue, which can deliver sustainable, new or improved health and care services in which public procurement approaches for innovative solutions lead to improved outcomes. Proposals should:

* Be driven by clearly identified procurement needs of the participating organisations and building on a complete understanding of the needs of the ageing population, as well as the needs of the relevant health and care providers;
* Support sustainable deployment of new or improved person-centred and outcome-based services by providers involved in the procurement of solutions for digital health and care providers;
* Contribute to the creation of scalable markets across Europe in innovative solutions for active and healthy ageing;
* Specify measures that will ensure the sustainability of solutions beyond the lifespan of the proposed project;
* Engage public and/or private procurers from each country participating (at national, regional or local level) that have responsibilities and budget control in the relevant area of care or supply of services;
* Be based on a complete set of common specifications for end to end services;
* Demonstrate that the implementation phase will reach "large scale" (i.e. sufficient scale to achieve statistical significance) through region-wide deployment across multiple regions of Europe;
* Contribute to the use of interoperable solutions based on open platforms and take into account existing best practices and standardisation initiatives;
* Provide robust safeguards to ensure compliance with ethical standards and privacy protections and take account of the gender dimension;
* Contribute with good outcome-based practices that are impact measured according to the MAFEIP methodology and can be made available for replication across other regions (e.g. "detailed plans" for larger scale sustainable uptake of innovative solutions for active and healthy ageing, reference material and guidelines, manuals and education materials) through the EIP on AHA innovative practices repository.
* Contribute to the development of national strategies to stimulate the procurement of digital innovation for health and care services based on the outcomes achieved at national level.

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

Expected Impact:

* Growing awareness and successful use of public procurement to boost ICT innovation applied to active and healthy ageing, ultimately benefiting the growing ageing population across Europe;
* Contribution with data and experiences to regulatory and legislative process development addressing potential barriers to procurement of innovative solutions for active and healthy ageing;
* Contribution of an open and comprehensive socio-economic evidence base for ICT investments in the field that can support the development of sustainable business models (e.g. cost-benefit analysis, increased efficiency of health and care systems, impact assessments, return on investments, quality of life improvements for users, ethics, safety gain and user satisfaction);
* Support initiatives on interoperability and standardisation that can contribute to defragmentation of the market for ICT based active and healthy ageing solutions;
* Creation of economic boundary conditions that can support long-term sustainability of health and care systems and emergence of new business models to develop ICT innovation for active and healthy ageing in Europe;
* Support forward-looking, concerted public-sector investment strategies that benefit from joint approaches across different regions;
* Create new opportunities for market uptake and economies of scale for the supply side for ICT based solutions and services for active and healthy ageing in a Digital Single Market for Europe.
* Contribute to inform policy measures that foster the take-up of ICT solutions for active and healthy ageing.

Type of Action: PPI

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

SC1-DTH-07-2018 (ex 30): Exploiting the full potential of in-silico medicine research for personalised diagnostics and therapies in cloud-based environments

Specific Challenge:

The progress in computer modelling and simulation applied in disease management is a European strength and various Decision Support Systems have been developed for different medical disciplines.

While the market is developing today, addressing the need of more precise and personalised diagnostics and treatments, the proposed software tools and platforms often need to further conquer visibility and trust from users and investors to get implemented in the routine clinical practice. The access of researchers to high quality big data and in particular to clinical multi-disciplinary data is crucial for validating the use of new tools and platforms in the right practice context.

Through its initiatives on open data and cloud computing, the European Commission aims at leveraging the potential of big data for the European research and economy. The European Cloud Initiative will facilitate the access of researchers to the newest data managing technologies and to a European Open Science Cloud list of ICT services while ensuring the appropriate data safety and protection.

Shared infrastructures, data and services in open cloud-based environments will stimulate the virtual complex experimentations in medicine and the link between researchers and healthcare practitioners, for their common benefit.

Scope:

Proposals are expected to develop and validate software tools and devices for diagnostic or treatment based on computational modelling and simulation applied in biology and physiology. The solutions should enable decision making in complex situations and contribute to a more precise and personalised management of diseases of high prevalence, including such as cancer.

Computer-based decision making can apply to the choice of drugs, devices or other biomedical products, procedures, interventions, in vitro and in vivo diagnostics methods and tools, or combined diagnostics and treatments. In order to ensure access to large multi-disciplinary high quality data sets and diminish the shortage of relevant data, the teams are expected to use shared infrastructures and e-infrastructures, building on existing capacity and expertise and linking where possible with the European initiatives that manage databases relevant for personal health, such as BBMRI, ELIXIR or EATRIS. They need to demonstrate access to the sufficient and relevant clinical data needed for advanced validations that can bring the technology at a TRL level higher than 6. Teams are encouraged to use EOSC services as appropriate and possible.

The Commission considers that proposals requesting a contribution from the EU of between EUR 10 and 15 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

* Better translation of big and multi-disciplinary data into predictors for medical outcome and personalised decision making;
* New digitised trusted diagnostic and treatment tools, and contributing to digitising clinical workflows;
* Improved disease management, demonstrated in the specific disease context;
* Links to other European research infrastructure projects and networks operating in related domains;
* Contribution to the European Cloud vision;
* Better data quality, interoperability and standards.

Type of Action: Research and Innovation action

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

SC1-DTH-08-2018 (ex 31): Piloting a cloud-based standardised Personal Health Record/Electronic Health Record for Europe

Specific Challenge:

Large amounts of valuable health data are created in personal and electronic health records (PHR and EHRs) during and between routine patient visits across Europe. However, opportunities to reuse these data for clinical research and public health are often missed because health data continue to be confined in data silos, ignoring semantic standards and safe data exchange techniques. With 24 official languages spoken across EU Member States, the EU eHealth interoperability task is even more daunting. In order to fully unlock these sources of value, effort must be invested in standardisation (including common clinical models, tools and norms), privacy and security (including data access and data integrity) and communication (towards patients and healthcare providers) to allow patient empowerment, advance medical science and improve health for everyone. Cloud-based infrastructures are nowadays mature enough to host PHR and EHR services that can extend the healthcare continuum across borders and possibly embrace social care as well as wellness data storage services. This innovation action aims at providing a cloud-based standardised PHR/EHR infrastructure at European level.

Scope:

This innovation action is expected to demonstrate on a large scale the feasibility of (i) the cross-border mobility of European patients data by offering to each European citizen the ability to build throughout their lifespan a comprehensive, easy-to-use and secure personal health record, constantly accessible and portable within any other Member States of the EU and (ii) a data-driven cloud platform to help the research community to benefit from user generated data (health, care and wellness) based on state of the art standards and technologies.

The proposal shall demonstrate its ability to:

* Ingest large data sets in real time or in batch mode, including multilingual text and binary data
* Ensure the translations, mappings of source information towards the clinical/database models while using appropriate standards and semantic services
* Ensure scalability and performance of the cloud services
* Ensure data and metadata quality and curation to provide analytics and reporting capabilities
* Provide rigorous security mechanisms such as identification, authentication and encryption services to allow secured data access and privacy, for example building on distributed ledgers such as blockchain
* Provide patient data import/export capabilities through a secured API
* Ensure patient/citizen consent and opt-in processes are properly undertaken in order to allow the secondary use of data for research and public health purposes
* Provide anonymisation/pseudonymisation capabilities to allow open access to health data for research and public health purposes
* Ensure the proper and legitimate governance of the platform, ensuring the privacy and confidentiality of all patients/users at all time
* Ensure compliance with relevant EU legislation, in particular REGULATION (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data

This cloud infrastructure and services should be primarily focused on patient's data generated by the citizens themselves, healthcare professionals or sourced from relevant healthcare organisations. It shall include relevant components to enable further clinical purpose and medical research. This cloud-based infrastructure should also be extensible so as to be able to integrate subsequent types of data such as quantified-self data or genomic data.

The consortium shall cover a wide range of relevant stakeholders with multi-disciplinary expertise in technology, health and care, legal, social and ethical aspects, standardisation and user engagement. It shall demonstrate its ability to deliver a large scale cloud infrastructure, ensure the availability of large scale datasets with a proven track record of successful implementations. Participation of Industry and Public health organisations is encouraged in the most appropriate phases of the project.

The design of the platform should be user driven as to ensure the early buy-in of final users (from patients to healthcare professionals and researchers). Additionally, a targeted communication and education campaign with reference material should be produced to explain the functioning and purpose of the infrastructure (from empowerment of the patient to the contribution to research) and incentives should be provided to users to accelerate the take-up and sustainability of the platform. Proven state of the art processes and structures shall be reused as appropriate and synergies with other relevant programmes and policy initiatives in Europe shall be explored.

Expected Impact:

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

* Standards for trusted and interoperable health data access across Europe for patients and healthcare providers
* Improved quality of care resulting in enhanced patient safety
* Improved efficiency gains in term of timeliness of intervention
* Extended healthcare continuum across borders
* Improved collection and re-use of a large data sets for research in health and care
* Quality PHR/EHR system for under-resourced groups within the EU
* Open, extensible and standards-based PHR/EHR solution for app developers
* Easy and safe for patients to donate their data for research

Type of Action: Innovation action

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

SC1-DTH-09-2019 (ex 32): Scaling up the univocal Identification of Medicinal Products

Specific Challenge:

Across the European Union, medicinal products display differences in names, variations in strength or their package size. The unavailability of a specific product may also necessitate substitution in many instances, if a patient is to be timely served in a pharmacy. Moreover, due to differences in marketing authorisation procedures, not every medicinal product is available in each Member State, and it is not unusual that the same product may have different names across Member States or the same name may identify a different product in another Member State. As substitution is regularly necessary to dispense a foreign ePrescription (eDispensation), a univocal identification of medicinal products would enable and enhance the dispensation of a foreign ePrescription and would provide benefits to patient health, patient safety, pharmacovigilance and would also allow better data analysis of clinical records. Most national ePrescription and medicines databases are not currently supporting relevant identification attributes and codes. As the EU-wide implementation of ISO IDMP (identification of medicinal products) standards is currently under way by the European Medicines Agency (EMA) and the EU Regulatory Network to comply with the EU Pharmacovigilance legislation, this action aims at enabling and fostering the use of a common EU medicinal Product repository (ISO IDMP compliant) to fulfil the ePrescription/eDispensation in a cross-border setting use case. This will provide a univocal identification of medicinal products across Europe and potentially beyond.

Scope:

This innovation action is expected to support two goals: (i) the cross-border mobility of European patients by offering safer eDispensations across borders, (ii) the implementation of the IDMP standards in Member States drug databases (including a possible linkage to the EU SPOR - Substance, Product, Organisation and Referential master data database) allowing the identification of locally available medicinal products which are equivalent to the one identified in a foreign prescription.

This requires creating an EU ePrescription/eDispensing approach to use the future EU SPOR database. A common approach and operating model needs to be developed, including common processes for validation of contents, error mitigation, linkage of the EU SPOR database with the ePrescription/eDispensing systems, updates and mappings to other systems for at least 5 Member States' organisations. Harmonisation guidelines of prescribing and dispensation practices in a cross-border setting could be a further focus.

The proposal shall demonstrate its ability to:

* Define the additional quality criteria, processes, actors, risk minimisation measures and safety nets to be applied to the data coming from the EU SPOR database to ensure that the data can be safely used by the ePrescription/eDispensing systems and any harm to patient is avoided.
* Define and implement APIs or use the ones that will be provided by the SPOR system) for data retrieval/view
* Ensure the quality of data, usability of data for national agencies, determine and support the implementation and validation of adaptations needed at national or regional levels
* Improved pharmacovigilance, inclusion of pharmacovigilance modules capable of reporting adverse drug reactions to relevant regulators using the format defined by the ISO ICSR (Individual Case Safety Report) standard into clinical software systems, validation and diffusion
* Establish a Working Group of European medicinal products database producers to support the implementation of the IDMP standard
* Raise awareness and ensure coordination of pre-competitive activities, cooperation with EMA and the EU Regulatory Network (e.g. national competent authorities), and other relevant stakeholders (producers of ePrescribing, clinical record systems)
* Raise awareness and explore benefits for both regulatory and clinical contexts, use cases for public health, big data
* Disseminate to clinical actors (prescribers, physicians, nurses) the ISO IDMP data base contents, usage, value generation and relevance for integrated care
* Contribute to EU-US Trans-Atlantic cooperation and trans-border medicinal products data access and exchange (semantic interoperability)
* Ensure compliance with relevant EU legislation, in particular REGULATION (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data
* Contribute, where relevant, to the sustainability and diffusion of CEF eHealth services

It is expected that Members of the Consortium shall include a wide range of relevant stakeholders and experts including inter alia National Competent Authorities, IT Integrators, producers of ePrescribing, clinical record systems, SDOs. It shall demonstrate its ability to deliver large scale implementation and coordination of European projects. Participation of Industry is encouraged in the most appropriate phases of the project.

The work shall also provide an assessment of impacts based on benefits and costs to be anticipated. This should include not only regulatory impact, but also impact on setting global standards and best practice, and impact on clinical data quality and interoperability along with the spill-over effects on pharmaceutical companies, data base producers and competitive advantage of European companies.

Synergies with actions and activities supported by different programmes and policy initiatives of the Commission should be encouraged and resources from previous European projects should be considered.

Expected Impact:

* Design and implementation of an IT solution based on the EU SPOR database to support ePrescribing/eDispensing in a cross-border setting is designed and implemented
* Better health data access across Europe for patients and healthcare providers
* Improved quality of care resulting in enhanced patient safety
* Improved efficiency gains in term of timeliness of intervention
* Extended healthcare continuum across borders
* Collection and re-use of a data set that is sufficiently large to detect (statistically) significant findings
* Provision of medicinal products information for under-resourced stakeholders

Type of Action: Innovation action

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

SC1-DTH-10-2019-2020 (ex 33): eHealth 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 utilisation 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.

Scope:

Support the health and care service provider to procure the development and testing of digital services and communication concepts 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. Key challenges that could be addressed are patient empowerment, self-management and safety, chronic disease management, diagnosing, hospital logistics, skills and independent living. This should result in early adoption and demonstration of the potential for scaling-up the services and positive impact.

Proposals should deliver and:

* be driven by clearly identified procurement needs of the buyers group;
* 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;
* 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 robust 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 made available by the Commission are strongly recommended to be used in particular as concerns the call for tender).

The procurers, hospital clusters and other parts of the regional ecosystems should be enabled to share knowledge, test results and needs to better coordinate the primary and community care towards more 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 but small or medium sized 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 proposal should include the methodology foreseen to measure progress towards the key performance areas of quality of care, sustainability and economic value within the selected key area of intervention, see e.g. MAFEIP[[59]](#footnote-59).

The Commission considers that proposals requesting a contribution from the EU of around €4-5M would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

* 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.
* 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: PCP

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

SC1-DTH-11-2019 (ex 39): Large Scale pilots of personalised & outcome based integrated care

Specific Challenge:

Senior citizens are statistically at greater risk of cognitive impairment, frailty and multiple chronic health conditions with consequences for their independence, their quality of life (and the one of their families) but also for the sustainability of health and care systems. There is also increasing evidence that interactions with the environment play an important role in the evolution of the patient's health status and condition. The challenge is now to foster secure, scalable and robust digital solutions for integrated care which will:

* Ensure a truly personalized delivery of health and social care, whilst supporting outcomes-based significant efficiency gains in health and care delivery.
* Promote a shift towards outcome-based delivery of integrated care, which can be realised in a realistic operational, organisational and financial setting.
* Ensure trust of users and policy makers with regard to data access, protection and sharing.
* Design flexible but replicable solutions with a potential for financial sustainability, large scale deployment and further business and job creation opportunities.

Scope:

The scope of this topic is to foster the large-scale pilots for deployment of trusted and personalised digital solutions dealing with Integrated Care, with a view to supporting and extending healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities. This in turn is expected to contribute to a patient-centred and truly individualized strategy in order to develop trusted, robust and financially sustainable services potentially useable in any Member States, and applicable to a very wide range of patient pathways.

Expected outcomes are in priority:

* Efficiency gains in terms of resource utilization and coordination of care.
* Flexibility and replicability of service delivery patterns to combine personalization and large scale adoption.
* Ensuring secure and efficient sharing and processing of all data and information involved in the supply chain at each step of data stream: access, protection, sharing, processing and storage.
* Improvement of quality of life for the patient and his/her family and also of working conditions of all health care and social care providers involved in the supply chain, taking into account multi-disciplinary environment and constraints. Working conditions of professionals must cover in priority: work time management, quality of data/information exchange and multi-disciplinary coordination.

Expected Impact:

Proposals should provide measurable progress towards:

* A common vision of technical prerequisites and framework to ensure users trust with regard to health and social data and information in IT supported environment, in line with existing EU data protection regulation (and if required with EU reflection on platforms).
* An evidence-based minimum data set on key points of the pathway:
	+ Clerical information: complete definition
	+ Clinical information: generic definition.
* Harmonisation, certification, approval labelling or reliable identification of adequate solutions for integrated care.
* Robust and reliable and replicable business models for IT supported solutions in a truly personalized and multi-disciplinary environment.

Outcome indicators should contribute to the assessment of the whole topic regarding trust, recruitment, added value for the patient (in terms of quality of life) and cost-efficiency altogether.

* Recruitment of professionals will be measured by the number of professionals registered as actual used compared with the number of professionals actually registered in the pilot site region
* Quality of life should be measured on the basis of commonly used questionnaires (like SF36) but also if required on the basis of specific disease-oriented measurement tools.
* Measurement of cost-efficiency should be measured on the basis of work time information dedicated to each patient.

Type of Action: Innovation action

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

SC1-HCC-01-2018 (ex CSA 13): Supporting investment in smart living environments for ageing well through certification

Specific Challenge:

The building stock in Europe today is not fit to support a shift from institutional care to the home-based independent living model for the ageing population.

There is a recognised need to facilitate the development of community-based services and to stimulate the emergence of "age-friendly home" conversions. These homes should enable independent living and remote health monitoring to the growing ageing population. In addition to physical / spatial alterations, making homes age-friendly should include upgrading existing ICT infrastructure to support digital services for independent living and connected care including telehealth and telecare, as well as solutions supporting health status and healthy lifestyle (e.g. sensor based physiological measurements, mHealth apps, telepresence, robotics supported living). Ideally, these ICT upgrades for independent living and health status management could be combined with the needs related to energy-efficiency, security, and entertainment.

Despite its proven potential for systemic change, large-scale investment (both public and private) in sustainable homes still faces barriers, often caused by insecurity about personal, societal and financial returns on investment and a lack of clarity about concrete elements of sustainable age-friendly living environments and the choice of building, retrofitting and adaptation measures to be implemented.

Coordination and support is needed to develop a sound basis for safe investment decisions in smart age-friendly, adaptable living environments made by procurers, public authorities, industry and citizens.

This must be achieved by bringing stakeholders together, synthesising innovation from European projects, aligning (emerging) national schemes and facilitating development and exchange of best practices.

This CSA shall aim to support the establishment of a European reference framework for age-friendly housing and shall build on the ongoing work in the emerging stakeholder-driven Reference Framework for Age-Friendly Housing and the smart living environments for ageing well as demonstrated in the Large-Scale Pilot on Internet of Things.

Scope:

The action will consolidate knowledge from related projects and initiatives to identify the most appropriate scheme for harmonisation, certification, approval labelling or other forms or reliable identification of adequate smart living environments for ageing well, including indicators and good practices.

In a coordinated effort with relevant R&I projects, national initiatives and other stakeholders (among them national schemes, procurers, civil society representatives, building and ICT industry), the scheme shall be developed and agreed for adoption.

Tasks include:

* Frequent exchange with relevant R&I projects which can contribute to certification, especially large-scale pilots on Internet of Things and other projects in the fields of independent living and ageing well
* Providing an overview of relevant standards
* Development of a comparative overview of several certification or labelling schemes with their respective advantages and disadvantages
* Development and validation of a full concept of European certification scheme based on results of comparison and validation
* Quality and risk management concept for sustainability and further development of the proposed scheme
* At all stages, the CSA must take into account outcomes of the working groups around the European Reference Framework on Smart Age-Friendly Housing and ensure that its subject and conclusions align with the framework.
* It will support the delivery on the Commission's commitment to Leadership in the Internet of Things as described in the Communication "Digitising European Industry - Reaping the full benefits of a Digital Single Market", particularly in the field of smart living environments.

Expected Impact:

* Agreed scheme for European certification with potential for wide-spread adoption across Europe;
* Adequate basis for investment decisions in smart living environments for ageing well (both private and public) based on expected returns;
* Proof of increased investment into building stock fit for the longevity challenge, i.e. to move from institutional care to the home-based independent living model for the ageing population.

Type of Action: Coordination and Support action

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

SC1-HCC-02-2019 (ex CSA 14): Support for the large scale uptake of open service platforms in the Active and Healthy Ageing domain

Specific Challenge:

In the past years several open service platforms for Active and Healthy Ageing domains have been developed, originating from the medical, independent living, and IoT domain. These platforms aim at building a common basis for application development, assuring interoperability at the application and service level, and reducing development cost by re-use of components. As these platforms mature more insight is needed in the way they contribute to the development of a scalable and open market for digital solutions for health and ageing, and which value is actually achieved through them. The integration of platforms between different domains will introduce new interoperability issues that need to be tackled. A coordination and support action that addresses these issues and gathers the insight referred above is needed in order to promote the effective uptake and impact of open platforms.

Scope:

Proposals should deliver an inventory of the state of the art and analyse the use of open service platforms in the Active and Healthy Ageing domain, covering both open platforms -such as universAAL and FIWARE- and partly-open/proprietary platforms developed by industry. In addition, proposals should address interactions between platforms.

Proposals should elaborate a methodology that monitors open platform development, adoption and spread across Europe, with relevant KPI’s, factors that support or hinder the uptake of open platforms in Europe, including the associated evolution of the ecosystems and stakeholder networks.

Proposals are then expected to put this methodology into practice and study the use of open platforms by, amongst other possible actions, collecting and processing data from running and recently ended projects –including EU funded projects- and initiatives that use the referred platforms, with special focus on those building upon UniversAAL and FIWARE. They should also address the evolution in the further development and maintenance of the platforms as well as the use and sustainability of relevant open platforms.

Proposals should elaborate evaluation guidelines aimed at collecting evidence on socio economic costs and benefits of the use of open platforms as means for service delivery to serve as a reference for promoting further use of this approach.

Proposals are expected to include activities aimed at fostering integration efforts and knowledge exchange between the projects and initiatives referred above and also the user communities around the platforms. Proposals should collect best practices and practical experience with integrating multiple platforms. Technical, organisational, financial/business and legal aspects should be taken into account. Proposals should explore and link relevant on-going policy initiatives in the field such as the Blueprint for digital transformation of health and care

Proposals should describe collaboration activities with other relevant European projects or initiatives, e.g. the European Innovation Partnership on Active and Healthy Ageing. They are also expected to include dissemination activities for different stakeholder groups -technology developers, policy makers, end users-, preferably in the context of major events such as EIP-AHA summit, AAL Forum and eHealth Week.

Expected Impact:

Proposal should present appropriate indicators to measure their progress and impact in these areas:

* Identification of the critical success factors of open platform development, deployment, and spread;
* Increased knowledge on the differences and synergies between open platforms, with regard to both their features and their interoperability on different levels (data / information / applications / services)
* Evidence for the socioeconomic benefit of open service platforms;
* Engagement of required stakeholders to ensure the reliability of the data collected and to maximize the value of results achieved;
* Increased levels of participation by service platform providers and platform users in networking and knowledge exchange events
* Contribution to the effective implementation of relevant policy initiatives in the field
* Enhanced synergies with other European projects to make joint progress on favourable framework conditions to scaling-up digital innovation for active and healthy ageing across the EU, including standardisation.

Type of Action: Coordination and Support action

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

SC1-HCC-03-2018 (ex CSA 15): Support to further development of international cooperation in digital transformation of health and care

Specific Challenge:

Citizens in ageing populations wish to stay in their homes for as long as possible. They are however at risk of age related impairments such as poor health, cognitive impairment, frailty and social exclusion with considerable negative consequences for their independence, quality of life, that of those who care for them, and for the sustainability of health and care systems.

There is an increasing global interest in cooperation on research and innovation addressing this issue with digital solutions and services. It is however necessary to identify the future areas for international cooperation which have the highest potential as well as support the identification and networking of the potential funding organisations which can promote future cooperation. The focus will be on co-operation with the US, Canada, Japan, South Korea and China.

Scope:

The action shall develop and deliver a roadmap for international cooperation which outlines key relevant research and innovation areas in digital solutions and services for active and healthy ageing. The selection of topics and potential funding schemes shall be based on a clear methodology which also takes into account the European added value and identifies relevant existing and emerging initiatives which can form the basis for such a cooperation. The action must also ensure that relevant stakeholders are engaged during the process through regional and international workshops and a set of communication and dissemination actions.

The consortium must include organisations from the different countries concerned which can demonstrate the necessary knowledge and can help mobilise the relevant international funding bodies. The work should also support the ongoing G7 work on innovation and demographic change.

Expected Impact:

* Increased awareness of relevant research and innovation initiatives by European and International stakeholders
* Increased international cooperation in research and innovation on ICT for active and healthy ageing through a roadmap of priority areas and potential funding schemes
* Increased networking of European and international stakeholders interested in international cooperation in the field
* Improve competiveness of European industry by opening up international open innovation possibilities and gaining access to future markets

Type of Action: Coordination and Support action

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

SC1-HCC-04-2018 (ex CSA 16): eHealth and care services – support for policy, strategy and post R&D

Specific Challenge:

Health and care service providers and users are increasingly facing complex decisions when exploring and investing in new health and care solutions. There is a need to support cross-border cooperation in preparation of procurement of research and innovative digital solutions, including on how to balance innovation risks with improved outcomes. Further support is also needed for implementing high quality policies, strategies and practises in a concerted manner and providing more confidence in addressing key areas of interventions and related unmet needs, procedures and other measures. In addition there is a need to facilitate an appropriate dialogue with the supply side and academic stakeholders to understand the constraints and possibilities.

Scope:

Create favourable framework conditions for cross-border Communities of Practise (CoP) and create a network that will assist the health & care research and innovation ecosystems in taking investment decisions on future procurement of research and innovation. The network shall support existing ecosystems, create capacities, promote, co-ordinate, collaborate with other innovation accelerators, accelerate and scale up the health innovation European wide. To facilitate sufficient knowledge brokerage all appropriate actors in the innovation chain and systems shall be engaged

The consortium should represent a well-designed network of procurers and demand side actors e.g., European regions, NGOs, patient and consumer organisations that have proven experience in the field and the capacity to engage and consult objectively all relevant actors.

Additionally, diverging expectations and risk management in innovation chain should be addressed by offering a set of support activities beyond the innovation procurement procedures.

Approaches addressing consumer health should be interlinked in those cases where the institutional health and care services are expected to contribute.

The consortium is expected to assist those procurers that intend to prepare for a cross-border innovation procurement e.g., guiding them to address well-defined unmet needs in health and care, use the repositories of best practises and implementation guidelines and providing opportunities for networking.

The findings in earlier co-ordination and support actions for procurers e.g., EPP eHealth[[60]](#footnote-60), Inspire[[61]](#footnote-61) and EAFIP[[62]](#footnote-62) should be taken on-board. Networking with supply and consumer market actors and business accelerators should be well established (e.g. eHealth hub[[63]](#footnote-63)[5] , EIT-KIC[[64]](#footnote-64), EIP-AHA[[65]](#footnote-65), ENoLL[[66]](#footnote-66)). The progress in Blueprint Digital Transformation of health and care[[67]](#footnote-67) and EU-US MoU on health IT innovation eco-systems[[68]](#footnote-68) should be incorporated.

The work is divided in parallel activities building up on the competences and capacities of the network:

1) Co-ordinate a multi-collaborative growth policy & strategy development of the European health & care procurers and other demand side actors in the quadruple helix[[69]](#footnote-69) systemic context. The brokerage should facilitate easy movement of competences benefitting the ecosystems at various maturity levels in the innovation chain in thematic Communities of Practise and other professional networks.

In particular, the following elements should be taken into account:

* facilitating the development of qualified key areas of interventions in brokerage settings to get validated and accepted in health & care delivery services,
* integrating data strategy as a fuel of novel digital health services,
* reinforcing the profiles of research institutions, university hospitals in the context of thematic CoP,
* planning and proof-of-concept education of health and care professionals,
* building upon national initiatives, however, taking into account the Lisbon treaty[[70]](#footnote-70) and
* developing the existing or building up repositories of methodologies and set-ups of CoPs.

2) Tailored assistance for procurers, regions, cities and users in post R&D activities e.g., by developing case specific innovation models, giving legal aid, addressing regulation, managing risks, sharing best practises, training and education, addressing procurement events etc., interlinking with innovation acceleration of eHealth and care industries, other actors and attracting investments.

3) The network must undertake activities that investigate the feasibility and facilitate the concrete preparation of a cross-border PCP for at least one shared common procurement need.

The Commission considers that proposals requesting a contribution from the EU of up to €3M over three years would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

* Concerted approach and solutions to the challenges faced by the health ecosystems as perceived by service providers and users in several countries. Increased opportunities for health and care services providers to address unmet needs. Reduced fragmentation of service providers’ demands.
* Evidences of support and collaboration with consortia developing unmet needs for innovation procurement and implementation aspects beyond the innovation procurement procedures.
* Concrete preparation of a cross-border PCP for at least one shared common procurement need.

Type of Action: Coordination and Support action

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

SC1-HCC-05-2018 (ex CSA 17): Support to a Digital Health and Care Innovation initiative and preparation for next framework programme

Specific Challenge:

The action shall support the further development of an ambitious European initiative on digital transformation of health and care, including preparation of further research and innovation activities beyond Horizon 2020. There is a need to support the engagement of relevant public and private stakeholders and initiatives (including at national level) to contribute to the definition and implementation of this initiative.

Scope:

Expected Impact:

Type of Action: Coordination and Support action

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

Conditions for the Call – Digital Transformation in Health and Care

Opening date(s), deadline(s), indicative budget(s):[[71]](#footnote-71)

|  |  |  |
| --- | --- | --- |
| Topics (Type of Action) | Budgets (EUR million) | Deadlines |
| 2018 | 2019 | 2020 |
| Opening: End of Year 2017 |
| SC1-DTH-03-2018 (RIA) | 25.00 |  |  | Spring 2018 |
| SC1-DTH-07-2018 (RIA) | 40.00 |  |  |
| SC1-DTH-08-2018 (IA) | 20.00 |  |  |
| SC1-HCC-01-2018 (CSA) | 1.00 |  |  |
| SC1-HCC-03-2018 (CSA) | 2.00 |  |  |
| SC1-HCC-04-2018 (CSA) | 3.00 |  |  |
| SC1-HCC-05-2018 (CSA) | 2.00 |  |  |
| Opening: Autumn 2018 |
| SC1-DTH-01-2019 (RIA) |  | 25.00 |  | Spring 2019 |
| SC1-DTH-05-2019 (PPI) |  | 10.00 |  |
| SC1-DTH-09-2019 (IA) |  | 15.00 |  |
| SC1-DTH-10-2019-2020 (PCP) |  | 22.00 |  |
| SC1-DTH-11-2019 (IA) |  | 20.00 |  |
| SC1-HCC-02-2019 (CSA) |  | 1.50 |  |
| Overall indicative budget | 93.00 | 93.50 |  |  |

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

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

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

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

Evaluation Procedure: The procedure for setting a priority order for proposals with the same score is given in General Annex H of the work programme.

The full evaluation procedure is described in the relevant [guide](http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/submit-proposals_en.htm) published on the Participant Portal.

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

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

FA-H2020-SC1-XX-2018-2020

***Mission statement:***

This call aims at multidisciplinary technologies and solutions in health and care with a focus on cybersecurity to assure data privacy, security and protection of health and care infrastructures. It addresses the need for secure and user-driven ICT-based solutions in early risk detection and interventions with big data approaches that enable aggregation of a variety of new and existing data sources such as medical records, registries, social platforms and other environmental, physiological and behavioural data, including data from large scale pilots on smart living environments. This call will contribute to the Focus Areas on 'Digitising and transforming European industry and services' and 'Boosting the effectiveness of the Security Union'.

Proposals are invited against the following topic(s):

DT-11-2019 (ex 24): Smart and healthy living at home (Focus Area "Digitising and transforming European Industry, Platforms and Pilots" topic only for 2019)

Specific Challenge:

Citizens in a rapidly ageing European population are at greater risk of cognitive impairment, frailty and multiple chronic health conditions with considerable negative consequences for their independence, quality of life and for the sustainability of health and care systems. The challenge is to foster large-scale deployment of integrated digital solutions which will bring improved quality of life to citizens while demonstrating significant efficiency gains in health and care delivery across Europe.

Scope:

A mix of advanced ICT ranging from biophotonics to robotics, from artificial intelligence to big data and from IoT to smart wearables can address these challenges. A platform for smart living at home should integrate these technologies in an intelligent manner.

The pilots should build on open platforms, standardised ontologies, APIs and results from IoT-based smart living environments, service robotics and smart wearable & portable systems and clearly go beyond current state of the art in terms of scale, the capabilities for personalisation, adaptation, and user acceptance of the proposed solutions and services. A clear methodology and impact indicators for socio-economic impact assessment from using the platform should be included, where possible using the MAFEIP[[72]](#footnote-72) framework. The number of users involved and duration of pilot services should be sufficient to ensure significance in impact analysis, with a minimum of 4 pilot sites in 4 countries.

The proposed pilots should also demonstrate feasibility of integration with other relevant application domains such as energy, transport, or smart cities, including interoperability, along with data security and integrity, and models for data sharing and valorisation are to be developed in order to create incentives for data aggregation across different platforms and application areas.

Two areas are of particular importance in this context:

1. Intelligent and personalised digital solutions for sustaining and extending healthy and independent living

The objective is to develop and deploy innovative and user-led digital solutions capable of supporting and extending healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities.

Innovative ways for ensuring user-friendly and accessible interface design and new intuitive ways of citizen interaction and trust creation are needed. Special emphasis should be given to viable concepts that ensure security and privacy by design, data protection, safety, security and trust in the resulting system and service delivery inside and outside the home.

1. Personalised early risk detection and intervention

The objective is to develop and deploy innovative and user-led solutions building on big data for personalised risk detection, advanced health monitoring and early interventions for people facing increased health and social risks. Proposals should design and demonstrate innovative personalised treatments and therapies based on early detection and risk avoidance. Because of the personal and sensitive nature of health data, special attention needs to be paid to trust, privacy and data protection.

Expected Impact:

* Emergence of European-led platform for smart and healthy and independent living at home;
* Increased competitiveness of the European ICT industry in the domain, through enhanced interoperability, best practices for viable business and financing models and scalable markets;
* Significant and measureable contribution to standards or pre-normative activities in the pilots' areas of action via the implementation of open platforms and systems
* Reaching a high leveraging effect on other sources of funding, in particular regional and national funding
* Evidence-based improved efficiency of health and care systems with demonstrated added-value underlying technologies.
* Improved quality of life and health status for involved users and carers, with demonstrated added-value of underlying technologies
* User accepted, validated innovative solutions addressing accessibility, privacy, security, vulnerability, liability, sustainability.

Type of Action: Innovation action The Commission considers that proposals requesting a contribution from the EU between 15 and 20 EUR million for Innovation Actions would allow the areas to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. Proposals should at least address one of the above-mentioned areas.

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

SU-TDS-01-2018 (ex 34): Toolkit for assessing and reducing cyber risks in hospitals and care centres to protect data/infrastructures (Focus Area "Boosting the effectiveness of the Security Union" topic only for 2018)

Specific Challenge:

Digital technologies such as Big data, Internet of Things, Robotics, Artificial Intelligence, High Performance Computing, Cloud and Cybersecurity offer new opportunities to transform healthcare systems and delivery, Connected medical devices, in particular if linked to Clinical Information Systems, can bring increased patient safety and efficiency into healthcare system(s). However, ICT infrastructures and data have become critical for the functioning of the hospitals and care systems and due to increasing connectivity, the exposure to risks of cyber-crime is constantly increasing. Healthcare ICT infrastructures are now considered to be part of the Critical Information Infrastructure. Cyberattacks are a potential danger to the safety of patients and to the privacy of sensitive health data.

Scope:

Development and implementation of innovative methods, tools, guidelines or best practices addressing the need for cybersecurity in hospitals including remote care and homecare settings e.g. for assessing risks and vulnerabilities of hospitals w.r.t cyberattacks; innovative cybersecurity measures; identification/authentication systems within hospitals taking into account cross-border requirements and usability; addressing cybersecurity in the whole lifecycle of a medical device; solutions addressing the need for cybersecurity certification of products/devices and services in the health and care domain; developing standards for security-by-design covering the whole lifecycle of eHealth applications; cybersecurity in remote healthcare provisions including homecare settings and in IT infrastructures supporting integrated care; secure information sharing between healthcare organisations (including cross border); security for cloud solutions supporting healthcare services; cybersecurity for Internet of Things (IoT) components supporting healthcare organisations in Europe.

Expected Impact:

* Improved security of Health and Care services, data and infrastructures
* Increased patient trust and safety

Type of Action: Research and Innovation action

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

SU-TDS-02-2018 (ex CSA 18): Raising awareness and developing training schemes on cybersecurity in hospitals, (Focus Area "Boosting the effectiveness of the Security Union" topic only for 2018)

Specific Challenge:

ICT infrastructures and data have become critical for the functioning of the hospitals and care systems. Due to increasing connectivity, the exposure to risks of cyber-crime is constantly increasing. Cyber-attacks are a potential danger to the safety of patients and to the privacy of sensitive health data. Some cybersecurity threats are caused by human errors or ignorance.

Scope:

Awareness raising of staff working in healthcare settings on security and data privacy is important to reduce cybersecurity vulnerabilities and exposure.

Training of IT staff working in healthcare settings is of high priority in order to enforce the knowledge on information security processes and data protection procedures. Appropriate training on the permitted use of patient health data/ information according to the requirements of relevant data protection law(s) is also a priority.

Expected Impact:

Increased hospital staff awareness and knowledge of cybersecurity risks and legal aspects of data protection will reduce cybersecurity vulnerabilities. Consequently, the number of human errors causing cybersecurity threats will be reduced.

Type of Action: Coordination and Support action

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

Conditions for the Call - Trusted digital solutions and Cybersecurity in Health and Care

Opening date(s), deadline(s), indicative budget(s):[[73]](#footnote-73)

|  |  |  |
| --- | --- | --- |
| Topics (Type of Action) | Budgets (EUR million) | Deadlines |
| 2018 | 2019 | 2020 |
| Opening: End of Year 2017 |
| SU-TDS-01-2018 (RIA) | 35.00 |  |  | Spring 2018 |
| SU-TDS-02-2018 (CSA) | 1.00 |  |  |
| Opening: Autumn 2018 |
| DT-11-2019 (IA) |  | 35[[74]](#footnote-74) |  | Spring 2019 |
| Overall indicative budget | 36.00 | 35.00 |  |  |

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

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

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

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

Evaluation Procedure: The procedure for setting a priority order for proposals with the same score is given in General Annex H of the work programme.

The full evaluation procedure is described in the relevant [guide](http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/submit-proposals_en.htm) published on the Participant Portal.

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

Other actions 2018-2019[[75]](#footnote-75)

1. Subscription fee: Human Frontier Science Programme Organisation

An annual subscription to the international Human Frontier Science Programme Organisation (HFSPO)[[76]](#footnote-76) will allow EU non-G7 Member States to fully benefit from the Human Frontier Science Programme (HFSP) and provide increased visibility for European research, as well as contributing to the implementation of the Union’s strategy for international cooperation[[77]](#footnote-77) in research and innovation.

Type of Action: Subscription

Indicative timetable: 2018 and 2019

Indicative budget: EUR 5.16 million from the 2018 budget (precise amount is EUR 5.158.000) and EUR 5.26 million from the 2019 budget (precise amount is EUR 5.261.000)

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

A number of specific contracts will be signed under existing framework contracts in order to support activities of the Scientific Panel for Health[[78]](#footnote-78); the tracking of research results, outcomes and impacts; the dissemination and exploitation of project results; in order to contribute to the definition of future challenge priorities; and to organise conferences, events and outreach activities. Should existing framework contracts prove unsuitable or insufficient to support the abovementioned activities, one or more calls for tender may be launched as appropriate.

Subject matter of the contracts envisaged: studies, technical assistance, conferences, events and outreach activities.

Type of Action: Public Procurement - specific contracts under an existing Framework Contract or direct service contracts

Indicative timetable: Some 10 contracts expected for 2018 (indicative, tbc); and 10 contracts expected for 2019 (indicative, tbc)

Indicative budget: EUR 1.5 million (tbc) from the 2018 budget and EUR 1.5 million (tbc) from the 2019 budget

3. External expertise

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

Type of Action: Expert Contracts

Indicative budget: EUR 2.00 million (tbc) from the 2018 budget and EUR 2.00 million (tbc) from the 2019 budget

4. Grant to the Global Alliance for Chronic Diseases

The European Commission will make a contribution towards activities of the Global Alliance for Chronic Diseases (GACD). This will enable the European Commission to take part in GACD, which brings together leading health research funding agencies of key countries (currently Australia, UK, Canada, China, India, Mexico, USA, Brazil, Japan, Thailand, Argentina and South Africa) to coordinate research activities addressing on a global scale the prevention and treatment of chronic, non-communicable diseases such as cardiovascular diseases, diabetes, mental health and cancer. Recommendations of GACD are expected to have a fundamental value for future orientation of public health research policy. This will also contribute to the implementation of the Union’s strategy for international cooperation[[79]](#footnote-79) in research and innovation.

Legal entities: XXX, London, UK (tbc)

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

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

Indicative timetable: Second quarter 2018 (tbc)

Indicative budget: EUR 0.24 million from the 2018 budget (tbc)

5. Grant to the NCP network HHN2.0

The European Commission will make a contribution towards activities of the NCP support services across Europe in the health research area (project HNN2.0). This will enable the NCP Network for Health to continue its activities including the coverage of the last calls of Horizon 2020 for the Societal Challenge 1.

The planned activities should XXXX.

Legal entities:

* Instituto De Salud Carlos III, Monforte de Lemos 5, 28029 Madrid, Spain
* Others (tbc)

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

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

Indicative timetable: First quarter 2018 (tbc)

Indicative budget: EUR 0.20 million (tbc) from the 2018 budget and 0.20 million (tbc) from the 2019 budget

6. Prize 1 (2019) – Horizon Prize on novel solutions to reduce the spread of AMR in the environment

Antimicrobial resistance (AMR) is recognised as a major health threat, as confirmed by world leaders at the 2016 UN General assembly. The increasingly reduced effectiveness of currently available antimicrobials leads to an increase in treatment failures and a deterioration of human health. The recent O'Neill review on AMR estimates that by 2050 10 million lives a year and a cumulative 100 trillion USD of economic output are at risk due to the rise of drug resistance. Increasing resistance to antimicrobials leads to the release of resistant microorganisms into the environment as well as the release of the active pharmaceutical products that act as a driver of drug resistance, creating environmental ‘reservoirs’ of antibiotic-resistant bacteria. This poses a threat to human and animal health. Therefore there is an urgent need to develop novel solutions/interventions capable of reducing the spread of resistant microorganisms or antimicrobials in the environment.

The specific rules of the contest will be published in XXX by the European Commission, which will directly launch and manage the contest and award the prize based on the judgement of independent experts.

Expected results:

A novel solution is expected to reduce the spread of resistant microorganisms and or antimicrobials in the environment. The effectiveness of the proposed solution will need to be demonstrated. Any solution must take account of issues related to implementation and uptake, and have the potential to be scaled up rapidly.

Eligibility criteria: xxx

The prize will be awarded, after closure of the contest to the contestants who in the opinion of the jury demonstrate a solution (which is at least a system pilot demonstrated in an operational environment) that best addresses the challenge.

Indicative timetable of contest(s);

Type of Action: Inducement prize

For the common Rules of Contest for Prizes please see XXX

Indicative budget: EUR 2 million

7. Prize 3 (2019) – Exemplary application of personalised medicine approaches at a local or regional level

Rationale:

The potential of personalised medicine (PM) in improving healthcare effectiveness is widely recognised. However, the full benefit of PM will only materialise when different actors in healthcare and related fields work together towards PM models that rely on sustainable healthcare costs, attractive business models for commercialisation (e.g., prevention therapy), patient engagement, and continuous model improvement (e.g., through citizen-driven or services-driven monitoring).

Scope:

Different models of personalised medicine approaches have been tested by authorities in various places in Europe. These have included a varying number of participating institutions in a particular location, city or region. The aim of this recognition prize is to assess different examples of these models and to highlight the ones that have shown successful real-life application of PM.

Impact:

* Support active comparison of the early examples of PM approaches with a view to demonstrate effectiveness of certain models that can be replicated elsewhere.
* Contribute towards implementation of the MS led IC PerMed initiative.

Type of Action:Recognition prize

Indicative budget: EUR 1 million

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

8. Prize 5 (2019) - Novel tool(s) to limit the use of test animals in biomedical sciences and safety testing – RTD – Inducement Prize

This inducement prize will reward a validated and exploitable new test method replacing, reducing or refining animal testing in any of the following applications: (i) safety assessment of chemicals, (ii) safety/efficacy/quality testing of vaccines/biologicals/drugs, (iii) understanding basic mechanisms of health, diseases or ageing, (iv) understanding the health effects of exposure, (v) education and training.

Expected results:

Development of an innovative test method that will accelerate the transition from animal to non-animal based research or safety testing.

General/essential award criteria:

The prize will be awarded, after closure of the contest, to the entry that in the opinion of the jury demonstrates a solution that best addresses the following cumulative criteria:

* Potential to replace or reduce the use of test animals. Applicants should include a robust quantitative estimation of the number of animals (by species) that will be spared.
* Potential to minimize suffering. Applicants should include a detailed analysis of the benefit to the severity of the test procedures and/or the animal welfare.
* Acceptance of the test method(s). Applicants should include a detailed analysis of the level of acceptance of the test method(s) by scientists in and outside Europe as well as by regulatory agencies if applicable.
* Accuracy and safety. Applicants should provide a risk/benefit analysis of the new test method(s) compared to current solutions.
* Cost and exploitability by numerous users/operators.
* Market opportunities.

Eligibility criteria: The contest is open to any legal entity (including natural persons) or group of legal entities established in an EU Member State or in a country associated to Horizon 2020.

Indicative timetable of contest(s): Stages Date and time or indicative period

Publication of the contest

First quarter – 2018

Mandatory registration of participants

Third quarter – 2018

Deadline for submission of proposals

Second or third quarter – 2019

Evaluation of proposals

Third quarter – 2019

Award decision

Fourth quarter – 2019

Type of Action: Inducement prize

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

Indicative budget: EUR 1 million from the 2019 budget.

YY. Mobilisation of research funds in case of Public Health Emergencies

In case of a public health emergency recognised by the Commission[[80]](#footnote-80) (such as a Public Health Emergency of International Concern (PHEIC) according to the World Health Organization, a public health emergency under Decision 1082/2013/EU or under applicable national frameworks and regulations), research grants will be awarded in line with specific provisions of the Financial Regulation[[81]](#footnote-81)&[[82]](#footnote-82), that allow the awarding of grants without call for proposals in exceptional and duly substantiated emergencies. At that time, the Participant Portal will open a dedicated section where research applications can be received. This will be communicated to the National Contact Points.

Type of action: RIA - Grants awarded without a Call for Proposals (Article 128 Financial Regulation and Article 190 of the Rules of Application

Indicative timetable: will depend of the Public Health Emergency

Indicative budget: EUR 10 million (tbc)

CALLS and OTHER ACTIONS for 2020

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! The topics under this section will not appear in an automated way on the Participant Portal.

! This section will be largely free text.

1. "Better Health and care, economic growth and sustainable health systems" (continued in 2020)

H2020-SC1-BHC-2018-2020-continued

'Mission statement'

The same 5 priority areas of 2018-2019 will apply

[corresponding to the objectives pursued and the expected results]

Indicative timetable

[of the call for proposals]

Indicative budget:

[of the call for proposals] : EUR 490 million

Maximum rate of co-financing

Topics

[titles only, for non-Focus Area topics]

**Priority 1.1 Personalised medicine**

SC1-BHC-06-2020 (ex-26): Digital diagnostics – developing tools for clinical decisions integrating in vitro and in vivo diagnostics

SC1-HCO-03-2020 (ex-CSA10): Improving EU-13 participation in EU-supported health research programmes

**Priority 1.2 Innovative health and care industry**

SC1-BHC-08-2020 (ex-16): New therapies for Non Communicable Diseases

SC1-BHC-11-2020 (ex-28): New, animal-free regulatory test methods for human safety testing at the horizon of 2030

SC1-BHC-12-2020 (ex-40): Boosting the translation of results of health research into validated, innovative applications

**Priority 1.3 Infectious diseases and improving global health**

SC1-BHC-17-2020 (ex-15): Global Alliance for Chronic Diseases (GACD) 2

SC1-BHC-20-2020 (ex-38): 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

**Priority 1.4 Innovative health and care systems - Integration of care**

SC1-BHC-24-2020 (ex-19): Healthcare interventions for the management of the elderly multimorbid patient

**Priority 1.5 Decoding the role of the overall environment for health and well-being**

SC1-BHC-29-2020 (ex-9): The Human Exposome Project: a toolbox for assessing and addressing the impact of environment and climate change on health

Call 2. – Digital Transformation in Health and Care (continued in 2020)

H2020-SC1-DTH-2018-2020

'Mission statement'

The same priority area of 2018-2019 will apply.

Indicative timetable

[of the call for proposals]

Indicative budget:

[of the call for proposals] : EUR 100 million

Maximum rate of co-financing

Topics

SC1-DTH-02-2020 (ex 20): Personalised early risk prediction, prevention and intervention, RIA

SC1-DTH-04-2020 (ex 22): International cooperation in digital solutions and robotics for independent living

SC1-DTH-06-2020 (ex 29) Accelerating the uptake of in-silico methods for testing medicines with dermatological use and cosmetic products

SC1-DTH-10-2019-2020 (ex 33) eHealth and care services

SC1-HCC-06-2020 (ex CSA 19) Support to eHealth Innovation ecosystems in Europe

SC1-HCC-07-2020 (ex CSA 20): Support for European eHealth Interoperability roadmap deployment

SC1-HCC-08-2020 (ex CSA 21): Scaling up innovation for active and healthy ageing

Other actions for 2020

1. Prize 2 - Surgical care in resource-poor settings

Type of Action: Inducement Prize

For the common Rules of Contest for Prizes please see General Annex F of the work programme

Indicative budget: EUR XX million from the 2020 budget

2. Prize 6 - Implantation of smart medical devices to (re-) establish neural &/or neuronal function

Type of Action: Inducement Prize

For the common Rules of Contest for Prizes please see General Annex F of the work programme

Indicative budget: EUR XX.00 million from the 2020 budget

Budget[[83]](#footnote-83)

This will be completed in a further version of the Work Programme

1. <http://www.imi.europa.eu/content/imi-2> [↑](#footnote-ref-1)
2. <http://www.edctp.org/> [↑](#footnote-ref-2)
3. <http://www.aal-europe.eu/why-another-aal-programme/> [↑](#footnote-ref-3)
4. <http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing> [↑](#footnote-ref-4)
5. Decision No 1082/2013/EU on Serious Cross-Border Threats to Health, article 12 [↑](#footnote-ref-5)
6. <http://ec.europa.eu/health/ern/policy/index_en.htm> [↑](#footnote-ref-6)
7. Including any national, EU or international resource or infrastructure if appropriate. [↑](#footnote-ref-7)
8. <https://www.elixir-europe.org/> [↑](#footnote-ref-8)
9. <https://www.ebi.ac.uk/ega/home> [↑](#footnote-ref-9)
10. <http://ihec-epigenomes.org/> and <http://ihec-epigenomes.org/about/policies-and-guidelines/> [↑](#footnote-ref-10)
11. <http://epigenomesportal.ca/ihec/> [↑](#footnote-ref-11)
12. <http://www.phenomecentral.org> [↑](#footnote-ref-12)
13. <https://dcc.icgc.org/> [↑](#footnote-ref-13)
14. <http://www.human-microbiome.org/> [↑](#footnote-ref-14)
15. <http://www.matchmakerexchange.org> [↑](#footnote-ref-15)
16. <https://www.oecd.org/health/health-systems/Recommendation-of-OECD-Council-on-Health-Data-Governance-Booklet.pdf> [↑](#footnote-ref-16)
17. <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/societal-challenges> [↑](#footnote-ref-17)
18. [ec.europa.eu/research/.../h2020-tpl-oa-data-mgt-plan\_en.docx](http://ec.europa.eu/research/participants/data/ref/h2020/gm/reporting/h2020-tpl-oa-data-mgt-plan_en.docx) [↑](#footnote-ref-18)
19. OJ L 324, 10.12.2007, p. 121. [↑](#footnote-ref-19)
20. Findable, accessible, interoperable, re-usable. [↑](#footnote-ref-20)
21. For the purpose of this call, eligible neglected diseases are: childhood diarrhoeal diseases, kinetoplastid diseases (human African Trypanosomiasis, leishmaniasis, Chagas disease) and helminth (Schistosomiasis, soil-transmitted helminthiases, food-borne trematodiases, filariasis, Onchocerchiasis, taeniasis/cysticercosis, dracunculiasis, echinococcosis) diseases, as well as bacterial diseases like Buruli ulcer, leprosy and yaws. Neglected viral diseases are specifically excluded from this topic. [↑](#footnote-ref-21)
22. <http://www.maternalhealthalliance.eu/pdf/Alliance%20Factsheet.pdf> [↑](#footnote-ref-22)
23. <http://www.europeristat.com/reports/european-perinatal-health-report-2010.html> [↑](#footnote-ref-23)
24. <https://data.unicef.org/resources/levels-trends-child-mortality-report-2014/> [↑](#footnote-ref-24)
25. <https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-4-18>

'Implementation Research is the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care. It includes the study of influences on healthcare professional and organisational behaviour [↑](#footnote-ref-25)
26. HIV/AIDS Surveillance in Europe, report November 2016, ECDC and WHO Regional office Europe <http://ecdc.europa.eu/en/publications/Publications/HIV-AIDS-surveillance-Europe-2015.pdf> [↑](#footnote-ref-26)
27. TB Surveillance in Europe, report November 2016, ECDC and WHO Regional office Europe <http://ecdc.europa.eu/en/publications/Publications/tuberculosis-surveillance-monitoring-Europe-2015.pdf> [↑](#footnote-ref-27)
28. http://www.mhlw.go.jp/seisakunitsuite/bunya/hokabunya/kokusai/g7kobe/KobeCommunique\_en.pdf [↑](#footnote-ref-28)
29. http://www.mentalhealthandwellbeing.eu/assets/docs/publications/Framework%20for%20action\_19jan%20(1)-20160119192639.pdf [↑](#footnote-ref-29)
30. <http://www.ilo.org/wcmsp5/groups/public/---ed_protect/---protrav/---safework/documents/publication/wcms_466547.pdf> [↑](#footnote-ref-30)
31. https://ec.europa.eu/health/mental\_health/eu\_compass\_en [↑](#footnote-ref-31)
32. https://www.headsup.org.au/docs/default-source/resources/developing-a-mentally-healthy-workplace\_final-november-2014.pdf?sfvrsn=8 [↑](#footnote-ref-32)
33. http://www.ilo.org/wcmsp5/groups/public/---ed\_protect/---protrav/---safework/documents/publication/wcms\_466547.pdf [↑](#footnote-ref-33)
34. broadly defined as research in which the investigator collects and analyzes data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or a program of inquiry  <http://journals.sagepub.com/doi/pdf/10.1177/2345678906293042> [↑](#footnote-ref-34)
35. According to WHO, palliative care is "an approach that improves the quality of life of patients and their families facing the problem associated with life threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual" (http://www.who.int/cancer/palliative/definition/en/). [↑](#footnote-ref-35)
36. Morin et al. Estimating the need for palliative care at the population level: A cross-national study in 12 countries. Palliat Med. 2016 [↑](#footnote-ref-36)
37. Involving patients and their caretakers (families, volunteers, nurses and others), and taking their views and values into account in care decisions. [↑](#footnote-ref-37)
38. According to WHO " A child is a person 19 years or younger unless national law defines a person to be an adult at an earlier age " (http://www.who.int/hiv/pub/guidelines/arv2013/intro/keyterms/en/). [↑](#footnote-ref-38)
39. EUnetHTA Joint Actions 1-3, AdHopHTA, ADVANCE-HTA, INTEGRATE-HTA, MedtecHTA, GetReal, ADAPT-SMART [↑](#footnote-ref-39)
40. Health technologies are broadly defined to include e.g. pharmaceuticals, medical devices, in-vitro diagnostics, medical procedures, screening tests, vaccination programmes, eHealth, and other measures for disease prevention, diagnosis or treatment used in healthcare. [↑](#footnote-ref-40)
41. Personalised medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention. [↑](#footnote-ref-41)
42. Synergies should be sought with related initiatives, e.g. EUnetHTA Joint Action 3 (Work Package 5), the EMA initiative for patient registries, and JRC activities on registries. [↑](#footnote-ref-42)
43. For rare diseases, involvement of European Reference Networks (ERNs) should be considered. [↑](#footnote-ref-43)
44. EUnetHTA Joint Action 3 is a European network of national/regional HTA bodies under the EU Third Health Programme. [↑](#footnote-ref-44)
45. Integrated care considers initiatives seeking to improve outcomes of care by overcoming issues of fragmentation through linkage or coordination of services of different providers along the continuum of care. (Nolte 2014, Economic impacts of integrated care) [↑](#footnote-ref-45)
46. WHO/UNEP-State of the science of endocrine disrupting chemicals – 2012: <http://www.who.int/ceh/publications/endocrine/en> [↑](#footnote-ref-46)
47. Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products: <http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm> [↑](#footnote-ref-47)
48. <https://eurl-ecvam.jrc.ec.europa.eu/alt-animal-testing-safety-assessment-chemicals/test_method_reg> [↑](#footnote-ref-48)
49. OECD work on endocrine disrupters: http://www.oecd.org/env/ehs/testing/oecdworkrelatedtoendocrinedisrupters.htm [↑](#footnote-ref-49)
50. Dr. Francis Collins, Director of the U.S. National Institutes of Health (NIH) [↑](#footnote-ref-50)
51. <http://www.eea.europa.eu/themes/human/about-environment-and-health> [↑](#footnote-ref-51)
52. Mainly DG RTD (member of the WHO Environment and Health Task Force), DG SANTE, DG ENV and DG JRC [↑](#footnote-ref-52)
53. The concept of the exposome refers to the totality of environmental exposures (diet, lifestyle, occupational and environmental factors) from conception onwards, including its external and internal components. [↑](#footnote-ref-53)
54. The former has as one of the key actions 'to safeguard the Union's citizens from environment-related pressures and risks to health and wellbeing' and calls for investing in research to fill knowledge gaps, and developing a more systematic approach to new and emerging risks. The Commission is has also been an active partner in the latter and has in the past endorsed the ministerial declarations and accompanying implementation plans. [↑](#footnote-ref-54)
55. The European Commission has been a signatory of the declaration and accompanying action plan in the past and negotiations are ongoing as to the Ostrava declaration. [↑](#footnote-ref-55)
56. The budget figures given in this table are rounded to two decimal places.

The budget amounts for the 2018 budget are subject to the availability of the appropriations provided for in the draft budget for 2018 after the adoption of the budget 2018 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

The budget amounts for the 2019 and 2020 budget are indicative and will be subject to separate financing decisions to cover the amounts to be allocated for 2019 and for 2020. [↑](#footnote-ref-56)
57. A Workplace is a location, which can be inside or outside, virtual or physical, and can include an office, factory or home – where a person´s primary occupation takes place. [↑](#footnote-ref-57)
58. <https://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/scaling_up_strategy.pdf> [↑](#footnote-ref-58)
59. Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing – MAFEIP http://ec.europa.eu/research/innovation-union/index\_en.cfm?section=active-healthy-ageing&pg=mafei [↑](#footnote-ref-59)
60. European Procurers Platform - eHealth - Transforming the market for eHealth Solutions <http://innovationithospitals.com/> [↑](#footnote-ref-60)
61. International Network Supporting Procurement of Innovation via Resources and Education, <http://inspirecampus.eu/> [↑](#footnote-ref-61)
62. European Assistance for Innovation Procurement (EAFIP) <http://eafip.eu/> [↑](#footnote-ref-62)
63. eHealth Hub: Integrated Support for eHealth SMEs and stakeholders, <https://ec.europa.eu/digital-single-market/en/news/ehealth-hub-integrated-support-ehealth-smes-and-stakeholders> [↑](#footnote-ref-63)
64. European Institute of Innovation & Technology - Health, <https://eit.europa.eu/eit-community/eit-health> [↑](#footnote-ref-64)
65. European Innovation Partnership on Active and Healthy Ageing, <http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing> [↑](#footnote-ref-65)
66. European Network of Living Labs <http://openlivinglabs.eu/> [↑](#footnote-ref-66)
67. Blueprint Digital Transformation of health and care: <http://ec.europa.eu/research/conferences/2016/aha-summit/index.cfm?pg=blueprint> [↑](#footnote-ref-67)
68. EU-US EHEALTH/ HEALTH IT MOU UPDATED ROADMAP Webinar New Roadmap Work-stream "Supporting Transatlantic eHealth/Health IT Innovation Ecosystems', 2016 <https://www.healthit.gov/sites/default/files/final_eu-us_updated_roadmap_webinar_22516_v2-1_as_delivered.pdf> [↑](#footnote-ref-68)
69. Open Innovation, Open Science, Open to the World – a vision for Europe, EC, 2016, p.12 [↑](#footnote-ref-69)
70. The Lisbon Treaty on the Functioning of the European Union & comments Part 3 - Union policies and internal actions , Title XIV - Public health (Article 168) <http://www.lisbon-treaty.org/wcm/the-lisbon-treaty/treaty-on-the-functioning-of-the-european-union-and-comments/part-3-union-policies-and-internal-actions/title-xiv-public-health/456-article-168.html> [↑](#footnote-ref-70)
71. The budget figures given in this table are rounded to two decimal places.

The budget amounts for the 2018 budget are subject to the availability of the appropriations provided for in the draft budget for 2018 after the adoption of the budget 2018 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

The budget amounts for the 2019 and 2020 budget are indicative and will be subject to separate financing decisions to cover the amounts to be allocated for 2019 and for 2020. [↑](#footnote-ref-71)
72. See [www.mafeip.eu](http://www.mafeip.eu) [↑](#footnote-ref-72)
73. The budget figures given in this table are rounded to two decimal places.

The budget amounts for the 2018 budget are subject to the availability of the appropriations provided for in the draft budget for 2018 after the adoption of the budget 2018 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

The budget amounts for the 2019 and 2020 budget are indicative and will be subject to separate financing decisions to cover the amounts to be allocated for 2019 and for 2020. [↑](#footnote-ref-73)
74. SC1 will contribute 35 million EUR and ICT-LEIT will contribute xx million EUR. Total budget approx.. 40 – 60 million EUR. [↑](#footnote-ref-74)
75. The budget amounts for the 2018 budget are subject to the availability of the appropriations provided for in the draft budget for 2018 after the adoption of the budget 2018 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths [↑](#footnote-ref-75)
76. The European Union is a member of the HFSP Organisation (HFSPO) and has funded HFSP under previous

Framework Programmes [↑](#footnote-ref-76)
77. COM(2012)497 [↑](#footnote-ref-77)
78. The Scientific Panel for Health is mandated by Regulation (EU) No 1291/2013 establishing Horizon 2020 [↑](#footnote-ref-78)
79. COM(2012)497 [↑](#footnote-ref-79)
80. Article 12 of Decision No. 1082/2013/EU [↑](#footnote-ref-80)
81. Article 128.1 of Regulation (RU, Euratom) 966/2012"Grants shall be subject to a work programme, to be published prior to its implementation. That work programme shall be implemented through the publication of calls for proposals, except in duly justified exceptional cases of urgency or where the characteristics of the beneficiary or of the action leave no other choice for a given action, or where the beneficiary is identified in a basic act." [↑](#footnote-ref-81)
82. *Article 190.1 (b) of the Commission Delegated Regulation (EU) No 1268/2012 "Exceptions to calls for proposals: 1. Grants may be awarded without a call for proposals only in the following cases: […](b) in other exceptional and duly substantiated emergencies[…]"* [↑](#footnote-ref-82)
83. The budget figures given in this table are rounded to two decimal places.

The budget amounts for the 2018 budget are subject to the availability of the appropriations provided for in the draft budget for 2018 after the adoption of the budget 2018 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

The budget amounts for the 2019 and 2020 budget are indicative and will be subject to separate financing decisions to cover the amounts to be allocated for 2019 and for 2020. [↑](#footnote-ref-83)