



EN

Horizon 2020

Work Programme 2018-2020

8. Health, demographic change and wellbeing

IMPORTANT NOTICE ON THIS WORK PROGRAMME

This Work Programme covers 2018, 2019 and 2020. The parts of the Work Programme that relate to 2020 (topics, dates, budget) have, with this revised version, been updated. The changes relating to this revised part are explained on the Funding & Tenders Portal.

(European Commission Decision C(2020)4029 of 17 June 2020)

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Introduction

Challenges

Europe is facing four main healthcare challenges: (i) the 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; (ii) the influence on health of external environmental factors including climate change; (iii) the risk to lose our ability to protect the populations against the threats of infectious diseases; (iv) health inequalities and access to health and care. Europe must invest in research, technology and innovation to develop smart, scalable and sustainable solutions that will overcome those challenges. Europe must work with other global actors and must grasp every opportunity for leadership.

Regarding the third challenge listed above, newly emerging infectious diseases such as COVID-19, or re-emerging ones, threaten the health and prosperity of people. The speed at which the virus spreads and the scale of its effects call for global coordinated action. European citizens expect the Union to tackle the current COVID-19 pandemic and to ensure preparedness and capacity to deal with possible future global health threats. Performant, readily available, testing tools, treatments and vaccines form the cornerstone of a Europe that is prepared for the next large epidemic or pandemic (the 'Test', 'Treat' and 'Prevent' three-pronged strategy).

Objectives and policy drivers

Building on the principle of openness – open science, open innovation and open to the world the societal challenge 1 on 'health, demographic change and well-being' (SC1) aims to deliver solutions for a better health for all by:

- Moving towards the effective integration of personalised medicine approaches into healthcare services and systems to the benefit of patients and citizens;
- Fighting infectious diseases and the growing threat of antimicrobial resistance; development and validation of effective interventions for better surveillance, prevention, detection, treatment and crisis management of infectious disease threats.
- Addressing the needs of the most vulnerable groups and the global increase of chronic diseases;
- Decoding the role of environment – including climate change and air quality – on health and developing mitigating measures;
- Exploring the digital potential for health innovation and healthcare, including the building of a 'European health research and innovation cloud';

- Stimulating innovation in the European healthcare domain and industry by exploring the application of advanced technologies, improve the health of the workforce and promote regulatory science.

These objectives implement the EU's commitment at international level and at EU level in particular the [2030 Agenda for Sustainable Development and its Sustainable Development Goals](#), the new European Consensus on Development “Our World, Our Dignity, our Future”, the [COP21](#)¹ and the goals of [the Ostrava Declaration on Environment and Health](#), the [Digital Single Market](#) (and its relevance for the digital transformation of health and care), the new [European One Health Action Plan against Antimicrobial Resistance](#), the [cross-border healthcare directive](#) (and its support to the European Reference Networks), the [Commission Communication on upgrading the single market](#) (and its proposed health technology assessments initiative), and the [Council Conclusions on Personalised Medicine and on Pharmaceuticals](#)

This Work Programme implements several overall recommendations expressed in the *Horizon 2020 interim evaluation*, such as enhancing societal involvement and societal impact. It also implements specific measures identified in the SC1 thematic assessment of the interim evaluation of Horizon 2020, such as applying further simplification processes with the pilot topic on lump sum cost reimbursement, and increasing the support for international co-operation.

In 2020 the Other Action on Public Health Emergencies is activated to launch actions addressing the Covid-19 pandemic. The Other Action is linked to initiatives of the ERAvsCorona Action Plan² (that resulted from dialogues between the Commission services and the national ministries over the period March-April 2020) and the EU's commitment³ on the call for global action against the coronavirus launched on 4 May 2020.

Expected impacts

The expected impacts of this work programme are described at the level of the calls and at the level of the call priorities further below.

Research synergies

Project proposers should consider and actively seek synergies with, and where appropriate possibilities for further funding from, other relevant EU, national or regional research and innovation programmes (including ERDF/ESF+ or the Instrument for Pre-accession Assistance [IPA II]), private funds or financial instruments (including EFSI).

¹ 21st annual Conference of the Parties (COP) in Paris from November 30th to December 11th 2015 of The United Nations Framework Convention on Climate Change (UNFCCC)

²

https://ec.europa.eu/info/sites/info/files/research_and_innovation/research_by_area/documents/ec_rtd_era-vs-corona_0.pdf

³

https://ec.europa.eu/commission/presscorner/detail/en/ip_20_797

Examples of synergies are actions that build the research and innovation capacities of actors; mutually supportive funding from different Union instruments to achieve greater impact and efficiency; national/regional authorities actions that capitalise on on-going or completed Horizon 2020 actions aimed at market up-take/commercialisation.

In order to explore options for synergies, project proposers could seek contact with national/regional managing authorities and the authorities who developed the Research and Innovation Smart Specialisation Strategies (RIS3)⁴. For this purpose the 'Guide on Enabling synergies between ESIF, H2020 and other research and innovation related Union programmes'⁵ may be useful. Horizon 2020 project proposals should outline the scope for synergies and/or additional funding, in particular where this makes the projects more ambitious or increases their impact and expected results. Please note, however, that while the increase in the impact may lead to a higher score in the evaluation of the proposal, the reference to such additional or follow-up funding will not influence it automatically.

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

International cooperation is encouraged all through the work programme, in line with the strategy for EU international cooperation in research and innovation (COM(2012)497).

In line with promoting 'Open Science', grant beneficiaries in this work programme will engage in research data sharing by default, as stipulated under Article 29.3 of the Horizon 2020 Model Grant Agreement (including the preparation of a data management plan), and in particular FAIR⁶ (findable, accessible, interoperable and reusable) data sharing. Participants may however opt out of these arrangements, both before and after the signature of the grant agreement. More information can be found under general annex L of the work programme.

In the context of a public health emergency grant beneficiaries will be subject to additional requirements with respect to timely sharing of data.

For ***clinical studies***, the 'Open Science' approach requires (i) the registration of the study prior to the enrolment of the first patient in a registry which is part of the WHO Registry Network⁷, and (ii) in line with the WHO 'Joint statement on public disclosure of results from clinical trials'⁸ the disclosure of the study results by posting on the results section of the registry and through journal publication within 12 months from primary study completion.

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

⁴ <http://s3platform.jrc.ec.europa.eu/map>

⁵ http://ec.europa.eu/regional_policy/sources/docgener/guides/synergy/synergies_en.pdf

⁶ <https://www.force11.org/group/fairgroup/fairprinciples>

⁷ <http://www.who.int/ictrp/network/en/>

⁸ <http://www.who.int/ictrp/results/jointstatement/en/>

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.

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/EU⁹.

Actions included in this work programme may also gain more impact and scope by envisaging *synergies with the European Structural and Investment Funds (ESIF)* in health and related fields¹⁰. It is therefore recommended, where relevant, to seek concrete synergies with ESIF in *smart specialisation priorities* within the EU regions.

Finally, SC1 also builds strong links and synergies with Joint Programming Initiatives (JPIs), with activities undertaken by the Innovative Medicines Initiative 2¹¹ (IMI2), the European and Developing Countries Clinical Trials Partnership 2¹² (EDCTP2) and the Active and Assisted Living Joint Programme 2¹³ (AAL2). Topics in this work programme also respond to the priorities of the European Innovation Partnership on Active and Healthy Ageing¹⁴ (EIP-AHA).

Contribution to focus area(s)

Focus Area 'Boosting the effectiveness of the Security Union' (SU): EUR 36.00 million

Focus Area 'Digitising and transforming European industry and services' (DT): EUR 130.00 million

⁹ http://ec.europa.eu/health/ern/policy/index_en.htm

¹⁰ In order to provide support for promoting synergies, the European Commission has produced guidance to the relevant authorities through a Staff Working Document (SWD (2014)205 final) and annexes which contains explanations on the basic rules and principles for obtaining synergies and combining the different funds, and which contains recommendations to the relevant actors as well as to the European Commission on how to facilitate synergies:
<https://ec.europa.eu/research/regions/index.cfm?pg=synergies>
https://ec.europa.eu/research/regions/pdf/publications/h2020_synergies_201406.pdf#view=fit&pagemode=None

¹¹ <http://www.imi.europa.eu/content/imi-2>

¹² <http://www.edctp.org/>

¹³ <http://www.aal-europe.eu/why-another-aal-programme/>

¹⁴ http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing

Call - Better Health and care, economic growth and sustainable health systems

H2020-SC1-BHC-2018-2020

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. To this end, the inclusion of private companies and other innovators in the projects is encouraged.

Research areas to be addressed under this priority will implement and provide the evidence base for global and EU policies mentioned as 'policy drivers in the Introduction'.

This call will be implemented through six 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, including climate change, for health and well-being
6. Supporting the digital transformation of health and care

1.1 Personalised medicine

This priority will aim at delivering personalised health and care solutions to benefit citizens. It will generate and translate knowledge on disease aetiology and technological innovation into personalised health and care solutions. Areas of application include chronic, rare and communicable diseases. This priority targets any type of population, including children, the ageing population and high-risk groups. Relevant links with the [European Reference Networks](#) will be sought. Research under this priority will also attempt to develop an understanding of the economic impact and the potential of personalised medicine to transform health systems. Key Public-public Partnerships will support joint efforts to address neurodegenerative diseases, cancer research and brain-related diseases.

The expected key impact of this priority is improved health outcomes for the citizens. Additional impacts are 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: Understanding causative mechanisms in co- and multimorbidities combining mental and non-mental disorders

Specific Challenge: The increasing number of individuals with co-and multimorbidities 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- and multimorbid 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 co- and multimorbidities is crucial for adequate management of these conditions and requires innovative approaches.

Scope: Proposals should identify and validate causative mechanisms (e.g. molecular, genetic, correlative, drug-drug interaction) of co- and multimorbidities combining mental¹⁵ and any non-mental disorders through the integration of basic, pre-clinical and/or clinical research¹⁶. Applicants should prove the relevance of the identified mechanisms for co-morbid development. Where pertinent, development of biomarkers and other technologies for diagnosis and monitoring of comorbid conditions in patients is encouraged. A purposeful exploitation of existing data, biobanks, registries and cohorts is expected¹⁷, but does not exclude generation of new data. Sex and gender aspects, age, socio-economic, lifestyle and behavioural factors and any other non-health related individual attributes should be taken into consideration. SME participation is strongly 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.

Expected Impact:

- New directions for clinical research to improve prevention, diagnosis, prognosis, therapy development, and management of co- and multimorbidities.

¹⁵ For the classification of mental disorders please refer to “Mental and behavioural disorders (FOO-F99) of WHO's International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10)”: <http://apps.who.int/classifications/icd10/browse/2016/en#/V> .

¹⁶ Clinical trials are excluded

¹⁷ Including any national, EU or international resource or infrastructure if appropriate.

- Whenever relevant identified biomarkers for more accurate and earlier diagnosis, prognosis 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: Systems approaches for the discovery of combinatorial therapies for complex disorders¹⁸

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: Research should aim to understand at systems level the pathophysiology of a disorder in groups of patients responding well or poorly to particular therapies and further develop combinatorial therapies tailored to the needs of individuals or stratified patient groups.

Projects should focus on already available and/or authorised therapies and 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 studies¹⁹ taking into account sex and gender differences. Funding of late stage clinical trials is not within the scope of this topic.

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 general concepts of the FAIR²⁰ principles.

The topic invites proposals in complex disorders of high prevalence and of a high economic burden (rare diseases are excluded). SME participation is strongly 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.

¹⁸ <https://www.nature.com/scitable/topicpage/complex-diseases-research-and-applications-748>

¹⁹ http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_en.pdf

²⁰ <https://www.force11.org/group/fairgroup/fairprinciples>

Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- New concepts of combinatorial therapies for complex disorders tailored to the needs of individuals or stratified patient groups.
- Improved efficacy and take-up in the clinical setting 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: Exploiting research outcomes and application potential of the human microbiome for personalised prediction, prevention and treatment of disease

Specific Challenge: The human microbiome plays an important role for health. Many different projects in 'metagenomics' and epidemiological research in recent years have delivered new knowledge on associations between the microbiome and a wide range of diseases. International initiatives such as the International Human Microbiome Consortium (IHMC) have generated large-scale data. These research efforts were first of all made to identify host-microbe-interactions and links of the microbiome with diseases. Now the challenge is to accelerate the translation of data and knowledge to define balanced healthy conditions and to predict and prevent diseases through the development of personalised approaches and clinical tools. Building on existing data it is necessary to produce also new data with the aim to make the research more comprehensive or more holistic and to achieve more valuable clinical tools. Whilst the promise of such tools is evident, they need to be validated and be part of personalised medicine.

This topic will focus on the clinical aspects of personalised prediction and prevention of disease. Other aspects of microbiome research in relation to food/nutrition will be addressed by a cluster of topics in Societal Challenge 2. Further topics may be launched under the IMI2 JU.

Scope: The aim is to achieve understanding of balanced states of health and on that basis to deliver personalised approaches and clinical tools for predicting and preventing diseases. Proposals should integrate and use high quality microbiome, metabolome and other -omics data produced by large scale international initiatives. They should combine and expand these data with approaches including disease-oriented functional analysis, endogenous and

exogenous factors, innovative imaging, functional, structural and lifestyle, ageing, dietary data, environmental data, mental disorders and/or any other comorbidity.

Proposals should build on data from existing microbiome projects and, as appropriate, on data from other international initiatives. Focussed production of new data should make subject coverage more comprehensive with the aim of delivering more valuable clinical tools. Proposals should address relevant ethical implications, take into account sex and gender differences, the effect of country-specific issues and should include a section on research data management. The proposed work should be connected to the future European Open Science Cloud²¹ to enable sharing and re-use of resources as well as interoperability with other types of data and tools across disciplines. Proposals should contribute to standardisation of sample collection and storage, methods (Standard Operating Procedures) and study designs. SMEs participation is encouraged.

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 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:

- 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 and sectors.

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.

²¹ In particular, microbiome data sharing is relevant for the future Health Research and Innovation Cloud, which will be a thematic component of the European Open Science Cloud: https://ec.europa.eu/research/openscience/pdf/realising_the_european_open_science_cloud_2016.pdf.

SC1-BHC-04-2018: Rare Disease European Joint Programme Cofund

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 close research collaboration between Member States. European Reference Networks (ERNs²²) 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 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 (EJP) 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 healthcare 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 integration, efficacy, production and 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. Reaching these objectives requires support of a wide range of activities and participants which cannot be achieved with an ERA-NET-Cofund.

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:

1. Research and innovation programme to be funded through transnational calls for proposals resulting in financial support to third parties, based on the annual work plans of the EJP Cofund;
2. Development of a virtual platform for rare diseases information, research data, data based on samples, tools and standards to support and accelerate rare diseases research;
3. Capacity building to improve the research and innovation potential of key stakeholders and enhance uptake of research results;

²² https://ec.europa.eu/health/ern/policy_en

4. Strategic coordination and management.

The research and innovation programme should encompass various aspects of rare diseases, such as development of new means for diagnosis and screening, 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, social, economic and healthcare oriented studies including burden of disease studies, and health services research to improve patient outcomes and healthcare systems. The calls should be implemented on the basis of the standards and good practice for calls implemented under ERA-NET Cofund actions (international peer review, Horizon 2020 evaluation criteria, proposal selection according to the ranking list etc.).

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 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.

The EJP Cofund for Rare Diseases will contribute to the Health Research and Innovation Cloud, one of the thematic clouds of the European Open Science Cloud²³.

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 priorities and policy questions in demand for evidence generation, as well as monitoring of the outcome of the EJP Cofund. Appropriate considerations of the relevant ethical, legal, sex/gender 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.

For grants awarded under this topic for EJP Cofund, beneficiaries may provide support to third parties as described in General Annex K of the Work Programme either in form of grants or prizes. The respective options of Article 15 of the Model Grant Agreement will be applied.

²³ https://ec.europa.eu/research/openscience/pdf/realising_the_european_open_science_cloud_2016.pdf

Financial support provided by the participants to third parties is one of the primary aims of this action. Therefore, the 60 000 EUR threshold provided for in Article 137(1)(c) of the Financial Regulation No 966/2012 and Article 210(a) of the Rules of Application Regulation No 1268/2012, does not apply .

The Commission considers that proposals requesting a contribution from the EU of between 50 and EUR 55 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 the EU's capacity to innovate in the field of rare diseases.
- Improve healthcare systems' capacity to take up research results.
- Reinforce the EU's role as a global leader 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: International flagship collaboration with Canada for human data storage, integration and sharing to enable personalised medicine approaches

Specific Challenge: The EU has ample experience in building and running data repositories to support biomedical research. Notable initiatives are ELIXIR²⁴ and the European Genome-phenome Archive²⁵, storing many types of data up to the population-wide level. Similar expertise exists in Canada notably via IHEC (International Human Epigenome Consortium²⁶) and its Data Portal²⁷ as well as PhenomeCentral, a repository for clinicians and scientists working on human rare disorders²⁸.

There is a recognised need for tools that allow researchers to manage, exchange and preserve their data efficiently. Data repositories are scattered around the world and often do not 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

²⁴ the pan-European infrastructure for life sciences data <https://www.elixir-europe.org/>

²⁵ <https://ega-archive.org/>

²⁶ <http://ihec-epigenomes.org/> and <http://ihec-epigenomes.org/about/policies-and-guidelines/>

²⁷ maintained at the Montreal Neurological Institute <http://epigenomesportal.ca/ihec/>

²⁸ <http://www.phenomecentral.org>

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 programme 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 policies developed by major international initiatives (e.g., IHEC, ICGC²⁹, IHMC³⁰, MME³¹).

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 data models should take into account sex/gender differences where relevant. 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 access, data transfers, and archiving complex datasets.
- Bioinformatics toolbox to support the analysis and 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 Governance³².

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, ELIXIR) and other on-going initiatives (e.g., International Consortium for Personalised Medicine³³, European Open Science Cloud³⁴, IHEC, etc.). Synergies should be sought with other projects (e.g. calls under the Innovative Medicines Initiative (IMI)³⁵ and running IMI

²⁹ <https://dcc.icgc.org/>

³⁰ <http://www.human-microbiome.org/>

³¹ <http://www.matchmakerexchange.org>

³² <https://www.oecd.org/health/health-systems/Recommendation-of-OECD-Council-on-Health-Data-Governance-Booklet.pdf>

³³ <http://www.icpermed.eu/>

³⁴ https://ec.europa.eu/research/openscience/pdf/realising_the_european_open_science_cloud_2016.pdf

³⁵ <https://www.imi.europa.eu/content/imi-2>

projects³⁶). 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. Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least one participant from Canada.

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 different amounts. In addition to the EU/Associated Countries and Canada, the proposed project consortia may include other international partners. SME participation is encouraged.

Expected Impact:

- Intensified sharing, reuse, collaboration and knowledge discovery in the health field, while ensuring legal safety on the use of the data.
- 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 2020³⁷.
- Strengthened position of the EU and Canada 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 and contribute to the Health Research and Innovation Cloud, one of the thematic clouds of the European Open Science Cloud.

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-06-2020: Digital diagnostics – developing tools for supporting clinical decisions by integrating various diagnostic data

Specific Challenge: The availability of appropriate decision support tools for healthcare practitioners can promote uptake of personalised medicine in health care. There is a need to

³⁶ ETRIKS: <https://www.etriks.org/>, EMIF: <http://www.emif.eu/>, OPEN-PHACTS: <https://www.openphacts.org/>

³⁷ <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/societal-challenges>

carry out research activities aiming to develop and validate such decision tools that would integrate available and/or emerging diagnostic means for the area concerned, enabling increased precision of diagnostics and clinical decision making. On-going progress in the fields of bioinformatics and biostatistics, advanced analytical tools (e.g. machine learning) up to Artificial Intelligence (AI) solutions, should make possible the development of devices, platforms or novel approaches leading to highly personalised diagnosis, based on the integration of data available from various sources. The ultimate result would be a detailed health status assessment from a multitude of viewpoints, in a systemic way and easy to use for clinical purposes, leading to better diagnostic accuracy, increased effectiveness and efficiency of treatments. Novel hardware enabling truly innovative, integrative diagnostic platforms can also be considered.

Scope: Proposals should develop tools, platforms or services that will use information provided by most relevant diagnostic means for a particular area, resulting in an accurate, detailed, structured, systemic and prioritised assessment of the health status in a patient. The proposed solutions should integrate various data sources such as medical records, *in vitro* and/or *in vivo* diagnostics, medical imaging, -omics data, functional tests (lab-on-a-chip) etc., while taking into account the actual needs of healthcare practitioners, and should be tested and validated in real-life settings in pilot centres, facilitating future Health Technology Assessment. These tools/platforms/services should contribute to improving diagnosis and clinical decision, not only integrate existing data, and should involve intelligent human-computer interface solutions to facilitate its daily use in clinical practice. Any medical data relevant for a particular disease (textual data, numerical measurements, recorded signals, images etc.) may be considered. The aim is to steer the development of solutions towards concrete patient and public sector needs, having the citizen and healthcare providers at the centre. Careful attention should be paid to appropriately addressing ethical and legal concerns, providing adequate information to health professionals and patients to support informed decisions, and ensuring data safety and privacy, in line with existing European and international standards and legislation. Gender and sex differences should be taken into consideration when relevant.

The Commission considers that proposals requesting a contribution from the EU of between EUR 8 and 15 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting different amounts.

Expected Impact:

- Increase EU's capacity to innovate in the area of medical instruments technologies through the development of new diagnostic tools, platforms or services integrating various diagnostic data and providing quick, detailed, accurate and highly personalised diagnostics for optimal decision in clinical practice.
- Improve the quality and sustainability of healthcare systems through quicker and more encompassing diagnosis of medical conditions, leading to quicker and better clinical

decisions and timely delivery of effective personalised treatments, with reduction of errors and delays (and costs associated to them).

- Contribute to the growth of the European diagnostics sector, in particular for SMEs.
- Reinforce EU's role among world leaders in the production of medical diagnostic devices.

Type of Action: Research and Innovation action

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

SC1-BHC-30-2019: Towards risk-based screening strategies for non-communicable diseases

Specific Challenge: Prevention and early detection continue to represent areas where effective strategies have the potential to generate major impacts. Effective screening may result in earlier disease detection which provides possibilities for more effective treatments, better disease control and care. It can diminish the disease burden and the costs of healthcare systems. Personalised medicine and health digitalisation provide new opportunities to improve targeted screening interventions through the identification of subpopulations at high risk of developing a disease.

Scope: Proposals should develop new or refined, targeted population-based screening interventions aiming at identifying populations or groups at high risk of developing disease. Stratification by health risk factors and determinants, such as (epi)genetic, exposomic, socio-economic, sex and gender, geographic, immunological, environmental, behavioural, occupational, cultural, and lifestyle habits should be addressed. Strategies may include the use of markers and digital applications.

The risk-adapted screening interventions should demonstrate a high level of accuracy, clinical value, cost-effectiveness, acceptability and the potential to be taken up by healthcare systems. Health inequities and ethics should be considered. Proposals should aim at providing sufficient evidence for health care systems implementation.

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:

- Established risk-based screening strategies, which have demonstrated to be effective, affordable, acceptable to the population, cost-effective and suitable for implementation.
- Demonstrated potential to improve health outcomes and equity across Europe.

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-31-2019: Pilot actions to build the foundations of a human cell atlas

Specific Challenge: For better understanding human health as well as improving the diagnosis, monitoring and treatment of diseases, greater knowledge is needed of the diverse cells found within the human body. Recent developments in single cell technologies, analytical methods and computational tools allow for unprecedented characterisation of human cells. A novel approach to address this challenge is the international Human Cell Atlas initiative (HCA) which will create molecular reference maps of all human cells. The potential scientific scope and organisation, including the community values to be adhered to by participating researchers, are described in a recent white paper³⁸.

European researchers are at the forefront of developments and thus, well-positioned to make an important contribution to building a human cell atlas. For this, it is imperative to bring together and strengthen European expertise to generate data and/or develop methods for in-depth, integrated molecular analysis and spatial resolution of single cells from complex biological systems such as human organs and tissues.

Scope: Each pilot action should demonstrate the utility of an interdisciplinary technological/biological platform to generate and integrate standardised molecular, cellular, biochemical and other data sets, characterising single cells or their nuclear components, their interactions and/or spatial location in tissues from **one** human organ. Platforms supporting analysis of tissues from more than one organ are also in scope. The primary focus should be on healthy tissues, though comparison between healthy and diseased tissues could be appropriate. Sex, age and ethnicity comparisons could also be considered. Proposals should provide detailed plans for quality management of tissue procurement and data in compliance with the relevant EU legislation (e.g. ethics, data protection).

Proposals supported under this topic must strictly adhere to the values, standards and practices of the HCA³⁹ and provide for co-ordination with ongoing European and international activities. Plans for building sustainability beyond the funding period and scalability should be included. Proposals for pilot phase actions under this topic should be ready to deliver results for the HCA quickly, therefore project should have a **duration of two years**. To ensure coherence and communication between projects funded under this topic and with the HCA, the Commission will ensure an overall coordination mechanism between the projects. Proposals are expected to budget for the attendance of co-ordinators to regular meetings, where communication of results and exchange of knowledge gained from each pilot will be the objective

³⁸ https://www.humancellatlas.org/files/HCA_WhitePaper_18Oct2017.pdf

³⁹ https://www.humancellatlas.org/files/HCA_WhitePaper_18Oct2017.pdf

The Commission considers proposals requesting a contribution from the EU of between EUR 3 and 5 million would allow for the specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Timely contribution of project results to the HCA
- Effective and sustainable biological and/or technological platforms.
- Competitive and sustainable European role in HCA
- Strong involvement of European technology SMEs
- Laying the groundwork for improving diagnosis and treatment of disease

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: Actions in support of the International Consortium for Personalised Medicine

Specific Challenge: Personalised Medicine is a very broad and multifaceted area where success relies on a well-functioning collaboration between several disciplines and different actors. While great advances have been made in some fields of medicine, in particular in stratification of cancer patients and in addressing rare diseases, most of today's healthcare protocols do not include personalised approaches apart from occasional division into broad age groups (children/adults/elderly), sex or ethnicity. Furthermore the prevention aspect of personalised medicine, i.e. identifying individuals prone to develop certain diseases, is largely isolated from treatment options. As is the case for a relatively nascent field there is a need for standardisation of approaches, including for sampling, data storage, interpretation and data exchange and also for clinical trials design and reimbursement models. European countries with their social model of healthcare along with (in several cases) centralised cost reimbursement, are ideally placed to lead the way for an integrated health management system. Many needs for coordination and support activities have been identified by ICPeMed⁴⁰, an EU Member States led initiative which includes representatives from most EU countries along with several other European countries, Brazil and Canada. The EC currently supports ICPeMed with a grant to operate its secretariat until October 2020⁴¹. Wider internationalisation of ICPeMed can be underpinned by coordinating networking activities with third countries.

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

⁴⁰ <http://icpermed.eu>

⁴¹ H2020 Grant Agreement 731366

1. International aspect: The action should focus on building links with third countries by analysing the potential and advantages of collaboration in personalised medicine (PM) with those countries, studying areas of interest for Europe in PM collaboration and promoting international standards in the field. In particular the uptake of personalised approaches in health systems and healthcare should be addressed, taking into account social, cultural, ethical and legal aspects, health economy issues and equitable healthcare. For the 2018 call, the project should focus on CELAC⁴² as a group of countries, and for the 2019 call on China. For the 2020 call, the project should focus on countries in Africa⁴³, linking also into the EU-AU (African Union) policy dialogue and taking into account the new Africa-Europa Alliance for Sustainable investment and Jobs⁴⁴. Alignment with activities of the Global Alliance for Chronic Diseases (GACD) and The European and Developing Countries Clinical Trials Partnership (EDCTP) activities should be explored. Special attention should be given to prediction and prevention, and to promoting well-being for all at all ages. Furthermore, the project should seek to integrate local knowledge and practice. Data safety and privacy should be addressed in line with existing standards and legislation. The project should have a duration of at least four years and address sustainability beyond that to ensure longer term structuring effect. Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least one participant based in the international partner region; CELAC (2018 call), China (2019 call) and Africa (2020 call).
2. Regional aspect: The action should establish and support networking between regions and interregional cooperation in different European countries, in particular linking remote or sparsely populated regions with regions harbouring critical mass of medical and PM expertise while taking into account broader socio-economic and cultural aspects. 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. Linkage to existing inter-regional projects (financed by INTERREG programmes) or interregional partnerships of Thematic Smart Specialisation Platforms will be actively encouraged. (2018 call).
3. 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 medicine development for

⁴² Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Grenada, Guyana, Jamaica, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Saint Lucia, Saint Kitts and Nevis, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago, Uruguay, Venezuela

⁴³ [African Union Member States](#)

⁴⁴ <https://www.africa-eu-partnership.org/en/stay-informed/news/european-commission-unveils-new-africa-europe-alliance-sustainable-investment-and>

citizens and their broader social environment while ensuring patient safety, access, equity, solidarity, data safety and financial sustainability of public health systems in the EU. The action should involve different relevant stakeholders and take into account work being carried out by other EU funded initiatives, such as EUnetHTA⁴⁵. SME participation is encouraged. Results of the studies and workshops should be actively disseminated to a wider audience, including relevant authorities, professionals and the wider public. (2018 call).

4. **Standardisation for clinical study design.** Establishment of innovative clinical trial design methodology for PM, including guidelines for research and reflection papers. The action should take into account sex/gender differences as well as the work done by relevant stakeholders and authorities such as EMA⁴⁶ and the HMA network⁴⁷, as well as the European legal framework⁴⁸. SME participation is encouraged. The results of the studies and workshops should be actively disseminated to a wider audience, including, industry, researchers and other professionals. (2019 call).
5. **ICPerMed secretariat:** The project should continue the work done by the secretariat for ICPerMed, e.g. maintenance of existing services, organising the meetings of the ICPerMed Executive Committee, convening dedicated workshops and preparing and issuing updates of the ICPerMed Action Plan. Furthermore maintaining the network of policy makers and funders gathered in ICPerMed and expanding the membership to new interested and complementary partners as well as maintaining communication with all EC funded activities related to ICPerMed (2020 call).

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

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

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

1. **International aspect:** Integrating the country/group of countries into ICPerMed activities. Support wider adoption of standards developed in Europe. Support the EU-AU policy dialogues relevant to research and health (2020 call). Contribute towards the UN Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages.

⁴⁵ European Network for Health Technology Assessment: <http://www.eunethta.eu/>

⁴⁶ European Medicines Agency: www.ema.europa.eu

⁴⁷ Heads of Medicines Agencies: <http://www.hma.eu/>

⁴⁸ Especially the clinical trials regulation (EU) No 536/2014 and the data protection regulation (EU) 2016/679

2. Regional aspect: Strengthened links between European regions setting up or planning 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.
3. Healthcare- and pharma-economic models: Increased understanding of personalised medicine perspectives on how to capture value, develop institutional support 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.
4. Standardisation for clinical study design: Contribute to standardisation of PM clinical trial 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.
5. **ICPerMed secretariat (2020 Call)**: Ensure continuity of the operations of ICPerMed beyond 2020. Increase the visibility of the consortium and ensure openness of the structure. Provide harmonised vision for the further development of personalised medicine. Contribute to the convergence of members' approaches to personalised medicine and further alignment of research efforts in the field.

Type of Action: Coordination and support action

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

SC1-HCO-02-2018: 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 proposal 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 (addressing relevant ethical implications and sex and gender differences) 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 proposal 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 general concepts of the FAIR⁴⁹ principles, establish links with relevant initiatives already supported by the European Commission and create a collaboration with the relevant ESFRI European infrastructures, IMI projects and the relevant standardisation initiatives e.g. European Metrology Programme for Innovation and Research.

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

The Commission considers that a proposal requesting a contribution from the EU of between EUR 1.5 and 2 million would allow this specific challenge to be addressed appropriately.

⁴⁹ <https://www.force11.org/group/fairgroup/fairprinciples>

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-03-2020: Bridging the divide in health research and innovation – boosting return on investment

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

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

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

Scope: Applicants should propose actions that would shift benefiting organisations' R&I performance and would eventually increase their participation in EU funded collaborative projects. Proposed activities should aim to strengthen research development; improve governance, managerial and administration practices; increase the organisations' international profile; develop HR policies to attract and retain talents, taking into account gender aspects;

and create a culture that rewards scientific performance and innovation. Applicants may propose any actions that contribute towards these goals.

Beneficiaries of the activities should be active in the field of health research and innovation and should come from low performing⁵⁰ Member States/regions that have identified health R&I as a priority in their Research and Innovation Strategies for Smart Specialisation (RIS3). Applicants shall seek synergies with European Structural and Investment Funds, with European and national research and innovation programmes and if applicable with EEA and Norway grants. Applicants are encouraged to leverage funding of this call with other resources.

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

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

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

Type of Action: Coordination and support action

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

SC1-HCO-04-2018: 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 pool the necessary financial resources from participating national or regional research programmes in the area of neurodegenerative diseases research by

⁵⁰ As defined by Widening Participation and Spreading Excellence: Member States below 70% of the EU average of the Composite Indicator of Research Excellence.

implementing a transnational joint call for proposals resulting in grants to third parties with EU co-funding, with a view to scale-up the implementation of the JPND Research Strategy. Proposers are requested to also implement other joint activities, including training and additional joint calls without EU co-funding.

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.

Participation of legal entities from third countries is encouraged in the joint call as well as in other joint activities including additional joint calls without EU co-funding. Participants from these countries may request a Union contribution (on the basis of the ERA-NET unit cost) for the coordination costs of additional activities.

The specific focus of the joint call will be further developed by the beneficiaries of this action.

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

Expected Impact:

- 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 Strategic Research Agenda.
- 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.

SC1-HCO-14-2020: ERA-NET: Sustained collaboration of national and regional programmes in cancer research

Specific Challenge: Common challenges in cancer research can only be met by effective transnational cooperation on prioritised efforts, using national, regional and charity-based resources. Important achievements have been obtained by TRANSCAN and TRANSCAN-2.

However, more efforts are warranted to address the potential for sustainable coordination, the access to and sharing of data on cancer research and treatment as well as alignment of national, regional and foundation or charity-based programmes and activities in Member States/Associated States and beyond.

Scope: The successful proposal should align national, regional research funding programmes on translational cancer research by implementing a transnational call with EU co-funding resulting in grants to third parties.

Proposals should pool the necessary financial resources from the participating national (or regional) research programmes as well, where appropriate, leverage resources from pertinent foundations, charities and transnational initiatives, with a view to implementing a joint call for proposals resulting in grants to third parties with EU co-funding in this area. The proposal should overcome hurdles that impede long-term coordination, involving research and innovation and cancer care stakeholders, taking into account relevant cancer research and innovation and cancer care initiatives. The proposal should build on previous EU-funded ERA-NET initiatives in this area.

The proposal should also demonstrate potential impact at national, regional and transnational research and innovation programmes as well as a leverage effect on national and European research and competitiveness using key indicators. Other joint activities may include: analyses of research and innovation funding and impact, dissemination, communication towards citizens, training, and are requested to include other additional joint transnational calls (without EU co-funding).

The proposal should demonstrate that these co-funded other activities exclude any overlaps with related on-going actions co-funded by the EU under Horizon 2020 SC1.

Participation of legal entities from third countries, and/or regions including those not automatically eligible for funding in accordance with General Annex A, is encouraged in the joint call as well as in other joint activities including additional joint calls without EU co-funding. Participants from countries not listed in General Annex A are eligible for EU funding under this topic and may request a Union contribution (on the basis of the ERA-NET unit cost) only for the coordination costs of additional activities. The proposal should demonstrate that these co-funded other activities exclude any overlaps with related on-going actions co-funded by the EU under Horizon 2020

The ERA-Net should envisage a duration which is appropriate to the ambition and complexity of the proposed topic. The Commission considers that proposals requesting a contribution from the EU of a minimum of EUR 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:

- Identification of common research and innovation priorities, taking into account international developments where relevant.
- Leveraged funding, through transnational collaborative research and innovation on cancer, based on a common strategic research agenda.
- Streamlined national, regional and foundation or charity-based practices in organising research and innovation funding.
- Demonstrated sharing of data and analyses of funded cancer research and their impact.

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.

SC1-HCO-16-2020: ERA-NET: Sustained collaboration of national and regional programmes in research on brain-related diseases and disorders of the nervous system

Specific Challenge: Cooperation at transnational level in the area of brain-related diseases has successfully been established but can be further enhanced and sustained through synergies between projects coming out from individual ERA-Net calls as well as pertinent partners beyond the ERA-Network itself.

Specific challenges include providing the necessary critical mass and resources to address commonly identified clinical needs. In particular, data sharing across funded projects should be enhanced. The overall aim is to nurture further collaboration amongst research funders as well as the projects in this field while extending its activities towards the intensification of cross projects collaborations within and beyond the ERANET projects.

Scope: Proposals should demonstrate the potential to coordinate in a sustained manner national and regional research programmes in the area of brain-related diseases, excluding neurodegenerative diseases, by implementing transnational calls with EU co-funding resulting in grants to third parties.

Proposed activities should promote wider collaboration between funded ERA-Net projects stemming from the same transnational call but also with relevant projects from other ERA-Net calls and pertinent H2020-funded projects and international partners active in this field of research.

More comprehensive and wider data sharing and early consideration of translational pathways should be inherent requirements for the translational calls to be launched by the ERA-Net.

Proposals should pool the necessary financial resources from the participating national (or regional) research programmes as well, where appropriate, leverage resources from pertinent foundations, charities and transnational initiatives, with a view to implementing a joint call for proposals resulting in grants to third parties with EU co-funding in this area..

Proposals are requested to implement other joint activities including additional joint calls without EU co-funding. The proposal should demonstrate that these co-funded other activities exclude any overlaps with related on-going actions co-funded by the EU under Horizon 2020 SC1. Proposals should engage with key stakeholders, including complementary ERA-Nets, competence partners on regulatory and guidelines issues. Collaboration with the EU funded European Brain Research Area Coordination and Support Action should be foreseen and integrated into the joint programming concept pursued by the funded ERA-Net project.

Participation of legal entities from third countries, and/or regions including those not automatically eligible for funding in accordance with General Annex A, is encouraged in the joint call as well as in other joint activities including additional joint calls without EU co-funding. Participants from countries not listed in General Annex A are eligible for EU funding under this topic and may request a Union contribution (on the basis of the ERA-NET unit cost) only for the coordination costs of additional activities. The proposal should demonstrate that these co-funded other activities exclude any overlaps with related on-going actions co-funded by the EU under Horizon 2020

The ERA-Net should envisage a duration which is appropriate to the ambition and complexity of the proposed topic. The Commission considers that proposals requesting a contribution from the EU a minimum of EUR 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:

- Joint investment of national and regional programmes in the area of brain-related neurological diseases;
- Increased common activities of national research programmes and projects;
- Leveraging synergies with other pertinent key players in Europe;
- Contribution to the establishment of Brain research ERA by addressing issues related for example to administrative hurdles, IPR management and different practices regarding resource sharing.

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.

SC1-HCO-17-2020: Coordinating and supporting research on the human microbiome in Europe and beyond

Specific Challenge: Integration and application of metagenomics data from the human microbiome has shown large potential for personalised medicine approaches, although causal relationships and confounders are still largely unknown. Comparable information and details about microbiome composition and functionality in healthy citizen and patients are very valuable to complete the picture i.e. to better understand the healthy microbiome and to predict its development.

The number of European and international projects and initiatives is increasing but their results and data cannot be properly compared as they have different underlying methods, standards and operating procedures. The International Human Microbiome Consortium (IHMC) as well as other current initiatives aim to strengthen international cooperation, to increase data comparability and to agree common standards, procedures and methods. There is a need to avoid having the same research carried out multiple times at different places and to better agree at European and at international level. This collaboration should increase coherence and data comparability to better exploit existing microbiome data and clinical information in a standardised way.

Scope: Proposals should aim for synergistic collaboration and agreement across various research and innovation programmes on the human microbiome, in Europe and worldwide, dealing with sample collection, processing, standardisation and healthy states references at different sites of the human body (not only one organ), including also interaction with omics, impact of drugs, nutritional and environmental aspects as well as sex and gender differences. In particular, they should support the agreement of concrete references of healthy human metagenomes across various different populations. Proposals should map the progress and the state of play for specific disease and health issues as well as the success and meaningfulness in different countries. They should propose concrete and strategic research actions on the human microbiome addressing gaps, emerging fields and political priorities. They should complement, support and enhance cooperation in similar activities within Europe and beyond⁵¹. In line with the strategy for EU international cooperation in research and innovation (COM(2012)497), international cooperation is encouraged with relevant partners from outside the EU. Proposals should cover the whole spectrum of human microbiome research from patient data collection all the way to study reporting in publications, social, ethical and legal aspects. Proposals should avoid networking without output and provide appropriate indicators to measure its progress and impact.

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

⁵¹ Proposals should take into account other relevant European and international research and networking initiatives as well as “one health initiatives”.

Expected Impact:

- International agreement on concrete methods, standards, procedures and in vivo models. Harmonisation and increased comparability of metagenomics, metabolomics and human microbiome data in Europe and beyond.
- International agreement on definitive references of healthy human metagenomes. These references should apply across various different populations and allow end-users and citizens to see which microbiome is clinically healthy.
- More meaningful results through collaborative synergistic collection of microbiome data from different directions. Improved coherence and reduction of overlap between national, EU and other funding in the area of human microbiome research, thus ensuring an efficient use of the available human and financial resources.
- Knowledge exchange and enhanced engagement of citizens, scientists and political stakeholders for priority health risks. Validated results will be delivered faster to people.
- Integration of metagenomics and human microbiome references into other multilateral co-operation areas or personalised medicine approaches.

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.

1.2 Innovative health and care industry

This priority will focus on turning 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 health and care research. Areas of research will include innovative diagnostics and therapeutics, including advanced therapies. It will improve the safety assessment of chemicals and the evaluation of high-risk medical devices. 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](#), the [Fast Track to Innovation](#) and the [Innovative Medicines Initiative \(IMI\)](#).

The expected key impact of this priority will be to stimulate the healthcare industry. This priority should (i) deliver applications and innovative products and services in the area of health; (ii) exploit the potential of the European health and care industry and contribute to growth, competitiveness and jobs in this sector.

Proposals are invited against the following topic(s):

SC1-BHC-07-2019: 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 should be based on new approaches such as genome editing or gene therapy, transdifferentiation or *in vivo* reprogramming, cell therapy and transplantation, 3D bioprinting, organoids or use of combined products (non-exhaustive list for illustrative purposes only). 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 on any step(s) on the innovation chain, from early testing and characterization of regenerative mechanisms to preclinical research, proof of concept or clinical trial. Sex and gender differences should be investigated, where relevant. 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-08-2020: New interventions for Non-Communicable Diseases

Specific Challenge: Non-communicable diseases represent a significant burden on individuals and healthcare systems, accounting for 86 % of all deaths in Europe. Innovative and effective healthcare interventions are required to find a cure or provide best quality of care when prevention strategies have failed. While considerable knowledge has been generated by biomedical research, potentially promising healthcare interventions often fail clinical validations and as a consequence do not reach patients.

Scope:

Proposals should conduct early stage⁵² clinical trial(s) to validate novel or refined healthcare interventions⁵³ for patients suffering from non-communicable diseases (Rare diseases and regenerative medicine are not within the scope of this topic). Clinical trial(s) should be supported by proof-of-concept⁵⁴ of clinical safety and efficacy⁵⁵ and may be investigator-initiated. Both preclinical research and the draft clinical trial protocol should be completed at the time of submission of the proposal. Applicants should present a sound feasibility assessment, including an appropriate patient selection and realistic recruitment plans, justified by publications or preliminary results. Proposals should demonstrate potential clinical benefit, including consideration of patient-reported outcomes when relevant. Sex and gender differences should be considered; age and other stratification criteria⁵⁶ should be considered when relevant. Where appropriate, patients and carers should be involved and their views reflected in research activities. Proposals should demonstrate evidence of preliminary consultations with ethics and regulatory authorities at the time of submission.

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:

- Candidate healthcare interventions that would generate meaningful advances in clinical practice and care for patients with non-communicable diseases for late stage clinical trials.
- Potential to improve patient-centred outcomes and to impact on the disease burden of individual patients and health care systems following validation in late stage clinical trials.

Type of Action: Research and Innovation action

⁵² For pharmacological interventions: phase 1 and phase 2 clinical trials

⁵³ Applicants may address any mono- or combinatorial pharmacological and/or non-pharmacological intervention.

⁵⁴ Comparative effectiveness studies are not within the scope of this topic.

⁵⁵ Clinical Trial Regulation EU No. 536/2014:
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

⁵⁶ Such as, clinical and molecular features of the patient and/or the disease, socio-economic status, etc.

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

SC1-BHC-09-2018: Innovation platforms for advanced therapies of the future

Specific Challenge: Advanced therapies are based on gene, cell or tissue-engineered products which are defined 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) 1394/2007⁵⁷, projects should create knowledge, testing 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 and/or aim to overcome particular development bottlenecks. Possible components could include studying the basic biology of the potential therapy and investigating its mode of action, proof of concept (*in vitro*, in animal models – where necessary - or first-in-man studies); safety, efficacy, characterisation, refinement and manufacturing of the product could be considered. 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, lack of adequate pre-clinical models, or responding to regulatory concerns, such as potency assays, product characterization, or bank-to-bank variability (non-exhaustive list for illustrative purposes only). Sex and gender differences should be investigated, where relevant. Potential ethical issues should be addressed.

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.

⁵⁷ OJ L 324, 10.12.2007, p. 121.

- 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: 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 inconvenience 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 healthcare systems. This includes organisational, economical, technical and clinical aspects. It should lead to NGS tests, clinically validated procedures (including sex analysis), 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. Input from initiatives like the EJP Cofund on rare diseases and ERNs⁵⁸ should be considered when relevant. Ethical issues should be addressed.

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

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

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

Expected Impact:

⁵⁸ https://ec.europa.eu/health/ern/policy_en

- 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 healthcare 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-BHC-11-2020: Advancing the safety assessment of chemicals without the use of animal testing

Specific Challenge: The reliability and relevance of animal studies to support chemical safety assessment are subject to increasing scrutiny from a scientific perspective and raises broader societal concerns. To address these challenges, the European Commission has been supporting the development and application of animal-free approaches to toxicological profiling of chemicals in support of chemical safety assessment. However, significant challenges remain regarding the provision of viable animal-free solutions to address systemic health effects in humans potentially linked to chronic exposure to chemicals across a variety of regulated sectors. Consequently, further efforts are needed to progress on the development, validation and translation of scientifically sound methods that not only decrease the reliance on animal testing but which also deliver more relevant, reliable and cost-effective means to facilitate decision-making to support regulation, innovation and competitiveness.

Scope: Proposals should consider integrative approaches that build on advances in all relevant fields of science and technology, including elements such as novel *in vitro*⁵⁹ and *in silico* tools and the understanding of human biology and related toxicity pathways, with the aim of proposing and demonstrating scientifically valid means for comprehensive safety assessment of chemical substances without resorting to animal testing. Priority should be on systemic health effects in humans. Exploitation of qualitative and quantitative information and knowhow from animal, clinical, epidemiological, exposure and biomonitoring studies is encouraged where appropriate to inform research strategies and to establish the scientific credibility of the approaches proposed for relevant decision-making contexts. In addition, attention should be given to establishing and pursuing concrete measures to seek acceptance and uptake by end-users striving to address safety assessment challenges in support of product development and addressing regulatory information requirements.

⁵⁹ *This may include animal-derived material*

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

As a way to facilitate progress and to accelerate the harmonisation, acceptance and promotion of new approaches worldwide, applicants are encouraged to seek cooperation with industry and collaboration with any relevant complementary initiatives as well as with regulatory bodies.

The Commission considers that proposals requesting a contribution from the EU of between EUR 10 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:

- Scientifically sound, practicably implementable non-animal solutions readily deployable to aid in meaningful safety assessment of chemicals.
- Recognition from regulatory bodies and their engagement to translate results, methods and solutions into safety assessment practice.
- Uptake and commercial exploitation of the developed safety assessment approaches, products and services.
- Contribution to the Three Rs (3Rs) principles ('Replacement', 'Reduction', 'Refinement'), with a particular emphasis on the 'Replacement' opportunities.

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-05-2018: Strengthening regulatory sciences and supporting 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 novel indications or new treatment/dosing schemes for already registered pharmaceutical products.

For such innovations to achieve full impact, it is necessary to file for new marketing authorisations or request significant changes of the regulatory labelling of existing marketing authorisations to bring improvements from academic research into clinical practice. However, in a majority of cases, the clinical research conducted by researchers in academia does not fulfil regulatory requirements and thus, innovations do not reach the patients in a timely and

efficient manner. Researchers often do not allocate enough time and resources and also lack specific relevant know-how to develop strategies enabling successful regulatory Scientific Advice procedures. This is partly because regulatory sciences are not well addressed in medical teaching and training programmes.

Scope: Proposals should; (i) establish, regularly update and disseminate a comprehensive inventory⁶⁰ of existing support activities for regulatory Scientific Advice and Protocol Assistance in Europe such as the Innovation Task Force (ITF⁶¹) briefing meetings; (ii) analyse the effectiveness of existing support activities and develop a common strategy for training programmes to strengthen regulatory sciences and improve support for successful outcomes from regulatory Scientific Advice and Protocol Assistance based on identified best practices; (iii) support and/or advice for the delivery of corresponding pilot training programmes in an efficient and collaborative manner, and (iv) assess the need for and possibly propose additional mechanisms sustainably supporting academic groups in regulatory Scientific Advice and Protocol Assistance procedures.

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

The relevant stakeholders must be involved in the consortium that will implement this action, in particular all interested national competent authorities (NCAs) alongside academic and industry representatives and associations with relevant experience. NCAs should have clearly identified contact points. Proposals should consider the involvement of the European Medicines Agency (EMA⁶²), the Heads of Medicines Agencies (HMA) network⁶³ and EUnetHTA⁶⁴ at European level, 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:

⁶⁰ Already existing initiatives and infrastructures should be integrated efficiently and to the fullest extent

⁶¹ The Innovation Task Force (ITF) is working on matters relating to emerging therapies and technologies. EMA and the EU national competent authorities (NCAs) strengthened their collaboration to support medicine innovation and early development of new medicines by establishing the EU innovation network.

⁶² European Medicines Agency: www.ema.europa.eu

⁶³ The Heads of Medicines Agencies is a network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area <http://www.hma.eu/>

⁶⁴ EUnetHTA Joint Action 3 is a European network of national/regional HTA bodies under the EU Third Health Programme <http://www.eunetha.eu/>

- 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 benefits for patients and healthcare systems.

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-18-2020: Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices

Specific Challenge:

- In May 2017, a new Regulation on medical devices, [Regulation \(EU\) 2017/745](#)⁶⁵ entered into force that will come into effect in spring 2020. This new Regulation sets forth reinforced rules for the generation of clinical evidence: for instance, clinical investigations⁶⁶ for high-risk devices will be compulsory⁶⁷ and the requirements regarding the clinical evaluation⁶⁸ throughout the product lifetime are more stringent.
- Medical devices have particularities that make the conduct of clinical investigations difficult. Taking into account these particularities, there is a need for methodologies that enable to generate improved clinical evidence. New developments in medical technologies such as mHealth, artificial intelligence, and combination products, pose additional challenges and opportunities for developers⁶⁹ to generate high-quality clinical evidence.
- Owing to rapid scientific progress and lack of knowledge on the regulatory frameworks among the scientific community, there is a need to raise awareness on new regulatory requirements in terms of clinical evidence. It is important to ensure a smooth transition from the former directive to the new regulatory framework, especially with regard to clinical evidence, by informing stakeholders involved in the clinical evaluation of high-risk medical devices (e.g. academic researchers, clinicians, manufacturers, notified bodies, contract research organisations).

⁶⁵ [Regulation \(EU\) 2017/745](#) of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

⁶⁶ As defined in Article 2 (44) of the Regulation (EU) 2017/745

⁶⁷ as provided for in Article 61.4 of the Regulation (EU) 2017/745 : implantable and class III devices with the exceptions listed in Article 61.5 and 61.6. Those devices are referred to as “high-risk” devices in the text.

⁶⁸ As defined in Article 2 (45) of the Regulation (EU) 2017/745

⁶⁹ Developers include manufacturers and other entities active in the development of medical devices

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

Scope: To address these challenges, the proposals should focus on i) methods to generate clinical data both within the context of a clinical investigation and in daily practice (i.e. real-world data) so that robust clinical evidence is available for high-risk medical devices, and ii) aggregation methods that will allow to make optimal use of all available data taking into account its heterogeneity (e.g. meta-analysis methods using different statistical approaches, methods to combine data from different types of sources) and iii) promote exchange of best-practices and support network activities among developers. Proposals should in particular:

- Analyse the particularities of high-risk medical devices and the potential resulting problems with regard to clinical evaluation, carry out a review of the currently used clinical investigation designs for the evaluation of such devices, provide a hierarchy of these approaches, identify gaps to be filled (in particular in view of new developments like e.g. mHealth, artificial intelligence, and combined products) and derive recommendations for the choice of clinical investigation methodology to obtain sufficient evidence.
- Develop methodologies for generating clinical data on high-risk medical devices enabling to collect sound data and to use data from different sources including real-world data. These methodologies should be adapted for the needs of conformity assessment and for continuous clinical evaluation throughout the lifetime of the device. Proposals should take into account the various specificities of high-risk medical devices and therapeutic areas if relevant.
- Contribute to the exchange of best practices among notified bodies with regard to the assessment of clinical data as provided by developers of high-risk medical devices.
- Support networking activities among developers and in particular academic centres with regard to regulatory requirements for assessing high-risk medical devices and foster a pool of scientific expertise on clinical evaluation of high-risk medical devices.

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

Proposals should complement or build on existing work, including results of EU-funded research projects and Joint Actions in the field of medical devices evaluation, and related activities, like e.g. those of the Competent Authorities for Medical Devices (CAMD) and the successor Medical Devices Coordination Group (MDCG).

Proposals could consider the involvement of The European Commission Joint Research Centre (JRC) to provide added value regarding aspects like interfacing among the different stakeholders (e.g. developers and regulatory bodies) or contributing to European and international harmonization. In this respect the JRC is open to collaborate with any successful proposal.

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

Expected Impact:

- Higher quality and reliability of clinical data needed for conformity assessment and continuous market access
- Improved knowledge of relevant legislative frameworks and regulatory requirements among all stakeholders involved in the development of high-risk medical devices
- Improved evidence on safety and efficacy of high-risk medical devices for the benefit of the patient and health systems.

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-19-2020: Reliable and accessible information on cell and gene-based therapies

Specific Challenge: Cell and gene-based therapies have the potential to treat many debilitating diseases and conditions. However, the pace of their clinical development does not meet public expectations. They face difficulties reaching patients because *inter alia* the complexity and costs of product development, regulatory hurdles and the non-harmonized procedures for reimbursements. In addition, there are concerns over patient safety due to the use of unproven treatments^{70 71}.

Scope: Proposals should offer well-structured and detailed strategies to convey accurate and up-to-date information on cell and gene-based therapies using multiple contemporary

⁷⁰ <https://blogs.scientificamerican.com/news-blog/embryonic-stem-cells-cause-cancer-i-2009-02-19/>

⁷¹ https://www.senato.it/application/xmanager/projects/leg17/file/repository/relazioni/libreria/novita/XVII/IC-41_stamina.pdf

modalities, including a website. The consortium should consist of diverse actors and could include experts in science communication, patients' representatives, industry, SMEs, clinical and academic researchers as well as the major European learned societies in the field. They should provide expertise across the field of human stem cells, regenerative medicine, genome-editing and gene therapy. All communication material/information should be translated to English and proposals should provide a detailed strategy on the linguistic approach of dissemination in order to reach a large EU audience. The website should be user-friendly and should contain tailored sections dedicated to at least researchers, patients, and the public.

For broader audiences proposals should create a reliable, transparent, accessible resource for patients to make informed decisions and for citizens to have access to scientifically viable information on cell and gene-based therapies, including sex and gender aspects when relevant. Proposals should provide state-of-the-art strategies to engage the public and foresee regular evaluation of whether they reach the targeted audiences. In addition, a series of communication events should be organised, also open to the public, where innovative technologies could be presented and discussed.

For the research community, proposals should create an information source on the practical steps needed for cell and gene-based therapy development. Proposals should provide a one-stop shop on where to seek further information and guidance relating to manufacturing guidelines, regulatory requirements, intellectual property rights, market acceptability and ethical matters. Proposals should provide a strategy on how they will liaise with regulatory agencies (e.g. national agencies, the European Medicines Agency (EMA⁷²), the Heads of Medicines Agencies (HMA⁷³) network, EUnetHTA⁷⁴ network). Finally, proposals should include a realistic sustainability plan which explores how the ownership of the information will be structured, and propose a defined organisation to take responsibility, manage and administer the information, and to which authorities/organisations the information will be delivered at the end of the project. Sustainability should be ensured for at least 5 years after the end of the project.

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

- Better informed decision making by patients and the public, due to objective, accurate and transparent communications of the latest developments and actual treatments available in the field in order to avoid misconceptions

⁷² European Medicines Agency: <http://www.ema.europa.eu/en>

⁷³ The Heads of Medicines Agencies is a network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area <http://www.hma.eu/>

⁷⁴ EUnetHTA Joint Action 3 is a European network of national/regional HTA bodies under the EU Third Health Programme <http://www.eunetha.eu>

- Better informed decision making by regulatory and healthcare authorities, due to better access to reliable and updated information, and to stronger synergies and knowledge sharing between decision-makers and other stakeholders including advanced therapies learned societies.
- Improved products development, by providing the research community and patients with a high-quality information source.

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

This priority will tackle infectious diseases and the health of vulnerable groups. Taking a 'One Health'- and a more personalised approach, it will target the improvement of risk assessment and surveillance tools, 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. It will address low-vaccine uptake. Also relevant to this priority are maternal and newborn health, global collaboration on non-communicable diseases and on brain research, 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, the EU and WHO (World Health Organisation) Global AMR (AntiMicrobial Resistance) action plans, the European One Health Action Plan against Antimicrobial Resistance, the global coordination of emerging infectious diseases research, and further multi-lateral research initiatives.

The key expected impact of this priority is to prevent, detect and treat priority diseases worldwide. Additional impacts are: (i) to position the EU as a leading partner in the promotion of global health and the fight against infectious diseases; (ii) to support research preparedness for epidemics and development of vaccines and medicines for communicable and non-communicable diseases; (iii) to implement the GloPID-R (Global Research Collaboration for Infectious Disease Preparedness) and GACD (Global Alliance for Chronic Diseases) agendas as well as the related G7, G20 and WHO actions; (iv) to provide evidence for addressing migration-related health issues.

Proposals are invited against the following topic(s):

SC1-BHC-13-2019: Mining big data for early detection of infectious disease threats driven by climate change and other factors

Specific Challenge: A range of factors is responsible for the (re-)emergence of infectious disease threats, including antimicrobial resistance, altering the epidemiology and spread of disease in a changing global environment. These include drivers such as climate change and

associated environmental impacts, population growth, unplanned urbanisation and high mobility, as well as animal husbandry or intensive farming practices.

At the same time, tools for infectious disease diagnostics and surveillance are evolving rapidly, allowing for ever more accurate diagnosis in ever shorter time. The use of next generation sequencing combined with surveillance data, health registries and societal data from informal/non-traditional sources (e.g. social media) holds promise for improving individual and population health. Current advanced IT technologies offer the opportunity to integrate such big data sets and could enable the rapid and personalised treatment of infected patients, and bolster the detection, tracking and control of infectious disease outbreaks.

Scope: It is expected that proposals develop:

1. the technology to allow the pooling, access, analysis and sharing of relevant data, including next generation sequencing;
2. the innovative bio-informatics and modelling methodologies that enable risk modelling and mapping; and
3. the analytical tools for early warning, risk assessment and monitoring of (re-)emerging infectious disease threats.

Proposals should be able to demonstrate the feasibility of such extended data mining for the purposes outlined above, as well as its European level added value. The ready-to-use analytical tools and services that are developed should be based on an assessment of the needs of potential end-users in the Member States and on European level, should as far as possible build on and be compatible with existing European initiatives, and should remain available for public use at the end of the project at a reasonable cost.

Proposals should be transdisciplinary and ensure an integrated One Health approach by linking data from a wide range of relevant sources depending on the infectious disease threat. These may include human (e.g. community, hospital or laboratory health services) and animal health surveillance, health registries, microbial and viral genomic data (including next generation sequencing), pathogen resistance data, mapping of vectors, climate and environmental data⁷⁵ as well as societal data that are correlates of disease; possible sex and/or gender differences should be taken into account. Solutions for gaps in existing data (addressing both a lack in quality and quantity) should be proposed.

Solutions for interoperability between different data sources should be addressed and integrated. It is expected that quality-controlled data are shared in accordance to the general concepts of the FAIR⁷⁶ principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose. Appropriate regulatory and governance mechanisms need to be foreseen, taking into account different data sharing needs, as well as data privacy and data security aspects for the different types of stakeholders providing and

⁷⁵ The use of climate change data from Copernicus is encouraged: <http://climate.copernicus.eu/>

⁷⁶ Findable, accessible, interoperable, re-usable: <https://www.force11.org/group/fairgroup/fairprinciples>

analysing 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. The proposal shall foresee, in case of public health emergencies, open access to data at the moment it is generated or no later than one month thereafter subject to any safeguards required to protect research participants and patients, in accordance with the relevant options in Article 29.3 of the Model Grant Agreement.

The use of advanced IT technologies like high performance computing, or geo-localisation data⁷⁷ are anticipated. The use of European health research (e-)infrastructures such as those included under CORBEL⁷⁸ is encouraged where relevant. 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. If more than one proposal is selected, they are expected to collaborate. 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 preparedness to address threats from (re-)emerging infectious disease threats, by making available the appropriate technology and tools for risk modelling and early threat detection, to support an appropriate public health response.
- Contribution to the European One Health action plan against antimicrobial resistance.⁷⁹
- Contribution to the digital transformation of health and care within the context of the EU Digital Single Market.⁸⁰
- Contribution to achieving Sustainable Development Goal (SDG) 3 and specifically the targets on 1) combating epidemics, and 2) strengthening capacity for early warning and response to health risks.⁸¹ Contribution to achieving of SDG 13 and specifically the targets on 1) integrating climate change measures into national policies, strategies and planning, and 2) improving education, awareness-raising and human and institutional capacity on climate change adaptation, impact reduction and early warning.⁸²

Type of Action: Research and Innovation action

⁷⁷ Use of data from the European global navigation satellite systems Galileo and EGNOS (Geostationary Navigation Overlay Service) is encouraged.

⁷⁸ <http://www.corbel-project.eu/home.html>

⁷⁹ To be published mid-2017.

⁸⁰ https://ec.europa.eu/commission/priorities/digital-single-market_en

⁸¹ <http://www.un.org/sustainabledevelopment/health/>

⁸² <http://www.un.org/sustainabledevelopment/climate-change-2/>

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

SC1-BHC-14-2019: Stratified host-directed approaches to improve prevention, treatment and/or cure 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 therapeutic, curative 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, cures 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 and/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 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 and will thus require expertise from the social sciences and the humanities.

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, cures and/or preventive measures for infectious diseases and/or validated biomarkers with potential for rapid uptake into clinical practice.
- Reduced burden of major infectious diseases.
- Contribute to the achievement of the [European One Health Action Plan against Antimicrobial Resistance](#).
- Contribute to the achievement of the Sustainable Development Goal 3, ensure health and well-being for all, at every stage of life.

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

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, driven by factors like the climate change and globalization. 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 diseases⁸³. Therefore, the proposed

⁸³ 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 helminthiasis, food-borne trematodiasis, filariasis, Onchocerciasis,

actions should focus on late preclinical (e.g. validation in animal models, toxicology, Good Manufacturing Practices (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. Sex and gender differences should be taken into account where relevant.

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 elements of the target-product profile (TPP): suitability, acceptability, adaptability of the intervention to be developed for different population groups, including particularly vulnerable ones (e.g. women and children), served by under-resourced health systems.
- 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 allow uptake by health systems in limited-resource settings.

Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least one participant from disease-endemic countries.

Please note that this topic is part of the lump sum funding pilot scheme. Funding for grants awarded under this topic will take the form of lump sums as defined in [Commission Decision C\(2017\)7151 of 27 October 2017](#). Details of the lump sum funding pilot scheme are published on the [Participant Portal](#) together with the specific [Model Grant Agreement for Lump Sums](#) applicable.

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:

taeniasis/cysticercosis, dracunculiasis, echinococcosis) diseases, as well as bacterial diseases like Buruli ulcer, leprosy, yaws and mycetoma. Neglected viral diseases are specifically excluded from this topic.

- Increase the number and quality of treatment and vaccine candidates for neglected infectious diseases appropriate for implementation and uptake by health systems with limited resources.
- Reduce the NIDs disease burden and their 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).
- Strengthen the pipeline of products 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).

Type of Action: Research and Innovation action Lump Sum

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

SC1-BHC-16-2018: Global Alliance for Chronic Diseases (GACD) - Scaling-up of evidence-based health interventions at population level for the prevention and management of hypertension and/or diabetes

Specific Challenge: The Global Alliance for Chronic Diseases⁸⁴ (GACD) aims to coordinate research on chronic diseases at a global level in order to enhance knowledge exchange across individual projects, and to better understand the impact of socio-economic, cultural, geopolitical and policy on research findings, so as to appropriately adapt interventions and scale-up to different geographical, economic and cultural settings. The GACD call will support research associated with the scale-up of interventions for the prevention and/or management of hypertension and/or diabetes in low- and middle-income countries (LMIC⁸⁵) and/or in vulnerable populations in high income countries (HIC).

Hypertension affects one billion people worldwide and is a major contributor to the growing global pandemic of cardiovascular disease and stroke. It is estimated that raised blood pressure indirectly currently kills approximately 8 million people every year⁸⁶, while cardiovascular disease accounts for approximately 18 million deaths a year⁸⁷, nearly one third of total deaths. Not only is hypertension more prevalent in LMIC, there are also more people affected because a larger proportion of the population live in those countries than in HIC.

Poor hypertension control and the absence of strategies to maintain normal blood pressure, particularly in LMICs and in vulnerable populations in HIC, reflect the challenges of effective and affordable implementation in healthcare and other sectors.

⁸⁴ <http://www.gacd.org/>

⁸⁵ World Bank country classification based on estimates of gross national income per capita: databank.worldbank.org/data/download/site-content/CLASS.xls

⁸⁶ Forouzanfar et al. JAMA. 2017;317(2):165-182. doi:10.1001/jama.2016.19043

⁸⁷ Roth et al. J Am Coll Cardiol. 2017 May 15. pii: S0735-1097(17)37244-3.

In the past twenty years the global death rate from diabetes has doubled and the World Health Organisation is predicting that this will increase by two thirds by 2030. It is currently estimated that 422 million adults worldwide suffer from diabetes of which 80% are from LMIC. In 2012, an estimated 1.5 million deaths were directly caused by diabetes and another 2.2 million deaths were attributable to high blood glucose⁸⁸.

Identifying and evaluating interventions to assess efficacy is not always enough to ensure their wide uptake in the real-world. Even when information, tools and interventions have been tested within real-world effectiveness studies, the development of knowledge to support their broader uptake⁸⁹ has often remained outside the remit of research. Effectively implementing and scaling-up interventions, programmes, and policies to the regional and national levels are persistent challenges.

It is essential that policy makers, communities, families, caregivers, patients, as well as healthcare practice and other settings are equipped with evidence-based strategies to integrate scientific knowledge and effective interventions into everyday use. Researchers have found it challenging to ensure that tools and interventions deemed efficacious within clinical or community-based trials are readily adopted and implemented. Scaling-up interventions to large populations is not a straightforward task. In practice, translation from a pragmatic trial to the real-life commissioning and continuous delivery of an intervention across a health system is a huge political and economic challenge. Without intentional, guided efforts to scale-up, a new evidence-based intervention might not be broadly implemented.

Scope: Proposals must focus on the scale-up of interventions at population level for hypertension and/or diabetes prevention and/or management in LMIC, and/or in vulnerable populations in HIC. Proposals addressing comorbidities with either hypertension or diabetes, including between them, are encouraged.

Proposals must align with commitments or planned commitments at a regional or country level to implement evidence-based interventions (including evidence of cost-effectiveness and affordability) across health or other sectors. Policymakers, intervention payers (excluding research funding agencies), researchers (including local researchers), implementers and beneficiaries should be involved at all stages of the intervention development and implementation design to identify the challenges to intervention delivery in real settings. Such partners will be integral to the success and sustainability of the programme and it is essential that they are engaged early, and participate actively in the design of the research proposal. Researchers should collaborate closely with the authorities responsible for the programme's delivery. Those authorities must pay for and provide the interventions, possibly through loans contracted from development banks or other financial providers. Proposals will carry out the research associated with the scale-up of the intervention.

⁸⁸ WHO Global report on diabetes: <http://www.who.int/diabetes/global-report/en/>

⁸⁹ For instance: cost and financing of the intervention, provider training, availability of resources, integration into healthcare systems, delivery to vulnerable or difficult-to-reach populations, monitoring the quality of intervention delivery

Proposals must build on evidence-based interventions (including evidence of cost-effectiveness and affordability) for the respective population groups under defined contextual circumstances and should seek to replicate and scale-up interventions. The selected interventions to be scaled-up should have been proven to be equitable, safe, effective, and efficient as well as making local health systems and health services more responsive and person-centred. In particular, proposals should:

- Be targeted at the regional or national level.
- Identify, develop, test, evaluate and/or refine strategies to scale-up evidence-based practices⁹⁰ into public health, clinical practice, and community settings.
- Identify, understand, and develop strategies for overcoming barriers to the adoption, adaptation, integration, scale-up and sustainability of evidence-based interventions, tools, policies, and guidelines. They should address a range of scale-up challenges, including complex processes, inefficient use of resources, inequitable allocation of resources, and supply and demand barriers to scaling-up and sustainability.
- Identify, understand, and develop strategies for measuring the unintended consequences of intervening at a system level.
- Use scale-up methods, tools, and approaches to enhancing equity, efficiency, people-centred, and responsive health systems, promoting a culture of evidence-informed learning, engaging stakeholders, and improving decisions on policies and programmes to achieve better health outcomes.
- Be aligned with existing policies, programme management, monitoring and evaluation processes. They may include important shifts in the practices, incentives, and engagement of global, national and regional health policy, regulatory frameworks, management, research, publication, and civil society stakeholders.
- Include health economic assessments as an integral part of the proposed research.
- Demonstrate that policy makers and health authorities are supportive of, and have been engaged in designing the research proposal.

Proposals should be multidisciplinary and cross-sectorial. Relevant gender and cultural aspects, as well as vulnerable populations, should be taken into account. Proposals may build on previous hypertension and diabetes projects supported under the GACD that have demonstrated the potential for impact.

The proposal will cover the research around the scaling up of the interventions. The research may cover:

- Identification of the best evidence-based interventions;

⁹⁰ For instance: behavioural interventions; prevention, early detection, diagnostic, treatment and disease management interventions; quality improvement programmes

- Definition and implementation of optimum scale-up methods (e.g. pilots in multiple settings, defining a scalable unit);
- Embed real time monitoring/evaluation to refine protocols and ensure adaptability and effective uptake;
- Evaluation of health outcomes;
- Where appropriate, make recommendations for the replication of the applied scale-up interventions to other countries or very large regions.

Research under GACD involves regular exchange of research findings and information across participating projects by means of cross-project working groups and annual joint meetings. Wherever feasible, projects should harmonise and standardise their data collection and exchange data. Applicants must budget for annual costs of having two team members participate in one annual face-to-face meeting of the Annual Scientific Meeting (location to vary annually).

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: (one of or combinations of):

- Enhanced programmes and policies that can significantly reduce the numbers of patients with hypertension and/or diabetes through prevention.
- Enhanced programmes and policies that can significantly increase the number of patients for whom hypertension and/or diabetes was previously undetected.
- Enhanced programmes and policies that can significantly increase the number of patients for whom hypertension and/or diabetes is controlled.
- Enhanced effective, efficient, equitable and sustainable health systems, to lesser inequalities and greater health equity and additional societal benefits, in the medium and long-term.
- Improved health services more responsive to the need of the comorbidities of hypertension and diabetes and other non-communicable diseases.
- Recommendations to translate findings to other countries or very large regions.
- Contribute to the attainment of the sustainable development goals for non-communicable diseases⁹¹.

Type of Action: Research and Innovation action

⁹¹ <https://sustainabledevelopment.un.org/sdg3>

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

SC1-BHC-17-2020: Global Alliance for Chronic Diseases (GACD) - Prevention and/or early diagnosis of cancer

Specific Challenge: The Global Alliance for Chronic Diseases⁹² (GACD) call will focus on implementation research proposals for the prevention⁹³ and/or early diagnosis of cancer in Low and Middle-Income Countries (LMIC) and/or in vulnerable populations⁹⁴ in High-Income Countries (HIC)⁹⁵.

The world is facing a critical healthcare problem due to ageing societies, unhealthy lifestyles, socio-economic inequalities, and a growing world population. Cancer is becoming one of the most important public health problems worldwide. In 2018, it is estimated that 181 million⁹⁶ people have been diagnosed with cancer and 9.6 million have died from it. Predictions suggest that 30 million people will die from cancer each year by 2030, of which three-quarters in low- and middle-income countries (LMICs).

With an estimated 30-50% of avoidable cancers, it is a leading cause of premature death, reducing a country's productivity. Current cancer prevention and control do not fully reflect ethnic, cultural, environmental, socio-economic and resource differences. In particular, limited implementation research is conducted on cancers primarily found in LMICs and vulnerable populations in HIC. In order to achieve the United Nations' sustainable development goal 3.4⁹⁷, implementation research and healthcare efforts are needed to prevent and control cancers in these countries and populations.

Scope: Proposals should focus on implementation research for the prevention and/or early diagnosis of cancer on in LMIC and/or in vulnerable populations in HIC. Proposals should build on interventions with promising or proven effectiveness (including cost-effectiveness) for the respective population groups under defined contextual circumstances. For promising interventions, a limited validation period can be envisaged. However, the core of the research activities should focus on their implementation in real-life settings. The proposed interventions should gender-responsive.

The aim should be to adapt and/or upscale the implementation of these intervention(s) in accessible, affordable and equitable ways in order to improve the prevention and early diagnosis of cancer in real-life settings. Interventions should meet conditions and requirements of the local health and social system context and address any other contextual factors identified as possible barriers.

Each proposal should:

⁹² <http://www.gacd.org/>

⁹³ Tertiary prevention is excluded from the topic.

⁹⁴ Proposals should demonstrate the vulnerability of the targeted population in HIC.

⁹⁵ <https://databank.worldbank.org/data/download/site-content/CLASS.xls>

⁹⁶ GLOBOCAN and CONCORD-3

⁹⁷ <https://www.un.org/sustainabledevelopment/health/>

Focus on implementation research addressing prevention, and/or early identification strategies derived from existing knowledge about effective and/or promising interventions.

For screening interventions, the pathway to referral for positive cases should be included.

Include a strategy to test the proposed model of intervention and to address the socioeconomic and contextual factors of relevance to the targeted region and community.

Lead to better understanding of key barriers and facilitators at local, national and international level that affect the prevention and/or early diagnosis of cancer.

Include health economics assessments as an integral part of the proposed research, including considerations of scalability and equity.

Propose a pathway to embed the intervention into local, regional or national health policy and practice, addressing:

A strategy to include policy makers and local authorities (possibly by being part of the consortium), as well as other relevant stakeholders such as community groups, patient groups, formal and informal carers and any other group, where ever relevant from the beginning of the project, which will contribute to the sustainability of the intervention, after the end of project.

Relevance of project outcomes/evidence for scaling up the intervention at local, national and international level and then scaled-up appropriateness with respect to the local social, cultural and economic context.

Research under GACD involves regular exchange of research findings and information across participating projects by means of cross-project working groups and annual joint meetings. Wherever feasible, projects should harmonise and standardise their data collection and exchange data. Applicants must budget for annual costs of having two team members participate in one annual face-to-face meeting of the Annual Scientific Meeting (location to vary annually). Applicants must budget their involvement in GACD working groups and other GACD wide activities, beyond their projects.

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

Expected Impact: The proposals should address one of or combinations of:

- Advance local, regional or national cancer prevention and/or early diagnostic health policies, alleviating the global burden of cancer;
- Establish the contextual effectiveness of cancer intervention(s), including at health systems level;

- Improve tailored and affordable prevention and/or early diagnosis;
- Provide evidence and recommendations to national programmes and policies focusing on prevention, screening, and/or early diagnosis;
- Inform health service providers, policy and decision makers on effective scaling up of cancer interventions at local, regional, and national levels, including affordability aspects for users and health providers;
- Reduce health inequalities and inequities, including due consideration of socio-economic, gender and age issues where relevant, in the prevention and/or early diagnosis of cancer at both local and global levels;
- Provide pathway to cancer care for the patients diagnosed with cancer;
- Maximise the use of existing relevant programmes and platforms (e.g. research, data, and delivery platforms);
- Contribute to the United Nations' Sustainable Development Goal 3.4.

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-18-2018: Translational collaborative cancer research between Europe and the Community of Latin American and Caribbean States (CELAC)

Specific Challenge: The world is facing a critical healthcare problem: due to a growing and aging population increasingly exposed to a number of well-known and new risk factors, cancer is becoming one of the most important public health problems worldwide.

In 2012, the incidence of new cancer cases in the Community of Latin American and Caribbean States (CELAC) countries was 1.1 million, with 0.6 million deaths; in Europe the incidence was 3.45 million new cases, with 1.75 million deaths⁹⁸. Moreover, about two-thirds of all cancer deaths occur in low- and middle-income countries and incidence and mortality are expected to increase by about 75% in these countries by 2030⁹⁹.

Current cancer care does not fully reflect ethnic, cultural, environmental and resource differences. In addition, limited research is being conducted on tumours primarily found in CELAC countries.

There is a need to establish evidence obtained through international high-quality translational collaborative research to tailor cancer control to specific patient groups.

⁹⁸ <http://www.iarc.fr>

⁹⁹ <http://www.iarc.fr>

Scope: Proposals must focus on translational and multidisciplinary research to identify specific patient groups in view of improving one or more of the following aspects: screening, early detection, diagnosis, and/or prognosis.

Proposals must build on the diverse genetic backgrounds, risk factors, cancer incidence¹⁰⁰, geographical environment, and/or different healthcare models (including social care and volunteers) in European and CELAC countries.

Proposals may integrate molecular, behavioural, nutritional, clinical, social and environmental epidemiology¹⁰¹ data from cohorts; registries; biobanks; repositories; research infrastructures;

Considerations of effectiveness and potential clinical benefit should be integrated in the proposals where relevant.

Specific population age groups, sex and gender aspects, socio-economic, ethical, ethnic, cultural, lifestyle and behavioural factors and any other non-health related individual attributes should be taken into consideration where relevant.

Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least two participants from two different CELAC countries¹⁰².

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: The proposals should address one of or combinations of:

- Identify high-risk populations with a view to tailor early detection and diagnosis or to optimise prevention.
- Improve early detection and/or diagnosis and/or prognosis of cancer adapted to specific settings.
- Provide evidence to national programmes and policies focusing on screening, early detection and/or diagnosis and/or prognosis.
- Provide novel opportunities for the development of targeted therapies.
- Contribute to attaining sustainable development goals for non-communicable diseases¹⁰³

¹⁰⁰ For instance, cancers proportionally more frequent in the CELAC region include gastric, cervical, gallbladder, childhood leukaemia

¹⁰¹ including environmental carcinogens, e.g. in homes, occupational, urban and rural settings

¹⁰² CELAC countries: Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Grenada, Guyana, Jamaica, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Saint Lucia, Saint Kitts and Nevis, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago, Uruguay, Venezuela.

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: Implementation research for maternal and child health

Specific Challenge: Each year, an estimated 213¹⁰⁴ million women become pregnant and 140 million newborn babies are delivered. However, many of the women and infants receive no appropriate care or care that is below evidence-based standards; others suffer from over-medicalisation. Access to quality care, during and after pregnancy, is essential to ensure good maternal health and the favourable early development of the child.

The gap between countries with the lowest and highest maternal mortality rates has doubled between 1990 and 2013 and huge differences exist within countries in Europe and globally. The burden of maternal mortality in both contexts falls disproportionately on the most vulnerable groups of women and girls: Every day approximately 830 women die from preventable causes related to pregnancy and childbirth; 99% of maternal deaths occur in developing countries¹⁰⁵

Although there is a consolidated evidence base of what works in improving maternal and newborn health, the "knowledge-do" gap has not been bridged and evidence based guidelines are insufficiently implemented or integrated in routine training and service provision. Therefore, more and better targeted implementation research is needed.

Scope: Proposals should focus on implementation research¹⁰⁶ for improving maternal and child health with a focus on the first '1000 days' from pregnancy until two years of age.¹⁰⁷ This research can take place in either high income countries or low and middle income countries, or in a combination thereof.

The implementation research in the first 1000 days may cover:

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

Neither pre-clinical research nor clinical trials in the context of product development are within the scope of this call.

¹⁰³ <https://sustainabledevelopment.un.org/sdg3>

¹⁰⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4727534/>

¹⁰⁵ WHO, Maternal mortality fact sheet (n. 348), Nov 2015 - <http://www.who.int/mediacentre/factsheets/fs348/en/> Lancet Series on Maternal Health (2016).

¹⁰⁶ 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

¹⁰⁷ Lancet Series on Maternal and Child Nutrition (2013).

The research should take into account the specificities of different contexts and situations. 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; avoiding the creation of parallel or vertical programmes, etc;. Research may cover physical and/or mental health, as well as communicable and non-communicable diseases. The integration of social sciences including gender analysis and the use of mixed methods research¹⁰⁸ is strongly encouraged. In addition, particular attention should be given to equity issues.

The interventions should build on but may go beyond existing state-of-the art knowledge on biological, psychological and social determinants of maternal and child health. 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, and the media, to ensure that evidence can be translated into policy and practice.

The Commission considers that proposals 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:

- Research-supported solutions to maternal and child health challenges.
- Providing evidence of successful and/or innovative approaches for bridging the "knowledge-do" gap in improving maternal and child health.
- Better understanding of scaling-up processes with regard to different contexts and resource requirements.
- Contribution to the achievement of 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) and Goal 10 (on reducing inequality within and between countries).

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

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.

¹⁰⁸ 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>

SC1-BHC-20A-2020: Pre-commercial procurement (PCP) for integrated care solutions

Specific Challenge: The challenge is to enable public procurers to collectively implement PCPs in order to close the gap between supply and demand for innovative integrated care solutions. The objective is to bring radical improvements to the quality and efficiency of public services and service delivery by encouraging the development and validation of breakthrough solutions through Pre-Commercial Procurement¹⁰⁹.

Scope: PCP actions targeting consortia of procurers with similar procurement needs that want to procure together the development of innovative integrated care solutions to modernize public services whilst creating growth opportunities for industry and researchers in Europe in addition to new markets. These can include, but are not limited to formal or informal organisational solutions, personal-health and self-care solutions, professional care solutions and ICT-based solutions. This topic is open to proposals for PCP actions in all areas of public sector interest requiring innovative integrated care solutions. It is open both to proposals requiring improvements mainly based on one specific solution/technology field, as well as to proposals requiring end-to-end solutions that need combinations of different innovative solutions from the healthcare point of view.

Proposals should demonstrate sustainability of the action beyond the life of the project. Activities covered should include cooperation with policy makers to reinforce the national policy frameworks and mobilise substantial additional national budgets for PCP and PPI, collaborating with respective EU funded projects in the area, as well as awareness raising, technical assistance and/or capacity building to other procurers beyond the project to mainstream PCP implementation and to remove obstacles for introducing the innovative solutions to be procured into the market.

The Commission considers that proposals requesting a contribution from the EU of up to EUR 5 to 6 million (corresponding up to 90% of the total budget) would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Specific requirements for PCP actions are described in part D and E of the General Annexes of the Work Programme.

Expected Impact:

- Reduced fragmentation of demand for innovative solutions in the area of integrated care;
- Increased opportunities for wide market uptake and economies of scale for the supply side through the use of joint specifications, wide publication of results and where relevant contribution to standardisation, regulation or certification.

Type of Action: Pre-Commercial Procurement

¹⁰⁹ <https://ec.europa.eu/digital-single-market/en/pre-commercial-procurement>

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

SC1-BHC-20B-2020: Public procurement of innovative solutions (PPI) for diagnostics for infectious diseases

Specific Challenge: Implementation of timely and correct diagnostics for infectious diseases (ID) that will speed up the identification of the causative infectious disease pathogens, possible drug resistances and drug susceptibility is crucial for tailoring the antimicrobial treatment, thus ensuring appropriate antimicrobial drug use. A combination of rapid, accurate and specific diagnostics and correct treatment promises not only to reduce caseloads of multi-drug resistant infections, but also to limit public spending for necessary isolation and hospitalisation by early and correctly identifying the appropriate treatment. In practice however, cost issues hamper the implementation of rapid diagnostics for ID in public health institutions, as innovative rapid diagnostics are still significantly more expensive than culture-based diagnostics. This issue and the lack of consideration of total cost of care limits the uptake of innovative rapid diagnostics in hospitals, which could result in a continued unspecific use of antimicrobials, prolonged hospitalisations and a non-patient centred provision of care.

Scope: This topic will contribute to the EU One Health Action Plan on Antimicrobial Resistance and should specifically consider the following:

- Development of proposals for ‘Public Procurement of Innovative Solutions’ for the implementation of rapid diagnostic tools for infectious diseases in clinical practice. Proposals should be driven by clearly identified procurement needs of the participating organisations. In order to ensure compatibility and interoperability between infectious disease diagnostics and avoid technical/technology standardisation issues, public health procurers should also develop specifications that are applicable for EU-wide deployment of the innovative diagnostics.
- Applications should be driven by public and/or private procurers from each participating country (at national, regional or local level) that have responsibilities and budget control in the relevant area of supply of health and care services. They should demonstrate the applicability of the ‘Most Economically Advantageous Tendering’ approach in cross-border collaboration of public procurers in the EU, defining specific outcome criteria of importance for patients well-being, and for innovation of public procurement in the area of infectious diseases and AMR, taking also into account overall economic and societal benefits, and sex and gender differences when relevant..
- Proposals should include clear communication and outreach strategies aiming to actively promote and support public health procurement organisations and health care providers across regions and borders of the EU in adopting relevant innovation procurement approaches. They should specify measures that will ensure the sustainability of solutions beyond the lifespan of the proposed project.

- Synergies with the Structural Reform Support Program and the European Structural and Investment Fund are encouraged.

Activities covered should include cooperation with policy makers to reinforce the national policy frameworks and mobilise substantial additional national budgets for PCP and PPI, searching support and collaborating with respective coordination and networking projects, e.g. PIPPI and HCO-12. Likewise, awareness raising, technical assistance and/or capacity building beyond the project to mainstream PPI implementation and removing obstacles for introducing the innovative solutions to be procured into the market could be included.

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.

Specific requirements for PPI actions are described in part E of the General Annexes of the Work Programme.

Expected Impact:

- Implementation of innovative procurement practices for diagnostics for infectious diseases in the EU, based on the ‘most economically advantageous tendering’ approach and involving newly acquired rapid diagnostic tests in hospital and ambulatory settings.
- Contribute to the EU One Health Action Plan on Antimicrobial Resistance, in particular in relation to ‘Better Prevention and Control of AMR’ and the goal to address patient safety in hospital environments by supporting good practices in infection prevention and control.
- Create new opportunities for market uptake and economies of scale for the supply side of rapid diagnostics in the area of respiratory tract infections across the EU.
- Reduced fragmentation of demand for innovative solutions.

Type of Action: Public Procurement of Innovative solutions

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

SC1-BHC-21-2018: Research on HIV, tuberculosis (TB) and/or hepatitis C (HCV) in patients with mono-, co-infections and/or comorbidities in the context of fostering collaboration with the Russian Federation

Specific 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^{110,111}.

For TB, in particular diagnosis and treatment of multidrug-resistant TB (MDR-TB) poses a major challenge. In the east of Europe 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-DR-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.

Furthermore, in the WHO European Region an estimated 15 million people live with hepatitis C (2.0% of adults) with two-thirds of infected persons in the Region living in eastern Europe and central Asia¹¹². Also for HCV there are many challenges, including the need to analyse genetically determined factors affecting disease progression in HCV infected patients (with mono-infection or HIV-HCV co-infection).

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 to address the issues outlined above.

Scope: Proposals should address one or more of the following subtopics:

1. **TB:** To investigate biomarkers or new diagnostic tests for early screening of TB risk groups for TB infection and identification of antimicrobial drug resistance.
2. **HIV:** To investigate the susceptibility to HIV and/or disease progression rate after infection, including various HIV subtypes and/or transmission clusters, and/or the development of adverse effects during antiretroviral therapy and concomitant diseases (comorbidities and/or co-infections, including with tuberculosis).
3. **HCV:** To evaluate the genetic determinants of the virus and the host, and comorbid conditions that can be involved in disease progression and create the basis for the development of future HCV treatment strategies.

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

¹¹⁰ <http://ecdc.europa.eu/en/publications/Publications/HIV-AIDS-surveillance-Europe-2015.pdf>

¹¹¹ <http://ecdc.europa.eu/en/publications/Publications/tuberculosis-surveillance-monitoring-Europe-2015.pdf>

¹¹² <http://www.euro.who.int/en/health-topics/communicable-diseases/hepatitis/data-and-statistics>

collaborations thus widening their geographical scope and include HIV, HCV and/or TB mono or co-infected individuals and perform retrospective or prospective studies. Proposed actions should take into consideration vulnerable groups and target populations, which may include, but not limited to: ageing subjects, injecting drug users and other social risk groups. Sex and gender differences should be taken into account where relevant.

Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least one participant from the Russian Federation. Also, the duration of the proposed action cannot exceed 24 months (until end of 2020), with a foreseen start of the action no later than 1 January 2019. For more information, interested entities in the Russian Federation shall consult the website of the Russian NCP for Health at <http://www.h2020-health.ru/ru/competition-ru-eu>, as well as the website of the Ministry of Education and Science of the Russian Federation http://www.fcpir.ru/participation_in_program/contests/list_of_contests/, where the corresponding Russian call will be published.

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 the submission and selection of proposals requesting other amounts.

Expected Impact:

- Improvement of coordination and integration between European and Russian clinical and research centres dealing with HIV, TB and/or HCV 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 HCV, HIV and/or TB infections (mono or co-infections) and comorbidities.
- Contribute to the achievement of the Sustainable Development Goal 3: Ensure Healthy lives and promote wellbeing for all at all ages, the WHO end TB strategy¹¹³, the WHO global health sector strategy on HIV¹¹⁴, and the WHO global health sector strategy on viral hepatitis¹¹⁵.

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.

¹¹³ <http://www.who.int/tb/strategy/end-tb/en/>

¹¹⁴ <http://www.who.int/hiv/strategy2016-2021/ghss-hiv/en/>

¹¹⁵ <http://www.who.int/hepatitis/strategy2016-2021/ghss-hep/en/>

SC1-BHC-32-2019: Towards a next generation influenza vaccine to protect citizens worldwide – an EU-India collaboration

Specific Challenge: Seasonal influenza is a major health burden, with an estimated 500,000 deaths around the world each year.¹¹⁶ A further threat from influenza is the non-seasonal emergence of new strains, which have the potential to result in major influenza pandemics.

Despite the large danger posed by both seasonal and pandemic influenza, vaccines against flu are only moderately effective.¹¹⁷ In addition, current influenza vaccines need to be developed every year, as they only work against a narrow range of the hugely variable influenza subtypes, and are also highly vulnerable to strain mutations after an annual vaccine has been developed. Improved influenza vaccines would simultaneously ease a significant global health burden, and help the international community to better prepare in the event of an influenza pandemic.

The burden of seasonal influenza, and the ever-present threat of a new influenza pandemic, is a high priority for both Europe and India. In recent years, significant progress has been made by teams in India and Europe on influenza vaccination. To build on this shared recognition of the importance of influenza, as well as significant expertise available in both regions, a renewed effort by India and Europe towards the development of a next generation influenza vaccine is needed. Furthermore, utilisation of the human challenge model of influenza, or work to improve the model itself, may be an important step to progress this essential field.

Scope: Proposals should further the advancement of next generation influenza vaccine candidate(s) with improved efficacy and safety, duration of immunity, and reactivity against an increased breadth of influenza strains. Proposals should make use of new knowledge of, for example, structural biology, immunology, genetics and genomics, influenza transmission modelling, vaccine production, formulation and delivery methods.

Proposals should cover at least pre-clinical and/or early clinical research, selecting promising vaccine candidate(s), supporting their proof of concept, showcasing new pre-clinical or clinical knowledge.

The approach taken should include validation of one or more candidate vaccine(s) in a human challenge model¹¹⁸ of influenza, and/or work to improve the influenza human challenge model itself. This latter work could include comparative testing of potential human challenge strains, and the responses they elicit in volunteers.

The suitability of the interventions to be developed should be addressed and assessed for different population groups, as should the suitability of the candidate(s) to low- or middle-

¹¹⁶ World Health Organization seasonal influenza factsheet: <http://www.who.int/mediacentre/factsheets/fs211/en/>

¹¹⁷ ECDC, Influenza vaccination: <https://ecdc.europa.eu/en/seasonal-influenza/prevention-and-control/influenza-vaccination>

¹¹⁸ Human Challenge Trials for Vaccine Development, World Health Organization: www.who.int/biologicals/expert_committee/Human_challenge_Trials_IK_final.pdf

income settings. The downstream constraints for the uptake of the intervention by national health systems should be taken into account.

Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least three participants from India. For more information, interested entities in India shall consult the website of the Department of Biotechnology (DBT) <http://www.dbtindia.nic.in/funding-mechanism/call/#> , where DBT will indicate the eligibility conditions to Indian applicants. Proposals should include participants from a variety of different disciplines.

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:

- Further the development of a vaccine that could be effective against an increased breadth of seasonal strains and/or from the outset of a large-scale influenza pandemic.
- Utilisation of and/or further improvement of the human challenge model of influenza as a tool for candidate vaccine(s) assessment.
- Contribute to the reduction of the burden of influenza outbreaks worldwide, particularly in Europe and India. Contribute to the achievement of Sustainable Development Goal 3, to ensure health and well-being for all, at every stage of life.
- Specific to India, boost initiatives like the National Health Mission¹¹⁹ and Biopharma Mission [Innovate in India (I³)]¹²⁰ of the Government of India by developing affordable biopharmaceuticals, including vaccines, for citizens the world over.

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-33-2020: Addressing low vaccine uptake

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

¹¹⁹ National Health Mission, Government of India: <http://www.nhm.gov.in/nhm.html>

¹²⁰ Innovate in India (i3), Government of India: <http://www.dbtindia.nic.in/press-release-for-launch-of-national-biopharma-mission/>

towards the safety and effectiveness of vaccines, and the importance of childhood vaccination¹²¹.

Recent figures on collected by the World Health Organization (WHO) show that in 2016 only one vaccine had a coverage rate of over 95% in Europe.¹²² Seasonal influenza vaccination also remains significantly below the 75% coverage target for older age groups.¹²³

Thus, coverage for many vaccines is below the recommended limit. Due to the low vaccine coverage rates, several EU Member States have faced considerable outbreaks of vaccine-preventable diseases in recent years. For example, more than 14,000 cases of measles were reported across the EU in 2017¹²⁴, which is more than three times the number of cases reported in 2016. During the same period 50 people in the EU died due to measles¹²⁵.

These figures highlight the urgent need to get to grips with vaccine uptake issues, whether uptake of existing or new vaccines. Research has an essential role to play in understanding the underlying causes of poor vaccine uptake, including vaccine hesitancy, and to develop strategies and guidelines to help Member States and Associated countries increase vaccination coverage. A detailed understanding of the obstacles to, and drivers of, vaccination uptake in various settings is necessary to provide appropriate recommendations.

Scope: Proposals should work to increase understanding of the determinants of low vaccine uptake in specific contexts situated in the EU and/or Associated Countries (AC), and should develop strategies to increase vaccination rates of essential vaccines within these contexts. From this work, proposals should aim to develop a series of recommendations that national and regional public health authorities in the EU and/or Associated Countries could implement in order to increase vaccine coverage. Proposals should build on existing research, findings and available information in this domain, as well as existing guidelines and recommendations from public health authorities, including those from the European Centre for Disease Prevention and Control and WHO/Europe (such as ECDC reports and guidance on vaccine coverage and hesitancy¹²⁶, "WHO/SAGE Working Group on Vaccine Hesitancy"¹²⁷, WHO/Europe "Guide to tailoring immunization programmes (TIP)"¹²⁸.

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

¹²¹ [http://www.ebiomedicine.com/article/S2352-3964\(16\)30398-X/fulltext](http://www.ebiomedicine.com/article/S2352-3964(16)30398-X/fulltext)

¹²² http://www.who.int/immunization/monitoring_surveillance/data/gseurprofile.pdf

¹²³ <http://ecdc.europa.eu/en/publications/Publications/Seasonal-influenza-vaccination-antiviral-use-europe.pdf>

¹²⁴ <https://ecdc.europa.eu/sites/portal/files/documents/Monthly%20measles%20and%20rubella%20monitoring%20report%20-%20JAN%202018.pdf>

¹²⁵ <https://ecdc.europa.eu/en/news-events/measles-cases-eu-treble-2017-outbreaks-still-ongoing>

¹²⁶ <https://ecdc.europa.eu/en/immunisation-vaccines/vaccine-hesitancy>

¹²⁷ http://www.who.int/immunization/programmes_systems/vaccine_hesitancy/en/

¹²⁸ <http://www.euro.who.int/en/health-topics/communicable-diseases/poliomyelitis/publications/2013/guide-to-tailoring-immunization-programmes>

lower than average vaccination coverage should be examined. Interventions to improve vaccine uptake should be based on existing high-quality research findings, with a sound hypothesis for why the chosen intervention(s) could be effective at increasing vaccine coverage in the target population(s). These interventions could be made in a wide variety of ways, for example content and style of online or offline media, educational material, modification of primary healthcare practices, access to vaccination, incentivisation, or any other strategies that are supported by a strong hypothesis. Also, the proposals should include a strategy for measuring the impact/success of the proposed interventions.

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

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

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

Expected Impact:

- Contribute to increasing vaccine coverage in Europe, in particular in specific populations with low vaccine uptake and in specific contexts.
- Develop practical and readily implementable guidelines to aid national and regional public health authorities in the EU and Associated Countries to increase vaccination rates.
- Work towards meeting the goals on vaccination set out in President Juncker's State of the Union address in September 2017¹²⁹, the EC Communication on strengthened cooperation against vaccine preventable disease (COM/2018/245)¹³⁰ and the Council Recommendation on strengthened cooperation against vaccine preventable diseases¹³¹.

Type of Action: Research and Innovation action

¹²⁹ http://europa.eu/rapid/press-release_SPEECH-17-3165_en.htm

¹³⁰ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A245%3AFIN>

¹³¹ <http://data.consilium.europa.eu/doc/document/ST-14152-2018-REV-1/en/pdf>

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

SC1-BHC-34-2020: New approaches for clinical management and prevention of resistant bacterial infections in high prevalence settings

Specific Challenge: Antimicrobial resistance represents a serious threat to public health in Europe and beyond. Within the last decades resistance has increased considerably in many clinically important pathogenic bacteria. Data collected by the European Centre for Disease Prevention and Control (ECDC)¹³² shows that nowadays in several European countries prevalence levels of infections that can no longer be treated with last-line classes of antibiotics have reached levels where isolation measures may no longer be feasible. In addition to this, prevalence levels of resistant infections are likely to increase in countries where currently such levels are relatively low. This may lead to an increasing number of outbreaks of resistant infections in these countries. The challenge is to address this threat via a multi-disciplinary approach by developing suitable clinical management and infection prevention plans detailing how to deal with resistant bacterial infections in high prevalence settings. The spread of AMR across borders has been recognised globally and improving knowledge on clinical management and infection prevention in high prevalence settings might also benefit other countries around the globe, including low and middle income countries and thereby diminish the spread of resistant bacteria. This topic will contribute to the implementation of the EU One Health Action Plan against Antimicrobial Resistance¹³³.

Scope: Proposals should focus on the identification of best practices, and the development and validation of interventions, infection prevention and clinical management plans for dealing with resistant bacterial infections in high prevalence settings. The research needs to take into account the variety and capacities of local health care/nosocomial infrastructures, and the trends of resistance patterns on local, national and international level, as well as sex and/or gender differences, when relevant. Furthermore, research needs to lead to management plans that take into account commonalities as well as differences between different pathogens and resistance determinants.

The costs and benefits of the infection prevention and clinical management plans to be developed should be assessed as well as the feasibility of their implementation. Research into the practicalities and challenges to introduce such novel infection prevention and management plans is essential and their practical implementation, as pilot actions, in 2 or more European regions with high prevalence levels is strongly encouraged, while taking into account that the infection prevention and clinical management plans to be developed should be applicable for large geographical areas. The potential challenges in the uptake of interventions/management plans by national health systems should be researched and addressed and cooperation with the Joint action AMR and healthcare-associated infections (JAMRAI), ECDC and the EU Health Security Committee is recommended.

¹³² <https://ecdc.europa.eu/en/antimicrobial-resistance>

¹³³ https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf

The Commission considers that proposals requesting a EU contribution of EUR 10-15 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:

- Availability of tested cost effective models for prevention and treatment of bacterial infections in health care settings with high prevalence levels of resistant infections.
- Reduced spread of resistant hospital acquired infections in these settings.
- Knowledge that can be of use for other countries around the globe, including low and middle income countries, benefitting their local population and diminishing the global spread of resistant bacteria.

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-35-2020: Creation of a European wide sustainable network for harmonised large-scale clinical research studies for infectious diseases

Specific Challenge: Infectious diseases pose a serious threat to human health and there are many challenges and needs to efficiently protect citizens across Europe and beyond. There is still a need to understand how antibiotics and other interventions work on patients and how to better assess the effectiveness of vaccines. Innovation is needed to overcome the problem of antimicrobial resistance, and in case of emerging epidemics and pandemics, a timely response to a rapidly emerging infectious diseases is significantly challenging and often delayed. In this context there is a need to establish a pan-European clinical research network that has the capacity and capability to directly enrol patients with infectious diseases, and to increase efficiency for testing and developing new diagnostic, preventive and/or therapeutic strategies and therapies. Europe should also contribute to the G7 aim concerning the need to establish a global clinical studies network on drug resistance that provides access to a large clinical research infrastructure for the design, coordination and conducting of clinical trials and studies. It should also respond to the Council Recommendation on strengthened cooperation against vaccine preventable diseases¹³⁴, which calls for the reinforcement and establishment of novel infrastructures to increase the effectiveness and efficiency of EU and national vaccine R&D funding.

Scope: Proposals should set up a European-wide multidisciplinary network able to provide a platform for a rapid response in the conduct of clinical studies in relation to any severe infection. The initial clinical studies to be performed should be included in the proposal, whereas criteria and processes for including further clinical studies in the project should be clearly described. This should include provisions for flexibility (including re-allocation of

¹³⁴ <http://data.consilium.europa.eu/doc/document/ST-14152-2018-REV-1/en/pdf>

budget and de-prioritisation) in case of new scientific developments and in particular the need to address newly or re-emerging infectious diseases.

The proposed consortium should comprise expertise of stakeholders from academic organizations, SMEs, larger industry, patient organisations, ethics committees, public health bodies and regulators. It is expected to perform clinical studies and further advance clinical research in the field of infectious diseases. It should develop new, or make use of existing, standardised methodological approaches to rapidly perform large-scale clinical trials with the view of delivering optimal diagnosis and preventive or therapeutic interventions to patients affected by infectious diseases, taking into account sex and gender differences when relevant. Applicants should build on the results of successful European collaborative initiatives such as PREPARE¹³⁵ and COMBACTE¹³⁶. Proposals should build on established structures for infectious disease clinical research at national or regional scales. To ensure the common benefit of the outcomes, it should also work in cooperation with existing global experts networks and infrastructures such as ECRIN¹³⁷ and BBMRI¹³⁸. Proposals should in particular take into account the available result of the H2020-funded project ECRAID Plan (*project resulting from SC1-HCO-08-2018*). The network should address all aspects of clinical trial conduct, from study preparation and design, trial management and reporting. It should develop and allow for innovative research approaches and enable flexibility in responding to unpredictable events during its implementation. The sustainability of the network should be carefully worked out in the proposal. Furthermore, the network should create synergies with global initiatives, enabling quick and smooth interactions and collaboration across the world.

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

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

Expected Impact:

- Reduced cost and time through efficiently implemented clinical trials for diagnosis, prevention and treatment of infections.
- Create and strengthen the operational capacity and the infrastructures for providing real-time evidence for optimal medical intervention and practice in infectious diseases.
- Contribute to existing EU policies, including the Council Recommendation on strengthen cooperation for vaccine preventable diseases, and the Communication "A European one health action plan against Antimicrobial Resistance (AMR)"¹³⁹.

¹³⁵ <http://www.prepare-europe.eu/>

¹³⁶ <https://www.combacte.com/>

¹³⁷ <http://www.ecrin.org/>

¹³⁸ <http://www.bbmri-eric.eu/>

¹³⁹ https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf

- To ensure the EU's worldwide leadership in controlling and responding to infectious diseases.
- Foster links between existing networks in Europe and other countries/regions in the world to optimise a coordinated response to infectious diseases for innovation and delivery of new preventive and therapeutic technologies.
- Foster collaboration between stakeholders from academic organizations, SMEs, larger industry, patient organisations, ethics committee, public health bodies and regulators.

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-06-2018: Establishment of an International Network of Social Sciences Research Centres to help address governance and other challenges in the preparedness for and the response to infectious threats

Specific Challenge: Infectious diseases, in particular epidemics and antimicrobial resistance, pose significant threats to the social, economic and health security of communities and countries around the world. However, these diseases also transcend borders and require multi-sectoral and multi-jurisdictional co-operation and preparedness to ensure the world is safe from global threats.

Many global infectious disease outbreaks are enabled, accelerated and allowed to spread by shortcomings in governance at all levels (national, regional as well as global). This governance challenge has been recognised and many initiatives are beginning to work in this space. However, communities would be better prepared to respond to infectious threats (public health emergencies or antimicrobial resistance) if such efforts and structures that govern the overall prevention and response were informed by research evidence from the range of social sciences and humanities disciplines.

The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R- <https://www.glopid-r.org/>) and the Joint Programming Initiative on Antimicrobial Resistance (JPI-AMR- <http://www.jpiamr.eu/>) have identified the need to establish an international Network of Social Sciences Research Expertise, to better address governance and other challenges in prevention and response to infectious threats, be it at local, national, regional or global levels.

Scope: The scope of this Coordination and Support Action (CSA) is to:

I. Initiate, in an organised and coordinated manner, the International Network of Social Sciences Research Expertise, addressing governance challenges, engage with stakeholders on behalf of network members, and work with research funding agencies to grow the network to an effective, internationally representative scale. The proposed network would have the following main objectives:

1. **Strengthen research capacity** and catalyse **social sciences researchers** to generate and apply new knowledge about effective governance arrangements for infectious disease preparedness, combating antimicrobial resistance, and prevention and response efforts. This would include addressing the ethical, legal and social aspects (ELSA) as well as among others the issue of accessibility;
2. **Foster cross-region and global research collaborations** to better connect researchers currently working in isolation and to support bigger, more robust social science research on the governance aspects of infectious threat prevention and response;
3. **Facilitate** ongoing **engagement between researchers and global policymakers** to inform national and global decision-making on appropriate governance arrangements for effective prevention and response measures;
4. **Inform and enable better preparedness and response** efforts through the application of knowledge, sharing of lessons learned, and creation of improved governance arrangements. But **also be a source of advice in case of a public health emergency**, to inform priority setting and response from a social science perspective. In this respect flexibility will be expected from the consortium.

Activities supported by this CSA should include among others the following:

1. Identifying best practices and lessons for enabling, coordinating, and supporting prevention and response efforts by international institutions and regional agencies across borders, while also taking into account research-constrained settings and systems;
2. Identifying strategies to strengthen the discovery, development, and take-up of existing and new innovative interventions and other measures across multiple sectors including examining their impact on health systems. This would include identifying the barriers and motivations that influence the wider use and uptake of these innovations such as vaccines;
3. Developing proposals for more effective raising of public awareness about infectious threats in general and AMR in particular, and inducing behaviour change;
4. Conducting socio-economic and cultural analyses to better understand the societal cost/benefit of different strategies to prepare for and prevent AMR and epidemics.

II. Establish the central coordinating hub for the network under development, focusing on maximising opportunities for collaboration, learning and data sharing in order to scale-up evidence.

The consortium is expected to collaborate with GloPID-R members and JPI AMR and their various initiatives in this domain, as well as other relevant initiatives already existing or under development at national, regional, and international level, in order to maximise synergy and complementarity. Specific propositions on how this can be achieved should be included in the

proposal. It is expected that, at a minimum, the network hub will host an annual meeting for the network, and additional thematic workshops as appropriate.

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:

- Effective cross-region and global research collaborations that better connect multidisciplinary researchers currently working in isolation.
- Strengthened capacity to address the socio-economic and governance dimensions of an effective research preparedness and response to infectious threats.
- Robust evidence to guide policy makers on global infectious disease governance.
- Built in-country capacity in low and middle income countries to better support global efforts.
- Contribution to the implementation of the 'European One-health action plan against AMR and the WHO Global Action Plan on AMR'.
- Contribution to the achievement of SDG 3, and in particular the targets 3 on combatting communicable diseases, B on supporting the research and development of vaccines and medicines for diseases that primarily affect developing countries, and D on strengthening capacity on early warning and management of global health risks.

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-07-2020: ERA-NET to support the Joint Programming Initiative on Antimicrobial resistance (JPIAMR)

Specific Challenge: Antimicrobial resistance (AMR) is a serious challenge that has reached alarming levels in the EU and globally. There is an urgent need to address this major health threat by actions that should include boosting research and innovation as well as strengthening coordination and cooperation in this area

The Joint Programming Initiative on Antimicrobial resistance (JPIAMR) enables the participating countries that include EU Member States and other countries on five different continents, to address the global threat of AMR. It allows the establishment, alignment and building of national research programmes to increase their effectiveness and the impact of research efforts.

Building on earlier successes in implementing the JPIAMR Strategic Research Agenda, in scaling up research efforts and establishing synergies with Horizon 2020, there is a need to continue and consolidate the successes in defragmentation, better coordination and alignment amongst the countries participating in JPIAMR. In addition to this, there is a need to boost research, development and innovation on AMR and improve global coordination in this area as stated in the European One Health Action Plan against AMR¹⁴⁰.

Scope: Proposals should pool the necessary financial resources from participating national or regional research programmes in the area of AMR by implementing a transnational joint call for proposals resulting in grants to third parties with EU co-funding. This should scale up the implementation of the JPIAMR Strategic Research Agenda and the European One Health Action Plan against AMR. Proposals must also implement other joint activities, including additional calls without EU co-funding.

Proposals should take the full One Health approach into account. They should aim at supporting research and innovation for the development and testing of strategies and methodologies to reduce the transmission and spread of AMR. They should also further align national research plans and strategies in Europe and beyond. Proposals should demonstrate the expected impact on national and transnational programmes as well as the leverage effect on European research and competitiveness.

Participation of legal entities from third countries, and/or regions including those not automatically eligible for funding in accordance with General Annex A, is encouraged in the joint call as well as in other joint activities including additional joint calls without EU co-funding. Participants from countries not listed in General Annex A are eligible for EU funding under this topic and may request a Union contribution (on the basis of the ERA-NET unit cost) only for the coordination costs of additional activities. The proposal should demonstrate that these co-funded other activities exclude any overlaps with related on-going actions co-funded by the EU under Horizon 2020. The Commission considers that proposals requesting a contribution from the EU of minimum EUR 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:

- Funding of research proposals on a topic identified in the JPIAMR Strategic research agenda, which needs to be addressed at European level or wider, and which is complementary to topics of the EC work programmes.
- Leverage transnational excellent research with EU-added value in the area of AMR.
- Increased commitment of participating countries to the implementation of the JPIAMR Strategic research agenda

¹⁴⁰

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

- Strengthening and supporting the implementation of the European One Health Action Plan against AMR.
- Strengthening alignment of national and regional plans and activities in the area of AMR research.
- 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.

SC1-HCO-08-2018: Creation of a European wide sustainable clinical research network for infectious diseases

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 as indicated in the European One-Health Action Plan against AMR. 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 and infrastructures such as ECRIN¹⁴¹ to ensure the common benefit of the outcomes¹⁴².

Scope: Proposals should build on successful European collaborative initiatives such as PREPARE¹⁴³ and COMBACTE¹⁴⁴ 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 (sex and gender differences analysis to be included where relevant). 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

¹⁴¹ <http://www.ecrin.org/>

¹⁴² http://www.mhlw.go.jp/seisakunitsuite/bunya/hokabunya/kokusai/g7kobe/KobeCommunique_en.pdf

¹⁴³ <https://www.prepare-europe.eu/>

¹⁴⁴ <https://www.combacte.com/>

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.
- Ensure global collaboration between networks in Europe and other countries/regions to optimise a coordinated response to 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: Building international efforts on population and patient 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 and in close alliance with relevant research infrastructures, proposals should establish a strategy for the development of the next generation of integrated cohorts, including:

1. Map the cohort landscape in Europe and large international initiatives. The mapping should include, for instance meta-data on purpose, coverage and measurements and any other relevant information.
2. Identify best strategies for cohorts' integration, taking into account relevant ethical issues.

3. Promote the harmonisation of past and future data collection and provide recommendations on standards to improve future sample and data collection.
4. Foster the inclusion of data emerging from new technologies (e.g. ICT, social platforms), new type of data (e.g. lifestyle, geographical, genetic, eHealth records) and exposure, including to new and emerging products (e.g. novel tobacco products, e-cigarettes, waterpipes).
5. Promote best practises to optimise access to existing and future cohorts.
6. 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 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.
- Improve the understanding of the complex interactions of environmental, social, occupational and lifestyle determinants of health.

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: Coordinating European brain research and developing global initiatives

Specific Challenge: The EU and its Member States have made considerable investments in brain research. The European Commission alone has invested some EUR 5.3 billion over the past 10 years. At the same time, many large research initiatives such as the Human Brain Project (HBP), the Joint Programming on Neurodegenerative Diseases (JPND), the ERA-Net NEURON and the Innovative Medicines Initiative (IMI) have been established in parallel. The numerous resulting research projects have generated considerable amounts of knowledge and innovative approaches. However, translation into new health interventions is below expectations and needs.

Therefore, in many areas of brain research, there is a particular need for better networking and coordination of efforts, at both European and global level, in order to minimise fragmentation and duplication. At the same time, better access to and sharing of data and holistic analysis of results are of crucial importance in line with the EC's Open science policy. Addressing these

gaps would create new synergies and open new avenues of research and to which in turn will foster understanding of diseases, innovation and accelerate innovation through the development of new diagnosis, prevention and treatment options in areas of high and unmet medical needs.

Scope: Proposals should:

1. Identify areas of neurosciences where the need for enhanced coordination of research communities into active clusters is particularly acute;
2. Accelerate exchange between researchers in different European research initiatives to promote cooperation and to minimise fragmentation and duplication;
3. 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 data and enhancing the exploitation of results, fostering new collaborations and identifying future research objectives;
4. Identify and develop tools and support activities implemented by EU funded initiatives and infra-structures suitable to develop Open Science policy in the neurosciences by sharing and better utilisation of clinical data via IT platforms and also considering any relevant regulatory requirements and policies;
5. Explore possibilities for broader scale cooperation at global level by fostering dialogue with researchers outside Europe in coordination with research funders around the world, in order to foster the global brain research agenda.

The relevant stakeholders must be involved, in particular thematically focussed research communities, learned societies, large research initiatives, infrastructures as well as relevant funding bodies and regulatory authorities, in order to ensure effective implementation and impact of this coordination action.

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 brain research efforts at EU and at global level.
- Improve access to and optimise the use of research infrastructures and data sources by the neuroscience research communities, thus ensuring better exploitation of the large investments made in brain research.
- Achieve critical mass and economies of scale by initiating and fostering new global research initiatives.

- Enable and accelerate the translation of breakthroughs in brain research into relevant clinical applications.

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: Strategic collaboration in health 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 challenges 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, whose solution may benefit from closer bi-lateral and/or multi-lateral cooperation between EU and China, to facilitate and develop collaborative research initiatives between EU and Chinese stakeholders.

The Commission considers that a proposal requesting an EU contribution between EUR 0.8 and 1 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Increased bi-lateral and multi-lateral cooperation on health research strategic items between EU and China.
- Higher participation of Chinese researchers in SC1 and future EU health research programmes, but also 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.

SC1-HCO-15-2019: Support for the functioning of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)

Specific Challenge: Human health worldwide is increasingly threatened by potential epidemics caused by existing or newly emerging infectious diseases, including those that are

resistant to antimicrobial agents. With globalisation, people movement and trade at record highs, pathogens can spread further and faster than ever before in human history. To fight such an international challenge, the EU must think globally and coordinate with international infectious disease research funders.

It is for this reason that the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)¹⁴⁵ was established in 2013 in response to a request for coordination by the Heads of International Research Organizations. Years on, GloPID-R now provides an important platform for infectious disease research funders to work together to better tackle deadly outbreaks such as Ebola, yellow fever, Zika and plague.

In order to save lives, a research response to an epidemic needs to be quick, flexible, comprehensive and global. For this reason, besides directly coordinating research to infectious disease outbreaks GloPID-R Members also work to improve the underlying international framework in which this research takes place. Ongoing efforts with the network include in-depth discussions on improved data-sharing during outbreaks, creating links between clinical trial networks, and the inclusion of social science into research responses to public health emergencies.

The above work, and more, requires a large amount of administrative support to GloPID-R Members. To maintain GloPID-R, facilitate its ongoing and new work streams, and to increase the effectiveness of the network, further administrative and technical support in the form of a secretariat is warranted.

Scope: Proposals should provide administrative and organisational support to the Chair and Vice Chairs of GloPID-R, in close collaboration with the European Commission. This includes, but is not limited to, the organisation of meetings and teleconferences, including basic costs associated therewith as required; note-taking and record-keeping; management of information dissemination and communication between the Chairs, Members, Scientific Advisory Board (SAB), Industry Stakeholder Group (ISG), working groups, enquiries, and outside stakeholders. Proposals should also maintain and expand GloPID-R's external communications activities, such as the website and newsletter, as requested by the Chairs.

Further to administrative and organisational issues, proposals should also provide more technical support on topics requested by the GloPID-R Chairs or groups such as the SAB or ISG. This may include preparing briefings, reports, mapping exercises or presentations. Furthermore, proposals shall take the lead in facilitating the work of the SAB, ISG and a number of GloPID-R working groups. For these reasons, proposals should have a familiarity with research preparedness and responses to infectious disease outbreaks, as well as the ability to facilitate and follow-up on discussions between high-level individuals in a professional manner.

Proposals should also provide a high level of adaptability. The GloPID-R secretariat primarily supports the work of the Chairs of GloPID-R, and should this work alter in scope or direction,

¹⁴⁵ GloPID-R website: <https://www.glopid-r.org/>

remove or add work streams, or otherwise change the activities of the secretariat then it will be expected to have flexibility to change accordingly. In this regard, the selected consortium will be expected to submit an annual work plan to the Commission each year following the annual meeting of GloPID-R. This will take into account the conclusions of the annual meeting and will lay out an adapted plan for activities of the secretariat over the following 12 months as a result. Despite this, changes that alter the grant agreement will require approval by the Commission.

The Commission considers that proposals requesting a contribution from the EU of around EUR 1 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. Funding may be complemented at a later date by additional funding from other members of GloPID-R.

Expected Impact:

- Effective operation of GloPID-R for at least three years.
- Reinforced international cooperation in funding of research in new and emerging infectious diseases, both between for-profit and not-for-profit research funders.
- Improved framework for a rapid and effective research response to prepare for or respond to public health emergencies, in areas such as data sharing, social science, clinical trial networks and others.
- Better communication of the activities of GloPID-R members, both as a group and individually, to the research community and other stakeholders.

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

This priority will aim at developing 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 considers the management of elderly multimorbid patients. It addresses also the dimension of new financing and business models, which will also require contributions from the disciplines of social sciences and humanities. This priority includes the integration of the care dimension by better coordinating primary and community care with the specific needs of the patient.

The expected impact of this priority is 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: 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 years¹⁴⁶. Mental health conditions such as depression, anxiety and stress represent substantial financial costs for employers and employees, as well as a significant loss for society at large. An EU-level estimate of the overall costs, direct health costs and lost productivity is more than 450 billion EUR per year.^{147,148,149} 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. It is important to create mentally healthy workplaces, i.e., promoting and protecting employees' good mental health and supporting them when they experience mental health problems, and their return to work. A healthy workplace involves creating an environment that is supportive of the psychosocial aspects of work, recognising the potential of the workplace to promote workers' mental health and wellbeing, and reduce the negative impacts of work-related stress. Many of the factors that influence the positive mental health and wellbeing of workers relate to the social environment at work such as the working conditions, style of management, working culture and levels of supports, as well as job security.

More knowledge is needed about effective interventions by employers to promote good 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: Proposals should develop and implement intervention(s) that an employer/organization can take to promote good mental health and prevent mental illness in the workplace. These interventions can be newly developed or improvements on existing ones. They should address challenges in mental health in the workplace¹⁵⁰ in the EU. The interventions should be assessed in terms of direct and indirect individual and collective health outcomes and cost-effectiveness, implementation facilitators and barriers.

¹⁴⁶ http://ec.europa.eu/research/participants/data/ref/h2020/other/guides_for_applicants/h2020-SC1-BHC-22-2019-framework-for-action_en.pdf

¹⁴⁷ http://www.ilo.org/wcmsp5/groups/public/---ed_protect/---protrav/---safework/documents/publication/wcms_466547.pdf

¹⁴⁸ [http://www.mentalhealthandwellbeing.eu/assets/docs/publications/Framework%20for%20action_19jan%20\(1\)-20160119192639.pdf](http://www.mentalhealthandwellbeing.eu/assets/docs/publications/Framework%20for%20action_19jan%20(1)-20160119192639.pdf)

¹⁴⁹ https://ec.europa.eu/health/mental_health/eu_compass_en

¹⁵⁰ 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

Proposals should build on existing knowledge but may well go beyond. Co-morbidities in mental and/or physical health should be addressed. Research should be multidisciplinary, including social sciences and the humanities. 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. Mixed-methods research¹⁵¹ is encouraged. 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. Proposals should address relevant gender issues (e.g. gender equality at the workplace). Ethics and data protection aspects should be addressed where they are relevant.

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 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.
- Improved policies on mental health in the workplace based on the broader evidence base of effective interventions.

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: Novel patient-centred approaches for survivorship, palliation and/or end-of-life care

Specific Challenge: Health conditions linked to end-of-life issues, acute and chronic pain, 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. Palliative¹⁵², end-of-life 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 the affected population¹⁵³ is

¹⁵¹ Broadly defined as research in which the investigator collects and analyses data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or a programme of inquiry <http://journals.sagepub.com/doi/pdf/10.1177/2345678906293042>

¹⁵² 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/>).

¹⁵³ Morin et al. Estimating the need for palliative care at the population level: A cross-national study in 12 countries. *Palliat Med.* 2016

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, the effectiveness and cost-effectiveness of new, improved or specifically adapted pharmacological and/or non-pharmacological interventions to either relieve symptoms (e.g. pain) and suffering caused by life-threatening non-communicable diseases (including disabilities), or 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 and/or family centred¹⁵⁴ interventions, targeting children¹⁵⁵ and/or adults, should be considered for this topic. Proposals should give a sound feasibility assessment justified by available publications or preliminary results.

Proposals should prove the feasibility of integrating the proposed interventions in current pain management, palliative and/or end-of-life and/or survivorship care regimes and healthcare systems across Europe while taking into account the complex human aspects which are necessarily managed by such regimes and systems.

The proposals should address sex, gender, age and socio-economic factors in health and any other factors (e.g. ethical, familial, cultural considerations, including personal beliefs and religious perspectives, 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.

Expected Impact:

- Reduced symptom burden and suffering or improved well-being of patients in need of palliative, end-of-life or survivorship care and their formal and informal caregivers.
- Improved clinical guidelines and policy recommendations with respect to pain management, 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.

¹⁵⁴ Involving patients and their caregivers (families, volunteers, nurses and others), and taking their views and values into account in care decisions.

¹⁵⁵ 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/>).

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

Specific Challenge: It is estimated that more than 50 million European citizens suffer from multimorbidity¹⁵⁶. As the global population continues to grow and age, multimorbidity is increasingly prevalent in elderly¹⁵⁷ patients.

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

Scope: Proposals should focus on interventions for effective, integrated patient-centred approaches, to improve the management of multimorbid elderly patients. Proposals should support the delivery of best care adapted to such patients. The patient-centred approach should be holistic, inclusive, cross-sectoral and interdisciplinary. Proposals should aim at improving the quality of life of the elderly patient, by targeting individuals, formal and informal caregivers and simplifying the care pathway of multimorbid patients, including through self-management. Proposals may stratify patients, develop the clinical concept of intrinsic capacity and use social innovation. Proposals should define quality performance indicators for the management of multimorbidity and aim to strengthen cooperation among different health disciplines and medical specialties. Sex and gender differences should be taken into account. Aspects of independent living, fragmentation of treatment, polypharmacy, adherence to treatments may also be addressed. Health economics, cost effectiveness and inequalities should also be addressed.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 to 6 million would allow this specific challenge to be addressed appropriately.

¹⁵⁶ Multimorbidity is defined as coexistence of multiple chronic diseases and medical conditions in the same individual (usually defined as two or more conditions).

¹⁵⁷ The elderly population is defined as people aged 65 and over (OECD definition).

Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact: Actions are expected to contribute to better management of multimorbid elderly patients and cost containment in healthcare interventions by addressing one or more of the following points:

- New validated, patient-oriented and stratified care pathways and healthcare models for the management of multimorbid elderly patients.
- New clinical guidelines and best practices for improved management of elderly multimorbid patients.
- Developed or modified quality key performance indicators for the management of multimorbidity.

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: Demonstration pilots for implementation of personalised medicine in healthcare

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 healthcare systems. With the increasing number of scientific approaches available, it is crucial to demonstrate the benefit of large scale deployment of personalised medicine to citizens and healthcare systems. This was also one of the conclusions of the Personalised Medicine Conference 2016 (<http://ec.europa.eu/research/conferences/2016/permed2016/index.cfm>).

Scope: The pilot projects should demonstrate the benefit for individuals as well as the implementability and economic viability of personalised medicine approaches 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 diseases with high burden to society (taking due account of sex/gender differences) and including multi-morbidity conditions if relevant. The use of big data approaches and high performance computing is encouraged. Applicants should ensure coordination with national, regional or local authorities engaging in healthcare environments and should aim at linking different institutions (hospitals, other healthcare facilities, public health authorities, payers etc.). The pilot projects should engage partners in regions or cities having adopted or that are in advanced planning for introducing PM approaches. Patient representatives as well as partners from countries that are in the process of upgrading their healthcare systems should be involved, ensuring a wide European dimension. Applicants should address the health economic, ethical, legal and societal aspects of the proposed action. Taking into account the advances already achieved for PM approaches in cancer and rare diseases, projects with primary focus on these diseases are excluded from the scope of this topic.

The Commission considers that proposals requesting a contribution from the EU of between EUR 18 and EUR 20 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- 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 in real-life settings and at a large scale, exemplifying potential for savings in overall healthcare costs.
- Widening of PM approaches to include diseases other than cancer and rare diseases.
- Linking of different actors for healthcare, economy, lifestyle, healthy living and regulation, making use of the multitude of data available.

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-BHC-26-2018: 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 projects¹⁵⁸, 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 technologies¹⁵⁹ 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

¹⁵⁸ EUnetHTA Joint Actions 1-3, AdHopHTA, ADVANCE-HTA, INTEGRATE-HTA, MedtecHTA, GetReal, ADAPT-SMART

¹⁵⁹ 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 used for health promotion, disease prevention, diagnosis or treatment.

use of "real-world" data, to inform the assessment of effectiveness under the usual circumstances of healthcare practice.

Thus the challenge is to address 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.

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

1. Specific types or groups of health technologies: Help adapt existing HTA frameworks to reflect the specificities of particular types of health technologies⁹⁷ 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 medicine¹⁶⁰ in healthcare.
2. 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.
3. 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. It should also contribute to broader efforts for improving the collection, comparability and analysis of real-world data across Europe¹⁶¹.
4. 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.

¹⁶⁰ 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.

¹⁶¹ 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.

The proposed consortium should bring together partners with relevant expertise from e.g. academia, HTA bodies, regulators, centres of expertise for clinical research and care¹⁶², 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. The composition of the consortium should ensure a broad geographical representation of European countries. Gender equality aspects should be taken into account in carrying out the relevant research objectives and activities.

Proposals should complement or build on existing work, including results of EU-funded projects in the field of HTA⁷⁶. The consortium should closely liaise with EUnetHTA¹⁶³ to avoid duplication, build on EUnetHTA existing work and create synergies with ongoing EUnetHTA activities and other relevant EU cooperation efforts.

The Commission considers that a proposal requesting an EU contribution between EUR 5 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, building on ongoing and planned efforts.

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.

¹⁶² For rare diseases, involvement of European Reference Networks (ERNs, see https://ec.europa.eu/health/ern/policy_en) should be considered.

¹⁶³ EUnetHTA Joint Action 3 is a European network of national/regional HTA bodies under the EU Third Health Programme.

SC1-BHC-37-2020: Towards the new generation of clinical trials – trials methodology research ¹⁶⁴

Specific Challenge: Efficient and effective clinical trials¹⁶⁵ are the primary means to provide scientific evidence to ensure optimal health interventions. Although the randomized controlled trial (RTC) design is regarded as the gold standard for evaluating the effectiveness of intervention in clinical research, there is a need for new trial methodologies that address current challenges such as:

- Globalization of clinical research;
- Use of emerging health technologies^{166,167,168};
- Defining patient populations and patient enrolment strategies;
- Data management¹⁶⁹.

Given that all clinical research relies on voluntary contribution of patients, new designs may reduce the operational complexity, assure transparency and build trust, meeting all ethics standards and protecting the individuals' personal identity and privacy¹⁷⁰.

Additionally, non-commercial trials often show suboptimal performance as compared to large commercial trials in terms of data collection, management and processing, good clinical practice compliance, and pharmacovigilance, there is a need of a new methodology that improves their legislative compliance and encourage clinical trials conducted by non-commercial sponsors.

Scope: Proposals should focus on methodology research and develop innovative solutions to improve the design, conduct and analysis of clinical trials. Proposals should identify and validate methods that will improve the generalizability of evidence generated through differently designed trials, including personalized medicine approaches and combinatorial interventions¹⁷¹. In order to draw meaningful conclusions following state of the art of

¹⁶⁴ Trials Methodology Research refers to research into the methods used in the design, conduct, analysis, reporting and knowledge translation of clinical trials to ensure that effective and efficient methods are available for the conduct of clinical trials.

¹⁶⁵ Clinical Trial Regulation EU No. 536/2014; https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

¹⁶⁶ https://www.who.int/medical_devices/innovation/new_emerging_techs/en/

¹⁶⁷ Regulation 2017/745 on Medical Devices; <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN>

¹⁶⁸ Regulation 2017/746 on In-Vitro Diagnostic Devices;

¹⁶⁹ Eichler HG and Sweeney F. The evolution of clinical trials: Can we address the challenges of the future? *Clin Trials*. 2018 Feb;15(1_suppl):27-32. doi: 10.1177/1740774518755058. PubMed PMID: 29452522

¹⁷⁰ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation); <http://data.europa.eu/eli/reg/2016/679/2016-05-04>

¹⁷¹ European Council Conclusion on personalised medicine for patients (2015/C 421/03) ([https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015XG1217\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015XG1217(01)&from=EN)) for combinatorial interventions, see <https://www.england.nhs.uk/wp-content/uploads/2015/03/test-bed-prospectus.pdf>

statistical analyses, applicants need to demonstrate access to adequate clinical trial data sets that will be included into the proposed research.

The proposed methodology should allow sound extrapolation in various subgroups of disease of high public health burden as well as integration of RTC data and post-approval evidence generation. Furthermore, applicants should identify best practices to prevent bottlenecks in execution of clinical trial, including issues related to patient recruitment, adherence and compliance, governance, ethics, sex and gender-based analysis as well as data sharing.

The special attention should be put on non-commercial trials, including quantifiable indicators to measure the qualitative improvement in terms of trial management, data processing, and reporting. Whenever relevant, proposals should cover different aspects of training exercises, including hands-on trainings and closer monitoring of the scientific and technical staff involved in the conduct, management and analysis of the trial.

All literature analyses to define the current state of the art in the clinical trial methodology research must be completed at the time of submission of the proposal. Methodology research related to clinical studies exclusively on medical devices is not in the scope of this topic.

In this topic, the European Medicines Agency¹⁷² (EMA) and the Commission Expert Group on Clinical Trials¹⁷³ will support the selected applicant consortium in the implementation of the action. Successful applicants under this topic are also expected to liaise with the successful applicants of the relevant coordination and support action (CSA) topics^{174,175}, in order to exchange information, avoid potential overlapping activities, create synergies and support the CSA goals. To maintain the interactions with the CSA consortia, specific tasks and a dedicated budget should be foreseen in the proposal. Additionally, consultations with the European Centre for Disease Prevention and Control¹⁷⁶ should also be envisaged as additional relevant activities of the successful proposals.

Please note that this topic will take the form of lump sums as defined in Commission Decision C(2017)7151 of 27 October 2017¹⁷⁷. Details of the lump sum funding pilot scheme are published on the Funding & Tenders Portal¹⁷⁸ together with the specific Model Grant Agreement for Lump Sums¹⁷⁹ applicable.

¹⁷² <https://www.ema.europa.eu/>

¹⁷³

<http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1464&NewSearch=1&NewSearch=1>

¹⁷⁴ Proposals funded under the SC1-HCO-18-2020 topic: “Developing an adaptive methodological framework for improved clinical investigation and evaluation of high-risk medical devices”

¹⁷⁵ The consortium of the project STARS (825881) “Strengthening training of academia in regulatory sciences and supporting regulatory scientific advice”; the project website is not yet established.

¹⁷⁶ <https://ecdc.europa.eu/en/home>

¹⁷⁷ http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/lump_sum/lumpsumdecision-2017-7151_en.pdf

¹⁷⁸ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home>

¹⁷⁹ http://ec.europa.eu/research/participants/data/ref/h2020/mga/lumpsum/h2020-mga-lumpsum-pilot-multi_en.pdf

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:

- Improved relevance, quality and efficiency of clinical trials conducted with public funding.
- Potential to establish a novel clinical trial methodology supported by regulatory authorities.

Type of Action: Research and Innovation action Lump Sum

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

SC1-HCO-12-2018: Innovation in healthcare - a CSA towards using pre-commercial procurement and public procurement of innovative solutions in healthcare systems

Specific Challenge: Innovative solutions for healthcare have the potential to improve patient care in European healthcare setting. Integrated care¹⁸⁰ 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.

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 to 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.

¹⁸⁰ 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

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 solutions in healthcare settings¹⁸¹.

Scope: The objective of this coordination and support action (CSA) is to create a Europe-wide consortium of healthcare providers and public procurers in the health and social care sector that define together unmet procurement needs to implement innovative solutions in healthcare.

The consortium should prepare future procurement topics to conduct:

- A PCP/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 Europe-wide deployment of the innovative diagnostics.
- One or more PCP/PPIs to drive the shift towards health systems reform. Clinicians, patients, public procurers in healthcare systems, health and social 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 healthcare.

Activities supported by this CSA should include the following aspects:

- preparation of innovation procurement calls to be published in topic SC1-BHC-20-2020 of the Work Programme 2018-2020. That topic will follow the specific requirements for innovation procurement PCP/PPI supported by Horizon 2020 grants as set out in General Annex E of the work programme.
- open market consultation with the industry, including on technical and service readiness
- analysis of the suitable testing environments
- analysis of differences in legal public procurement framework for the participating procurers in health and social care,
- market analysis and analysis of potential barriers (standardisation, certification, regulatory requirements, intellectual property rights, contracting models, payment schemes)
- consultations with relevant stakeholders, end-users (consumer organisations, reimbursement bodies) to prepare for a future market uptake of the solutions.

Expected Impact:

¹⁸¹ This call topic is complementary but separate from DTH-10-2019-2020 for digital solutions for health and care services

- Improved networking of health and social care providers and public procurers in healthcare 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 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.

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-20-2020: Coordination of clinical research activities of the European Reference Networks

Specific Challenge: European Reference Networks (ERNs) have been established under the Directive on Patients' rights in cross-border health care in view of tackling complex or rare diseases and conditions that require highly specialised diagnostic tools and treatments. ERNs in collaboration with other European initiatives will gain major research potential due to their network structure bringing together highly specialised multidisciplinary expertise across Europe and access to patient populations of rare diseases and complex conditions that require highly specialised treatments. Realisation of this potential requires highly organised coordination among the 24 ERNs, which operate in 26 countries, over 300 hospitals and more than 900 health care units, and also with other Europe-led research collaborations beyond the networks, with all the other actors in the field of rare diseases research, especially the European Joint Programme on Rare Diseases. Support for coordination of the research aspects of ERNs is currently limited.

Scope: This activity will aim at enhancing research and innovation capacity of the ERNs in view of achieving the goals of the International Rare Diseases Research Consortium (IRDiRC) for bringing new diagnostic tools and therapies more efficiently to the patients and for developing methodologies to assess the impact of diagnoses and therapies on rare disease patients, taking into account sex and gender differences where relevant. . Support will be given to identify research priorities and potential synergies among ERNs and coordinate research and innovation activities to be tackled by ERNs. The project should address fostering collaboration in the field of clinical research among ERNs, ERN-independent clinical research collaborations and other stakeholders, such as research infrastructures, industry and patient organisations, as well as international collaboration with other clinical research networks. Close collaboration with the European Joint Programme on Rare Diseases will be necessary to ensure complementarity, to achieve relevant synergies and avoid overlaps. To ensure broad geographical representation and participation across ERNs the proposals shall

involve participants from several countries and aim at engaging all approved ERNs and other relevant research networks in Europe.

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

Expected Impact:

- Along the IRDiRC vision to enable all people living with a rare disease to receive an accurate diagnosis, care, and available therapy within one year of coming to medical attention by 2027.
- Contribute to the development of a comprehensive European ecosystem for rare diseases and conditions that require highly specialised treatments, which brings efficiently results of research and innovation to the benefit of the patients.
- Enhance synergy with the Connecting Europe Facility Programme and the EU Health Programme which provides support for the functioning of the ERNs and the development of patient registries for ERNs.

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.

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

This priority will assess the impact of environment (i.e. factors external to the human body and to health and healthcare systems, including climate change) on health and well-being, and the related socio-economic impacts. This priority will address five main items: (i) the development of new testing and screening methods to identify endocrine disrupting chemicals; (ii) 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; (iii) understanding the impact of micro- and nano-plastics on human health; (iv) the development of a European environment and health research agenda for the future; (v) innovative actions for improving urban health and wellbeing This priority contributes to the Ostrava Declaration on Environment and Health¹⁸² and the EU chemical and other sectoral policies. Where appropriate, this priority will build on existing results from projects funded

¹⁸² <http://www.euro.who.int/en/media-centre/events/events/2017/06/sixth-ministerial-conference-on-environment-and-health/documentation/declaration-of-the-sixth-ministerial-conference-on-environment-and-health>

under previous EU research framework programmes and create links to the European Human Biomonitoring Initiative¹⁸³.

The expected key impacts are improved risk assessment and mitigation measures. This priority aims to reinforce health and wellbeing as a strong driver for the societal and political changes needed in support of a sustainable society. The research undertaken will provide tools and evidence enabling new approaches to estimate the environmental burden of disease and will through new knowledge reinforce the evidence base for preventive actions.

One of the priorities of the Work Programme for 2020 will be to support the implementation of some of the research aspects identified in the European Strategy for Plastics in a Circular Economy¹⁸⁴, the Bioeconomy Strategy¹⁸⁵, the Integrated Maritime Policy¹⁸⁶, and the European Strategy for Marine and Maritime Research¹⁸⁷. This priority will be implemented through several topics covered by different Societal Challenges and the Leadership in Enabling and Industrial Technologies (LEIT) pillar¹⁸⁸.

These topics promote a multi-disciplinary approach involving various research fields, such as environmental technology and sciences, ocean sciences, bio-medical sciences, materials science and nanotechnologies, exposure science, analytical chemistry, biotechnology, food sciences, business model and product design, systems thinking and behavioural sciences. They aim to enhance the understanding of the drivers and impact of plastic pollution, including pathways and fate of macro-, micro- and nanoplastics in the marine and terrestrial environments, to strengthen the means to reduce the plastic burden in the environment and to improve the design, production, use and reuse of materials and products. Taking a multi-faceted approach to address an issue crossing many regulatory boundaries and being of interest to the general public, this priority intends to strengthen the area of plastics research as a bridge to future activities.

Selected projects under these topics supporting the Plastics Strategy are strongly encouraged to participate in joint activities as appropriate, as indicated under the relevant topic text.

¹⁸³ www.hbm4eu.eu/

¹⁸⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516265440535&uri=COM:2018:28:FIN>

¹⁸⁵ <https://ec.europa.eu/research/bioeconomy/index.cfm?pg=policy&lib=strategy>

¹⁸⁶ https://ec.europa.eu/maritimeaffairs/policy_en; and http://ec.europa.eu/environment/marine/good-environmental-status/index_en.htm

¹⁸⁷ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Ari0008>

¹⁸⁸ SC1-BHC-36-2020 Micro- and nano-plastics in our environment: Understanding exposures and impacts on human health (Health, Demographic Change and Wellbeing, SC1); SFS-21-2020 - Emerging challenges for soil management (Food Security, Sustainable Agriculture and Forestry, Marine and Maritime and Inland Water Research, and The Bioeconomy, SC2); BG-07-2019-2020: The Future of Seas and Oceans Flagship Initiative: [C] 2020 - Technologies for observations (SC2); FNR-06-2020: Oceans Innovation Pilot for the Blue Economy (SC2); FNR-05-2020: Supporting the food safety systems of the future (SC2); CE-SC5-24-2020: Improving the sorting, separation and recycling of composite and multi-layer materials (Climate Action, Environment, Resource Efficiency and Raw Materials, SC5); CE-SC5-28-2020: Develop and pilot circular systems in plastics, textiles and furniture sectors (SC5); CE-SC5-25-2020: Understanding the transition to a circular economy and its implications on the environment, economy and society (SC5); CE-SC5-29-2020: A common European framework to harmonise procedures for plastics pollution monitoring and assessments (SC5); CE-SC5-30-2020: Plastics in the environment: understanding the sources, transport and distribution of plastics pollution (SC5); CE-BIOTEC-09-2020: Upcycling bio plastics of food and drinks packaging (LEIT).

Proposals are invited against the following topic(s):

SC1-BHC-27-2018: New testing and screening methods to identify endocrine disrupting chemicals

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 disruptors (EDs)¹⁸⁹. EDs are of increasing importance in chemical regulations in the European Union, and criteria to identify EDs have recently been presented for two pieces of EU legislation (Biocidal Product Regulation and Plant Protection Products Regulation)¹⁹⁰.

In the EU, the legislation regulating chemical substances often includes their screening and testing according to the EU test methods regulation¹⁹¹, which predominantly contains test methods developed under the OECD¹⁹². The current testing tools, including regulatory *in vivo* tests and novel *in vitro* assays, do not appropriately identify effects related to certain less studied endocrine-mediated pathways or health outcomes, in which EDs may be implicated. Moreover, the new ED criteria require information about both the adverse effects and the endocrine mode of action.

Scope: New and improved approaches are needed to increase the quality, the efficiency and the effectiveness of existing methods to meet demanding and evolving regulatory requirements worldwide. In consultation with relevant regulatory bodies, research should improve and harmonise screening and testing protocols/strategies and hazard/risk assessments by developing better and faster tools, test methods or models, including *in vitro* and *in vivo* tests, high-throughput and *in silico* methods (e.g. QSAR), potentially combined with research on adverse outcomes pathways. For *in vitro* tests, appropriate coupling of their results to human health effects should be ensured. 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 gain information about possible associations between levels of exposure to specific chemicals and ED-related effects. Focus should be on the most urgent regulatory needs, e.g., methods addressing the thyroid axis, developmental neurotoxicity, metabolic disorders, female reproduction and non-genotoxic carcinogenicity. Proposals should involve, in addition to academic researchers, regulatory agencies and other actors as appropriate. Proposers should consider sex and gender analysis when relevant. 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 tests, validation is an essential step to be included in the proposals.

¹⁸⁹ WHO/UNEP-State of the science of endocrine disrupting chemicals – 2012: <http://www.who.int/ceh/publications/endocrine/en>

¹⁹⁰ 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

¹⁹¹ [eurl-ecvam.jrc.ec.europa.eu/alt-animal-testing-safety-assessment-chemicals/test_method_reg](http://ecvam.jrc.ec.europa.eu/alt-animal-testing-safety-assessment-chemicals/test_method_reg)

¹⁹² OECD work on endocrine disruptors: <http://www.oecd.org/env/ehs/testing/oecdworkrelatedtoendocrinedisrupters.htm>

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.

Collaboration between successful proposals will be encouraged.

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.
- Support for the OECD work on testing and assessing chemicals for ED identification.
- Enhanced international cooperation.
- Contribution to the development of an international strategy and guidelines for testing EDs and assessing associated hazard and risk.

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: The Human Exposome Project: a toolbox for assessing and addressing the impact of environment on health

Specific Challenge: Despite the general acknowledgement by the scientific community that '*Genetics load the gun but environment pulls the trigger*'¹⁹³ when it comes to the causation of major non-communicable diseases (NCDs)¹⁹⁴, there is persistent uncertainty as to the global burden of disease attributable to environmental (including life-style and climatic) factors, including healthcare costs and negative economic impact. Deciphering the human exposome¹⁹⁵ 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 by which they affect health at different stages throughout the life course, including exposures in foetal life. Effective

¹⁹³ Dr. Francis Collins, Director of the U.S. National Institutes of Health (NIH) www.ncbi.nlm.nih.gov/pmc/articles/PMC2675383

¹⁹⁴ <http://www.who.int/mediacentre/news/releases/2016/deaths-attributable-to-unhealthy-environments/en/>

¹⁹⁵ 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.

preventive action will need to be designed, building on knowledge of various risk factors, including exposure to pollutants in daily life, individual behaviour and the social context, taking into account gender issues.

Developing a Human Exposome Project 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: Applicants should 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 use innovative approaches to the systematic and agnostic identification of the most important environmental risk factors for the development of major NCDs across the life course (including *in utero*), leading to preventive interventions at the individual, group or population level and contribute to sustainable healthcare. Well-designed retrospective epidemiological studies may be included and proposals may envisage the creation of a prospective Europe-wide exposomics cohort and biobank, integrating behavioural, socio-economic factors and clinical records.

The following components should be considered: agnostic evaluation of the role of multiple and unknown exposures; assessment of individual exposure to multiple stressors; sensors that combine external exposure and health data measurements; integration of external exposome data with cross-omics responses and (epi)genetic data; systematic evaluation and simulations of the health impacts; socio-economic modelling and econometric analysis including ethical and sex/gender aspects where relevant; better data mining tools, including advanced statistical analysis of complex data and high-performance/high throughput computing and storage; a long-term host and a single shared data infrastructure, taking into account existing structures and ensuring open access to data generated.

Innovation and connections 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 and outdoor air quality, waste, occupational health, noise).

In order to establish an overarching Human Exposome Project, 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. Grants awarded under this topic will be complementary. The respective options of Article 2, Article 31.6 and Article 41.4 of the [Model Grant Agreement](#) will be applied.

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.
- Enabling 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-BHC-29-2020: Innovative actions for improving urban health and wellbeing - addressing environment, climate and socioeconomic factors

Specific Challenge: The natural and built¹⁹⁶ environment as well as the social fabric are critical determinants of health and well-being. Three quarters of the European population now live in cities and urbanisation continues at high speed, driven by economic growth and employment opportunities. The related environmental changes e.g. pollution of air and water, transportation problems, reduced social cohesion and stress affect physical as well as mental health. Although health has improved in the EU over the last decades, large differences in health still exist between and within all countries in the EU. These differences are caused by many factors such as living conditions, health-related behaviour, education, occupation and income, health care. Some of these inequalities are widening¹⁹⁷. As European cities are growing, they are increasingly taking action and introducing policies to become more sustainable and liveable, adapting to climate change, investing in a range of smart and innovative solutions such as clean and sustainable transport, higher energy efficiency and stronger social cohesion. Similar initiatives are underway e.g. in Canada, USA as well as in Asia and Africa which could provide valuable knowledge.

At EU level, the Urban Agenda for the EU¹⁹⁸ focuses on improving the life of their citizens for example through the development of digital solutions, reducing urban poverty and better integration of migrants and refugees. The headline targets in the EU2020 strategy aim to turn

¹⁹⁶ Man-made structures, features, and facilities viewed collectively as an environment in which people live and work (https://en.oxforddictionaries.com/definition/built_environment)

¹⁹⁷ <http://www.health-inequalities.eu/about-hi/health-inequalities-in-the-eu/>

¹⁹⁸ <https://ec.europa.eu/futurium/en/urban-agenda>

the EU into a smart, sustainable and inclusive economy delivering high levels of employment, productivity and social cohesion¹⁹⁹.

Improving urban health and reducing health disparities can be achieved by changes in individual behaviour as well as policies such as urban design and sustainable transport, (re)creating green and blue space or improved housing standards. There is a need to address public policies across sectors to achieve health benefits, systematically taking into account the health implications of decisions, to seek synergies, and avoid harmful health impacts (health in all policies²⁰⁰).

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

Proposals should develop and test effective actions and/or policies for improved urban health and wellbeing in Europe. Where applicable, health inequalities and environmental aspects should be addressed. These actions or policies should also be assessed for cost-effectiveness as well as barriers and facilitators to implementation. Proposals should address improved physical or mental health, or both, while considering the relevant socio-economic and/or environmental determinants of health. They could address any sector (with priority on other sectors than health care) or policy area relevant to achieve a lasting health improvement. Proposals should include analysis of vulnerable groups and gender aspects and address any such inequities in the design of interventions. Research teams should bring in all appropriate scientific disciplines to design and test interventions. This includes social scientists not least for their role on behavioural aspects

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

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

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

Expected Impact:

¹⁹⁹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF>
²⁰⁰ http://www.who.int/healthpromotion/conferences/8gchp/statement_2013/en/

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

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-36-2020: Micro- and nano-plastics in our environment: Understanding exposures and impacts on human health

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

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

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

Scope: Proposals should use innovative approaches to provide policy relevant scientific data in support of improved human health hazard and risk assessment of micro and/or nano-plastics.

The following research priorities on micro- and/or nano-plastics, *inter alia*, can be considered²⁰¹:

- Environmental/food/water sources for micro- and/or nano-plastics and transmission to humans;

²⁰¹ Applicants may choose to address all or some of the items

- Methods for identification and quantification of micro and/or nano-plastics in foods, environmental media and tissues;
- Exposure levels of humans to micro- and/or nano-plastics and methods for human biomonitoring;
- Analytical methods for detection of micro- and/or nano-plastics particles and contaminants;
- Microbial colonisation of micro- and/or nano-plastics as vectors for potential pathogens;
- Micro- and/or nano-plastics as condensation nuclei and/or carriers for airborne particulate matter and chemicals harmful to health;
- Toxicology and uptake of micro- and/or nano-plastics and additives/adsorbed contaminants;
- Fate of micro- and/or nano-plastics in the gastro-intestinal or respiratory tracts and secondary organs;
- Effects and transport of micro- and/or nano-plastics across biological barriers, and bioaccumulation and cell uptake of micro- and/or nano-plastics, including studies at the cellular and molecular levels;
- Consideration of the effect of shape (as well as size) of micro- and/or nano-plastics, and comparison with the behaviour and effects of non-synthetic homologues, e.g. wool fibres;
- Immune responses;
- Preliminary investigations into long-term effects of micro- and/or nano-plastics.

Sex and gender differences should be investigated, where relevant.

This topic is in support of the European Strategy for Plastics in a Circular Economy²⁰². Selected projects under this topic as well as projects selected under other topics in Horizon 2020 supporting the Plastics Strategy²⁰³ are strongly encouraged to participate in joint activities as appropriate. These joint activities could take the form of clustering of projects, participation in workshops etc. The proposals will also be expected to demonstrate support to common coordination and dissemination activities. Applicants should plan the necessary budget to cover those activities without the prerequisite to define concrete common actions at this stage. The details of these coordination activities will be defined during the grant preparation phase with the Commission.

²⁰² <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516265440535&uri=COM:2018:28:FIN>
²⁰³ See footnote 186

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.

Proposals could consider the involvement of the European Commission Joint Research Centre (JRC) to provide added value regarding a number of aspects, e.g. interfacing between the scientific and regulatory communities, advancing the regulatory assessment frameworks, coordination of the development of relevant guidance documents, guidelines and international harmonisation. In this respect the JRC is open to collaborate with any successful proposal.

Expected Impact:

- Better understanding of health impacts of exposure to micro- and/or nano-plastics, including preliminary investigations into long-term impacts.
- Innovation in human health hazard and risk assessment methodologies of micro- and/or nano-plastics.
- Contribution to the health-relevant aims of the European Strategy for Plastics in a Circular Economy²⁰⁴ and of the Bioeconomy Strategy²⁰⁵.

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: Setting the priorities for a European environment, climate and health research 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 several overarching policy programmes governing environment and health: the Seventh Environment Action Programme²⁰⁶ to 2020, the WHO-led European Environment and Health Process²⁰⁷, the Paris agreement adopted under the United Nations Framework Convention on Climate Change²⁰⁸ and the United Nations Agenda 2030 for Sustainable Development²⁰⁹. In order to respond to the new and continuing challenges in environment, climate change and health in the next decade, identified in these and other policy programmes, increased coordination and cross-fertilisation of ideas between sectors is required. This will raise the visibility of the work undertaken, introduce a more strategic approach, thereby optimising and adding value to H2020 and the

²⁰⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0028&from=EN>

²⁰⁵ <https://ec.europa.eu/research/bioeconomy/index.cfm?pg=policy&lib=strategy>

²⁰⁶ <http://ec.europa.eu/environment/action-programme/>

²⁰⁷ <http://www.euro.who.int/en/health-topics/environment-and-health/pages/european-environment-and-health-process-ehp>

²⁰⁸ http://unfccc.int/paris_agreement/items/9485.php

²⁰⁹ sustainabledevelopment.un.org/post2015/transformingourworld

next EU research framework contributions to environment and health activities and policies in Europe.

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 relevant international actors. The objective is to identify proactively key policy areas requiring scientific support for environment, climate change and health related issues in the next decade and develop a European medium-term research and innovation strategy and agenda covering key 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, also in occupational settings. In addition to this strategy, 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, should be developed. 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 EU research framework programme, WHO environment and health process).

The Commission considers that proposals requesting a three-year duration and 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.

Expected Impact:

- Development of a research and innovation agenda for the environment (including climate change) and health nexus as input to the next EU research framework programme, including for occupational settings and quantification and monetisation of health impacts of policies.
- Contribution to the European WHO environment and health process and the implementation plan resulting from the Ostrava Declaration on Environment and Health.
- Increased coordination between environment, climate change 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.

1.6 – Supporting the digital transformation in health and care

This priority focuses on (i) improving person centred care by implementing innovative solutions using digital tools; (ii) using patient data to better manage complex chronic conditions and (iii) developing a Health Research and Innovation Cloud.

The outcomes and impacts of the selected proposals would respond to the Commission priority on "A connected Digital Single Market"²¹⁰ as updated in the Communication "On enabling the digital transformation of health and care in the Digital Single Market"²¹¹.

They would contribute to making the European health and care systems more accessible and sustainable by providing more digitised and community-based care models. They should allow developing a digital economy in the health and care sectors contributing to the United Nations Sustainable Development Goal to "Ensure healthy lives and promote well-being for all at all ages"²¹². Projects will have to further advance in Big Data analytics and Artificial Intelligence to enable the digitisation of the health and care systems. The generated data will have to be safe and interoperable as advocated in the European Free Flow of Data Initiative.

Proposals are invited against the following topic(s):

SC1-DTH-12-2020: Use of Real-World Data to advance research on the management of complex chronic conditions

Specific Challenge: The number of people with chronic illness is growing and almost half of them have multiple chronic conditions. Patients with complex chronic conditions (CCCs) have chronic multi-morbidities or chronic disease complications that require the attention of multiple health care providers or facilities as well as home-based care. A patient with CCC presents to the health care system with unique constellation of needs, disabilities, or functional limitations²¹³.

Managing patients with complex chronic conditions therefore needs approaches that ensure multi-disciplinary, personalised and well accepted by the patient ways of care and monitoring.

The controlled randomised clinical trials on chronic diseases provide important information that can be translated in the daily clinical practice, but they often do not comprise sufficient breadth and depth commensurate to the complexity of diseases, and to the degree of personalisation of treatment needed.

Real World Data (referring specifically to any type of data not collected in a randomised clinical trial) can complement these to fill the knowledge gap between controlled clinical trials results and clinical practice needs in real environments. They can provide new insights into disease patterns and help improve the safety and effectiveness of health interventions.

²¹⁰ Updated by the DSM mid-term review: http://europa.eu/rapid/press-release_IP-17-1232_en.htm

²¹¹ COM(2018) 233 final of 25.04.2018

²¹² <https://sustainabledevelopment.un.org/sdg3>

²¹³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2150604/>

Tapping into this rich resource of ‘real world data’ issued from daily clinical practice, either collected on a permanent/regular basis by public bodies or through devices and mobile applications, , and smartly assembled in combination with clinical studies, should boost both output and relevance of controlled clinical research results.

Scope: The topic will support clinical research integrating Real World Data from clinical practice or from patient’s daily life and linking them with data collected with a research purpose if relevant.).

The research focus will be on the use of real world data, either newly acquired or from existing sources (such as data from clinical professional societies/associations, cohorts, registers, biobanks or collected through genome research initiatives) to improve the clinical management of adults with complex chronic conditions. The use of new technologies for data analytics and interpretation such as artificial intelligence and computer modelling are encouraged.

The proposed intervention should allow better treatment or monitoring of the person and thus changes in disease progression and/or therapy response. Quality of life, patient safety, psychosocial aspects and well-being are important determinants of complex health conditions and should be addressed whenever relevant. The research should also assess the potential and use of RWD for different health authorities like regulators of safety and quality or health technology assessment bodies. Nevertheless, research has to take duly into account sex and gender differences.

The proposed intervention must add clinical value as well as societal benefits and show feasibility and sustainability in real-life settings. In order to ensure acceptability and sustainability of the intervention early involvement of patients and care providers in the design of the research is considered essential. Similarly, proposals should duly take into account the diversity of health systems in different regions of Europe.

Data protection, data privacy and ethical issues²¹⁴ have to be carefully considered as personal data from different sources are to be linked in the course of the proposed research. Data sets assembled under the project, including the linkage to ‘real world data’ should be preserved in a sustainable and accessible way so as to enable future research on the targeted CCC, thus contributing to the overall imperative of Open Science.

Research that focuses on self-management only is not in the scope of this topic. Research on rare and/or infectious diseases are supported through other sections of the programme and are excluded from the scope of this topic.

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

²¹⁴ http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf

Expected Impact:

- Demonstrate the potential of the use multi-disciplinary multi-source Real World Data to advance clinical research on complex chronic conditions;
- Demonstrate potential and use of RWD, in particular RWD from disease-specific professional societies/associations, by health authorities to understand safety, quality and effectiveness of therapies;
- Improve the clinical outcomes as well as quality of life of patients living with CCCs;
- Advance the understanding of management of complex diseases including the interdependence of co-morbidities, thus underpinning evidence based therapies and prognostic approaches;
- Further development of new technological tools and platforms for advanced data management;
- Contribution to the cross-border health data exchange and to the goals of the Digital Single Market²¹⁵.

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-13-2020: Implementation research for scaling up and transfer of innovative solutions involving digital tools for people-centred care

Specific Challenge: People-centred care is one of the main goals of health systems²¹⁶. It relates to a stronger orientation towards the needs of people and their involvement in the treatment process and decision-making. This is expected to result in a better care as experienced by people, in less inequality, better health promotion, better disease prevention, and treatments better targeted to people's needs. Health system transition to people-centred care requires empowering citizens²¹⁷ and integration of services²¹⁸.

²¹⁵ <https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering>

²¹⁶ World Health Organization 2016. What are integrated people-centred health services? <https://www.who.int/servicesafety/areas/people-centred-care/ipchs-what/en/>

²¹⁷ Empowering citizens refers among others to enhancing their self management, raising health literacy, involving people through co-production of care and supporting informal carers.

²¹⁸ The concepts of integrated services and people-centred care are complementary to each other. Person-centredness not only requires involving people to explore their needs and come to shared decisions about treatment, but also a system-wide policy and organisation of services. Integrated care principles allow care for patients to be better coordinated, and jointly planned by the health and social care professionals across relevant preventive and curative services.

The growing digital transformation of health and care offers great opportunity to achieve this transition. Innovative solutions²¹⁹ involving digital tools have the potential to improve people-centred care through self-management, goal orientation and shared decision-making. However, technical innovation is unlikely to achieve the anticipated improvements/impact if not accompanied by supportive organisational and policy innovations. Given the complexity and differences between health systems, cross-national comparative health services and systems research as well as implementation research are needed to better understand the contextual factors that impact the successful introduction, use and sustainability of innovative solutions. This will in turn facilitate their scalability²²⁰ and their transferability to other settings.

Scope: Proposals should study the scaling-up or transferability of an innovative solution involving digital tools, i.e. the conditions under which it can be implemented in other health systems and whether it can have the same intended effect.

To address this specific challenge, the proposals should:

- Identify an innovative solution involving digital tools (or a set of comparable innovations developed in parallel in different settings) with the potential to enhance people-centred care. The selected innovative solution should be described and supported by sufficient documented evidence on its effectiveness in specific contexts and if possible cost-effectiveness.
- Design and conduct an implementation study to collect either prospectively or retrospectively (depending on the maturity of the innovative solution) the evidence needed to inform the successful scaling up or transfer to different health systems with particular focus on the contextual factors including legal, ethical, behavioural and social issues.
- Identify the key aspects for scaling up or transfer, identify potential barriers, necessary measures/changes as well as facilitators to adopt the solution.
- Develop a prediction model to help decision-makers decide on the implementation of the solution as well as guidance to assess the future impact of the transferred solution on health system performance.

Proposals should be multidisciplinary, bringing together expertise in health services and systems research, human and social sciences and implementation research²²¹. The main focus should be on improving people-centeredness in Europe but solutions can originate from non-

²¹⁹ The term “innovative solutions” refers to any service or policy innovations. It encompasses technological innovations, organisational innovations and public health policies. Organisational innovation should be understood in a broad sense including governance, payment, information systems, roles and skills in attaining efficient health care organisations when introducing new technologies.

²²⁰ Scalability is used in the sense of the uptake in larger numbers of the same innovation in comparable organisations and/or in the same sector.

²²¹ Implementation research refers to the scientific study of methods to promote the uptake of research findings into routine healthcare in clinical, organizational or policy contexts

European countries. Gender aspects should be taken into account. Careful consideration should be given to vulnerable groups. Relevant stakeholders including end-users of research and patients' organisations should be identified and involved throughout the project lifetime. Innovative approaches in gathering patients input should be considered.

The proposals should complement or build on existing initiatives, including (but not limited to) results of EU-funded projects²²².

Selected proposals should provide evidence to support the third pillar of the Communication from the Commission on enabling the digital transformation of health and care in the Digital Single Market, "Digital tools for citizens empowerment and person-centred care"²²³.

The Commission considers that proposals requesting a contribution from the EU Horizon 2020 research programme 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.

Expected Impact:

- Availability of methods and strategies for the implementation of innovative, ethically and legally sustainable solutions aiming at improving people-centred care
- A better understanding of organisational and system changes, as well as social and behavioural changes required to successfully embed evidence-based innovative solutions involving digital tools into daily practice and ensure their sustainability
- Increased scaling up and transfer of innovative solutions improving people-centred care in Europe
- In the medium and long-term, health services more responsive to the needs of people and their carers (formal and informal), more effective, efficient and equitable health systems.

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-HCC-10-2020: Towards a Health research and innovation Cloud: Capitalising on data sharing initiatives in health research

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

²²² e.g. TO-REACH, ImpleMentAll, TICD, PROJECT INTEGRATE, SELFIE, SMART2D

²²³ <https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering>

research discoveries and bring them closer to clinical application for the benefit of EU citizens.

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

Properly addressing the security and privacy of health research data, and the compliance with various levels of legislations, in particular the General Data Protection Regulation (GDPR) together with the applicable National legislations in the EU Member States/Associated Countries and with different jurisdictions is a critical step for the design of a Health Research and Innovation Cloud (HRIC). These aspects need to be an integral part of the proposal so that the collection, governance, sharing, analysis and curation of health research data across different application domains can be achieved in ways that are technologically robust, scientifically reliable, and ethically and legally sound.

Scope: The successful project should bring together data-intensive EU health research initiatives to design an **implementation roadmap /strategic agenda for** a one-stop shop, a **HRIC FAIR data portal** respecting legal and ethics requirements. It should also define and promote, among research projects, procedures to make data FAIR as well as a standard way of communicating such data, so that any IT-system can easily provide metadata to the portal. This portal would serve as catalogue of all relevant publicly-funded health research databases, registries and infrastructures (e.g., ESFRI) and allow access to high quality health research data. The proposal is expected to build a **community** (i.e., a wider forum) in order to align strategies and capitalise on the work done by relevant European and international initiatives. The proposal should develop **two use cases**, where all the aforementioned aspects will be integrated and analysed. These use cases should link health research data, and if relevant, health research data with curated clinical data and health administrative data. The participation of experts in ethics and law as well as patient representatives is strongly recommended.

The proposal should also **produce guidelines for researchers to contribute to the proper application of the GDPR regulation, taking into account the specific features of processing personal data in the area of health.**

The HRIC should contribute to the European Open Science Cloud²²⁴.

Project results should be widely disseminated to the relevant stakeholders across the Member States and Associated Countries.

The implementation roadmap of the HRIC FAIR data portal will define how to address the specific requirements of health research data. In this sense, the selected proposal is expected

²²⁴

<http://ec.europa.eu/research/openscience/index.cfm?pg=open-science-cloud>

to collaborate with the projects funded under topics 'INFRAEOSC-04-2018' and 'INFRAEOSC-06-2019-2020: Enhancing the EOSC portal and connecting thematic clouds', in particular with those in the health field. Grants awarded under these topics will be complementary. The respective options of Article 2, Article 31.6 and Article 41.4 of the Model Grant Agreement will be applied.

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

Expected Impact:

- A HRIC FAIR data portal respecting legal and ethics requirements. This portal should serve as catalogue of all relevant publicly-funded health research databases, registries and infrastructures (e.g., ESFRI) and allow access to high quality health research data.
- Through use cases, demonstrate the added value of close collaboration of health researchers with healthcare providers and other actors in health care systems.
- Guidelines on application of the GDPR and the EU Member States and Associated Countries national legislations. The developed guidelines should cover the processing and further processing of health research data.
- Contribute to the setup of a Health Research and Innovation Cloud, the Health thematic cloud of the European Open Science Cloud.
- Contribute to the Digital Single Market through piloting IT health research solutions.

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):²²⁵

Topics (Type of Action)	Budgets (EUR million)			Deadlines
	2018	2019	2020	

²²⁵ The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts for the 2020 budget are subject to the availability of the appropriations provided for in the draft budget for 2020 after the adoption of the budget 2020 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

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Opening: 07 Nov 2017				
SC1-BHC-15-2018 (RIA-LS)	52.00			06 Feb 2018 (First Stage) 04 Sep 2018 (Second Stage)
SC1-BHC-03-2018 (RIA)	50.00			18 Apr 2018
SC1-BHC-04-2018 (COFUND-EJP)	55.00			
SC1-BHC-05-2018 (RIA)	40.00			
SC1-BHC-09-2018 (RIA)	54.00			
SC1-BHC-16-2018 (RIA)	20.00			
SC1-BHC-18-2018 (RIA)	25.00			
SC1-BHC-21-2018 (RIA)	10.00			
SC1-BHC-23-2018 (RIA)	44.00			
SC1-BHC-26-2018 (RIA)	10.00			
SC1-BHC-27-2018 (RIA)	52.00			
SC1-HCO-01-2018-2019-2020 (CSA)	8.00			
SC1-HCO-02-2018 (CSA)	2.00			
SC1-HCO-04-2018 (ERA-NET-Cofund)	5.00			
SC1-HCO-05-2018 (CSA)	2.00			
SC1-HCO-06-2018 (CSA)	3.00			
SC1-HCO-08-2018 (CSA)	3.00			
SC1-HCO-09-2018 (CSA)	2.00			
SC1-HCO-10-2018 (CSA)	2.00			
SC1-HCO-11-2018 (CSA)	1.00			
SC1-HCO-12-2018 (CSA)	2.00			
SC1-HCO-13-2018 (CSA)	3.00			
Opening: 26 Jul 2018				

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SC1-BHC-01-2019 (RIA)		70.00		02 Oct 2018 (First Stage) 16 Apr 2019 (Second Stage)
SC1-BHC-02-2019 (RIA)		50.00		
SC1-BHC-14-2019 (RIA)		95.00		
SC1-BHC-19-2019 (RIA)		25.00		
SC1-BHC-22-2019 (RIA)		30.00		
SC1-BHC-25-2019 (IA)		60.00		
SC1-BHC-30-2019 (RIA)		40.00		
SC1-BHC-07-2019 (RIA)		50.00		16 Apr 2019
SC1-BHC-10-2019 (PCP)		30.00		
SC1-BHC-13-2019 (RIA)		30.00		
SC1-BHC-28-2019 (RIA)		50.00		
SC1-BHC-31-2019 (RIA)		15.00		
SC1-BHC-32-2019 (RIA)		15.00		
SC1-HCO-01-2018-2019-2020 (CSA)		4.00		
SC1-HCO-15-2019 (CSA)		1.00		
Opening: 04 Jul 2019				
SC1-BHC-08-2020 (RIA)			80.00	26 Sep 2019 (First Stage) 15 Apr 2020 (Second Stage)
SC1-BHC-24-2020 (RIA)			50.00	
SC1-BHC-29-2020 (RIA)			35.00	
SC1-DTH-13-2020 (RIA)			20.00	
SC1-BHC-37-2020 (RIA-LS)			6.00	15 Apr 2020
SC1-BHC-06-2020 (RIA)			40.00	15 Apr 2020
SC1-BHC-11-2020 (RIA)			60.00	
SC1-BHC-17-2020 (RIA)			20.00	
SC1-BHC-20A-2020 (PCP)			25.00	
SC1-BHC-20B-2020 (PPI)				

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SC1-BHC-33-2020 (RIA)			9.00	
SC1-BHC-34-2020 (RIA)			25.00	
SC1-BHC-35-2020 (RIA)			30.00	
SC1-BHC-36-2020 (RIA)			25.00	
SC1-DTH-12-2020 (RIA)			41.00	
SC1-HCC-10-2020 (CSA)			3.00	
SC1-HCO-01-2018-2019-2020 (CSA)			4.00	
SC1-HCO-03-2020 (CSA)			2.00	
SC1-HCO-07-2020 (ERA-NET-Cofund)			5.00	
SC1-HCO-14-2020 (ERA-NET-Cofund)			5.00	
SC1-HCO-16-2020 (ERA-NET-Cofund)			5.00	
SC1-HCO-17-2020 (CSA)			2.00	
SC1-HCO-18-2020 (CSA)			2.00	
SC1-HCO-19-2020 (CSA)			2.00	
SC1-HCO-20-2020 (CSA)			2.00	
Overall indicative budget	445.00	565.00	498.00	

In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects supported under the following topics: SC1-BHC-01-2019, SC1-BHC-02-2019, SC1-BHC-03-2018, SC1-BHC-04-2018, SC1-BHC-05-2018, SC1-HCO-01-2018-2019-2020, SC1-HCO-02-2018, SC1-HCO-04-2018, SC1-BHC-07-2019, SC1-BHC-09-2018, SC1-BHC-10-2019, SC1-HCO-05-2018, SC1-BHC-13-2019, SC1-BHC-14-2019, SC1-BHC-15-2018, SC1-BHC-16-2018, SC1-BHC-18-2018, SC1-BHC-19-2019, SC1-BHC-21-2018, SC1-HCO-06-2018, SC1-HCO-08-2018, SC1-HCO-09-2018, SC1-HCO-10-2018, SC1-HCO-11-2018, SC1-BHC-22-2019, SC1-BHC-23-2018, SC1-BHC-25-2019, SC1-BHC-26-2018, SC1-HCO-12-2018, SC1-BHC-27-2018, SC1-BHC-28-2019, SC1-HCO-13-2018, SC1-BHC-30-2019, SC1-BHC-31-2019, SC1-BHC-32-2019, SC1-HCO-15-2019, SC1-BHC-06-2020, SC1-HCO-03-2020, SC1-HCO-14-2020, SC1-HCO-16- 2020, SC1-HCO-17-2020, SC1-BHC-08-2020, SC1-BHC-11-2020, SC1-HCO-18-2020,

SC1-HCO-19-2020, SC1-BHC-17-2020, SC1-BHC-20A-2020, SC1-BHC-20B-2020, SC1-BHC-33-2020, SC1-BHC-34-2020, SC1-BHC-35-2020, SC1-HCO-07-2020, SC1-BHC-24-2020, SC1-BHC-37-2020, SC1-HCO-20-2020, SC1-BHC-29-2020, SC1-BHC-36-2020, SC1-DTH-12-2020, SC1-DTH-13-2020 and SC1-HCC-10-2020

Beneficiaries in grants signed under this call will be allowed to charge the cost of clinical studies on the basis of unit costs established in line with a methodology set up in the Commission Decision C(2016) 7553, which is available on the Funding and tenders Portal.

Beneficiaries in grants signed under this call may be required by the European Commission, in the context of a public health emergency, to provide timely open access or access rights to research data which are relevant for addressing a public health emergency. Therefore the relevant option of Article 29.3 of the Horizon 2020 Model Grant Agreement will be applied. It is expected that quality-controlled data are shared in accordance with the FAIR²²⁶ principles.

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

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

For two stage procedure:

- Information on the outcome of the evaluation: Maximum 3 months from the final date for submission for the first stage and maximum 5 months from the final date for submission for the second stage; and
- Indicative date for the signing of grant agreements: Maximum 8 months from the final date for submission of the second stage.

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

SC1-BHC-05-2018	Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least one participant from Canada.
SC1-HCO-01-2018-2019-2020	Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals under 1. "International Aspect" shall include at least one participant from the international partner region CELAC

²²⁶ <https://www.force11.org/group/fairgroup/fairprinciples>

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	(2018 call), China (2019 call) or from African Union Member States (2020 call).
SC1-BHC-15-2018	Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least one participant from disease-endemic countries.
SC1-BHC-18-2018	Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least two participants from two different CELAC countries.
SC1-BHC-21-2018	Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least one participant from the Russian Federation.
SC1-BHC-25-2019	Taking into account the advances already achieved for Personalised Medicine approaches in cancer and rare diseases, projects with primary focus on these diseases are excluded from the scope of this topic.
SC1-BHC-32-2019	Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposal(s) shall include at least three participants from India.

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

SC1-BHC-03-2018, SC1-BHC-04-2018, SC1-BHC-05-2018, SC1-BHC-06-2020, SC1-BHC-07-2019, SC1-BHC-09-2018, SC1-BHC-10-2019, SC1-BHC-11-2020, SC1-BHC-13-2019, SC1-BHC-16-2018, SC1-BHC-17-2020, SC1-BHC-18-2018, SC1-BHC-20A-2020, SC1-BHC-20B-2020,	The thresholds for each criterion in a single stage process will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
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<p>SC1-BHC-21-2018, SC1-BHC-23-2018, SC1-BHC-26-2018, SC1-BHC-27-2018, SC1-BHC-28-2019, SC1-BHC-31-2019, SC1-BHC-32-2019, SC1-BHC-33-2020, SC1-BHC-34-2020, SC1-BHC-35-2020, SC1-BHC-36-2020, SC1-BHC-37-2020, SC1-DTH-12-2020, SC1-HCC-10-2020, SC1-HCO-01-2018- 2019-2020, SC1-HCO- 02-2018, SC1-HCO- 03-2020, SC1-HCO- 04-2018, SC1-HCO- 05-2018, SC1-HCO- 06-2018, SC1-HCO- 07-2020, SC1-HCO- 08-2018, SC1-HCO- 09-2018, SC1-HCO- 10-2018, SC1-HCO- 11-2018, SC1-HCO- 12-2018, SC1-HCO- 13-2018, SC1-HCO- 14-2020, SC1-HCO- 15-2019, SC1-HCO- 16-2020, SC1-HCO- 17-2020, SC1-HCO- 18-2020, SC1-HCO- 19-2020, SC1-HCO- 20-2020</p>	
<p>SC1-BHC-01-2019, SC1-BHC-02-2019, SC1-BHC-08-2020, SC1-BHC-14-2019, SC1-BHC-15-2018, SC1-BHC-19-2019, SC1-BHC-22-2019, SC1-BHC-24-2020,</p>	<p>The thresholds for each criterion for the second stage of the two-stage calls for these topics will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

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SC1-BHC-25-2019, SC1-BHC-29-2020, SC1-BHC-30-2019, SC1-DTH-13-2020	
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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](#) published on the Funding & Tenders Portal.

Grant Conditions:

SC1-BHC-10-2019, SC1-BHC-20A-2020	The funding rate for PCP actions is limited to 90% of the total eligible costs to leverage co-financing from the procurers in this specific case.
SC1-BHC-20B-2020	The funding rate for PPI actions is limited to 35% of the total eligible costs to leverage co-financing from the procurers in this specific case.
SC1-BHC-31-2019	To ensure coherence and communication between projects funded under this topic and with the HCA, the Commission will ensure an overall coordination mechanism between the projects. The respective options of Article 2, Article 31.6 and Article 41.4 2 of the Model Grant Agreement will be applied.
SC1-BHC-37-2020, SC1-HCC-10-2020	The respective options of Article 2, Article 31.6 and Article 41.4 2 of the Model Grant Agreement will be applied.

Consortium agreement:

All topics of this call	Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.
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Call - Digital transformation in Health and Care

H2020-SC1-DTH-2018-2020

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 digitised, person-centred and community-based care models, thereby enabling better access to healthcare and the sustainability of health and care systems. Secure and interoperable data as an enabler together with state of the art technologies such as Artificial Intelligence and Big Data analytics are essential building blocks for the digital transformation of health and care as addressed by this call. It is relevant to the Commission priorities 'A new boost for jobs, growth and investment' and 'A connected Digital Single Market'²²⁷, 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 aiming at sustainable development to the benefit of society, environment and citizens.

Proposals are invited against the following topic(s):

SC1-DTH-01-2019: 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 the impression of cancer being 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. Big Data can provide new opportunities to define statistical and clinical significance, but present also challenges as it requires specific analytical approaches.

Scope: Proposals should focus and deliver on how to better acquire, manage, share, model, process and exploit big data using, if appropriate, high performance computing 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 (taking also in account gender differences)

²²⁷ Updated by the DSM mid-term review: http://europa.eu/rapid/press-release_IP-17-1232_en.htm

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 preferably address relevant health economic issues, use patient reported outcome and experience measures (PROMs and PREMs) and take into account the relevant social aspects of health status and quality of life after cancer treatment. Integrated solutions should include suitable approaches towards security and privacy issues.

Information can be collected from traditional sources of health data (cohorts, comprehensive electronic health records or clinical registries, incl. genetic data, validated biomarkers for remission), from new sources of health data (mobile health apps and wearables) and from sources that are usually created for other purposes such as environmental data.

It is important to assure ethical aspects of data, confidentiality, and 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 by using proper annotation methodologies of the data. Involvement of those who work within healthcare systems, patients, family and relatives, and the general public is needed.

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. Participation of SMEs is encouraged.

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

- Mapped comprehensive big data in a reachable and manageable way by applying principles for sharing and reusability, creating a network of knowledge by linking translation tools, heterogeneous data sources and biomedical texts 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-02-2020: Personalised early risk prediction, prevention and intervention based on Artificial Intelligence and Big Data technologies

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

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

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

The challenge is to develop and validate these comprehensive models based on AI or other state of the art technologies for prediction, prevention and intervention using multiple available data resources and to integrate them in personalised health and care pathways that empower individuals to actively contribute to risk mitigation, prevention and targeted intervention.

Scope: Proposals should build on results of projects²²⁸ and the state of the art in ICT for early risk prediction and introduce innovative ICT solutions through data, data analytics, advanced or novel digital technologies, services, products, organisational changes, and citizens data ownership, that lead to more effective health and care systems. These innovative ICT based solutions may address one or multiple conditions and explore ways of inducing adequate personalised preventive measures (e.g. behavioural change, diet, interventions, medication,

²²⁸ For example project outcomes from the H2020 topic PHC-21-2015

primary prevention) from advanced predictive models. Sustainable behaviour change refers to efforts to change people's personal habits to prevent disease, stimulate healthy people to monitor their health parameters and thus lowering the risk of developing (chronic) conditions.

Proposals should build on the use of already existing and/or new data generated by individuals, health professionals and other service providers (including but not limited to data collected through IoT enabled devices, wearables, mobile devices, data source networks or data lakes etc. collected outside the controlled environment of clinical trials) by citizens, healthcare professionals, public authorities and industry, with a view to developing personalised early risk prediction, prevention and intervention approaches that meet the needs of individuals while providing them with adequate information to support informed decision making, improve the uptake of preventive approaches and lead to better health outcomes.

Proposals should also include actions aimed at increasing health literacy, including the role of the citizen as owner of his or her own personal data, as well as advancing health and care professionals' proficiency in novel, data-oriented health services through the use of digital solutions to increase knowledge about diseases and help them in the interpretation of symptoms and effects (e.g. with visualisations like dashboards, etc.), notably of early warning signs and medical information. Early warning signs relay to either healthy people monitoring several body parameters e.g. to conduct healthy life styles and increase physical activity levels or to the detection of the deterioration of the condition of already diseased patients. The latter could include advanced prediction models from aggregated patient data of certain health events/complications.

Proposals are expected to be built on realistic scenarios for new health and care pathways, and should integrate multi-disciplinary research involving behavioural, sociological, medical and other relevant disciplines. Stakeholder engagement (esp. considering vulnerable user groups, i.e. persons belonging, or perceived to belong, to groups that are in a disadvantaged position or marginalised, for example, elderly people, persons with special needs or chronic diseases) should be part of the research design for an agile approach to ensuring that relevant user needs (including social, age and gender aspects) are met and solutions find acceptance by users. Full account should be taken of ethical and legal aspects e.g. data protection, privacy and data security. This action should create a clear and coherent set of recommendations or guidelines for public health authorities in Europe together with a strategy to support their implementation.

No large-scale piloting or clinical trials are expected in this Research and Innovation Action. However, proposals should include validation (testing on a prototype and/or proof of concept) and demonstration of feasibility of their respective models, technologies and scenarios.

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

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

- Evidence of the benefits of delivering adequate information regarding personalised risk prediction, prevention and intervention, based on proof of concept and involvement and specified roles of relevant stakeholders.
- Clear improvements of outcomes for individuals, care systems and wider society from prevention measures and interventions based on personalised early risk prediction in comparison with current practices.
- Usefulness and effectiveness of integration and coordination of interventions in new health and care pathways based on person-centred early risk prediction, prevention and intervention models.
- Realise large-scale collection of user-generated data in compliance with data protection, privacy and security rules and principles.
- Support integration with tools and services under the European Open Science Cloud.

Type of Action: Research and Innovation action

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

SC1-DTH-03-2018: 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, recreational and working environments such as a shrinking workforce and increasing numbers of workers with functional impairments, chronic conditions, care duties or re-integration in and later retirement from 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 solutions²²⁹ leading to smart work environments for older adults, supporting them to remain actively involved in professional life, helping them to sustain and renew their work and personal life related skills and support independent active and healthy lifestyles while taking into account reduced capabilities due to age-related health risks and conditions.

²²⁹ Proposals should make use of the European global navigation satellite systems Galileo and EGNOS (Geostationary Navigation Overlay Service), if relevant.

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 workplaces²³⁰.

Proposals should build on active user engagement (e.g. employee participation at the workplace) in order to ensure the understanding of user needs, safeguarding ethics, privacy, security and regulatory aspects (e.g. labor law). Attention theft and impeding physical activity by ICT should be avoided.

Concepts should 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. Participation of SMEs is encouraged.

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 or return to work after severe disease;
- 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 and skills conducive work environments and socio-economic benefits;
- Competitive advantage for European industry through flexible and sustainable work arrangements for an ageing workforce;

²³⁰ 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.

- Global leadership in ICT based innovation for active and healthy ageing including the occupational environment.

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

Specific Challenge: Demographic change and the ageing of the population create new heterogeneous challenges for society and, in particular, for ageing people. On top of the health-related age impairments such as poor health, cognitive impairment and frailty, ageing people are at risk of facing situations leading to potential social exclusion with considerable negative consequences for their independence, quality of life, those who care for them, and for the sustainability of health and care systems.

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

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

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

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

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

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

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

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

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

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

1. Cooperation with Japan

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

Without limiting the use of specific applications or hardware systems, platform approaches are required to ensure interoperability and future expandability.

Proposals are recommended to foster the adoption of the existing standards (including de-facto/ consortium standards), contributions to appropriate ongoing standardization work, and suggestions of new standards by an EU-Japan joint consortium in order to accelerate practical introduction of the results into societies.

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

Proposals are expected to contribute to help ageing people remain active and healthy inside and outside their home, by providing action guidance and decision support derived from personal information such as memories and action histories through progress beyond the state of the art in interaction technology and ICT.

The proposed solutions on an open-platform where data collection by sensors, data analysis by artificial intelligence and user-friendly user interfaces cooperatively work are expected to be naturally integrated into ageing people's daily life and provide emotional support to ageing people.

Proposed solutions should make use and further develop multimodal interaction including voice-based conversation and gesture in order to help ageing people by the most effective and personalized way.

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

2. Collaboration with Canada²³¹

In addition to the scope and challenge of this topic as defined above, proposals addressing the international collaboration with Canada need to include the use of ICT-based solutions to support smart living environments that address transitions in care challenges for ageing people. Applications should focus on the development, integration and evaluation of eHealth innovations, in collaboration with stakeholders, including eHealth industry partners²³², clinicians, patient/family/caregivers and decision makers, in order to improve health outcomes.

In collaboration with stakeholders, applicants should consider ways to improve the quality of outcomes and the cost-effectiveness of smart living environments that support care transitions. This call supports the integration of smart living environment solutions which are ready to progress beyond the prototype stage for use into care delivery programs and undergo pragmatic evaluation. Applicants are required to use strong research designs; and should provide a clear description and justification of the proposed research methodology to be used.

Funding of the Canadian component of the proposal requires that a proposal also includes one or both of the following research areas as relevant to aging people.

Areas:

- 1) Changing health status or care: Individuals facing changes in their health status or living with chronic or complex health conditions. These individuals experience several handovers among health providers, institutions, hospital units and/or have a change in their care location (e.g., home vs. hospital; community care vs. tertiary care).
- 2) Key populations to optimize transition in care outcomes: Populations at increased risk of adverse transition in care outcomes include but not limited to: First Nations, Inuit and Métis Peoples; individuals residing in rural and/or remote communities; individuals who are transgender; individuals with an intersex condition; older adults and new aging populations (i.e., survivors of diseases/conditions that previously led to early death); new immigrants; and those who experience systemic, cultural and/or language barriers.

The consortium should also have the capacity to:

- Establish productive partnerships with eHealth innovation industries to co-design eHealth-enabled smart living environments to improve transitions in care;

²³¹ This collaboration is a component of the CIHR Transitions in Care Initiative, one of CIHR's multi-Institute Initiatives. This multi-Institute Initiative is led by the Canadian Institutes of Health Research (CIHR), and includes a number of dedicated funding opportunities focused on supporting research that aims to transform the Canadian health system to optimize the outcomes of patients experiencing transitions in care.

²³² In Canada small-to-medium enterprises (SMEs) are the primary driver of innovation in most industrial sectors, including eHealth. Team grants are intended to foster an alignment of funding and incentives with SME funding and support agencies at the federal, provincial, territorial and regional levels, as well as with national and multi-national industries. As such, eHealth Innovation partners are targeted towards (but not limited to) Canadian SMEs and foreign subsidiaries in the digital health care/medtech sector.

- Evaluate the impact, efficiency, and cost-effectiveness of eHealth innovations in addressing gaps and inefficiencies using smart living environments in servicing the identified research areas. The evaluation will utilize rigorous research design(s) to generate high-quality (valid and reliable) evidence that will assist in the subsequent spread and scale (sharing) of successful innovations; and
- Integrate successful eHealth innovations into care delivery programs and promote their uptake and use to support effective and efficient smart living environments.

Example of potential topics may include, but are not limited to the following:

- Ageing patients/survivors patients with acute, chronic or complex health conditions that are transitioning from hospital to home and supported by Information and Communication technology (ICT)-based solution (i.e. sensors monitoring their vitals and providing feedback to themselves and providers).
- Ageing patients/survivors of chronic conditions transitioning into a smart living long-term care facility.
- Implementing smart living environments for managing care transitions of ageing people within different culture and social groups, and/or geographic regions.
- Evaluation of smart living environment solutions that address transition in care challenges for ageing patients with the capability to progress beyond prototype stage, into care delivery programs for pragmatic evaluation. In alignment with the CIHR Sex, Gender and Health Research policy²³³, all proposals requesting funding from the CIHR are expected to consider how sex and/or gender might shape eHealth innovations to support transitions in care for ageing populations.

An amount of EUR 4 million will be reserved for proposals focusing on cooperation with Canada²³⁴.

At least one proposal collaborating with Japan and at least one proposal collaborating with Canada should be funded under this action. The evaluation of proposals will be jointly carried out by the Commission and the relevant Japanese and Canadian funding organisations as applicable.

The Commission considers that proposals requesting a contribution from the EU of between EUR 2 and 4 million would allow this specific challenge to be addressed appropriately.

²³³ Applicants are encouraged to visit the CIHR sex- and gender-based analysis resource page for more information on key considerations for the appropriate integration of sex and gender in their proposal.

²³⁴ In addition, the total amount available to the Canadian component of the team focusing on cooperation with Europe is expected to be CAD \$1,920,000, enough to fund up to two (2) grants. The maximum CIHR amount per grant is \$240,000 per year for up to four (4) years for a total of \$960,000, per grant. Of note, Canadian applicants must secure partnership contributions equivalent to a minimum of 30% of the total grant amount requested, with a minimum of half (15%) of the amount must represent a cash contribution (i.e., a total of \$288,000 partner match required per grant with a minimum of \$144,000 as a cash contribution per grant), for a total grant value of up to \$1.248 million per grant over four (4) years.

Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. Participation of SMEs is encouraged.

Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least one organisation as partner in the consortium from Japan²³⁵ or Canada²³⁶.

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

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

Type of Action: Research and Innovation action

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

SC1-DTH-05-2019: 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 have been tested and have demonstrated success in smaller scale settings. However, despite cooperation initiatives amongst regions through INTERREG programmes

²³⁵ Funding is expected to be made available in Japan by the Ministry of Internal Affairs and Communication (MIC) and/or the National Institute of Information and Communications Technology (NICT).

²³⁶ Funding is expected to be made available in Canada by the Canadian Institutes of Health Research (CIHR)

²³⁷or the transfer of innovation schemes of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA)²³⁸, large-scale deployment of digital health and care solutions across EU borders remains limited. 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 solutions²³⁹ 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. Supporting the public procurement of innovation helps public authorities by aggregating demand and sharing the inherent risks associated to deploying new innovative solutions that can be integrated with existing public health and care provision systems.

Scope: This topic will contribute to the Digital Single Market Strategy priorities on digital transformation of health and care (notably to the priority on user-centred integrated care), to the Scaling-Up Strategy²⁴⁰ 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, notably the priority focusing on user-centred integrated care. The actions supported will target large-scale deployment of digital health and care solutions across different regions in Europe. In line with the priority actions of the EIP on AHA Scaling-up Strategy, the scope of this PPI 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 promoting patient feedback in which public procurement approaches for innovative solutions lead to improved outcomes. Proposals should:

- Be driven by clearly identified procurement needs²⁴¹ of the participating organisations and building on a deep 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 promoting patient feedback by providers involved in the procurement of solutions for digital health and care providers, including networking of inpatient and outpatient care, nursing services and care homes;

²³⁷ http://ec.europa.eu/regional_policy/en/policy/cooperation/european-territorial/

²³⁸ Scale AHA <http://www.scale-aha.eu/2016-twinning.html>

²³⁹ Proposals should make use of the European global navigation satellite systems Galileo and EGNOS (Geostationary Navigation Overlay Service), if relevant.

²⁴⁰ https://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/scaling_up_strategy.pdf

²⁴¹ Proposals are encouraged to follow the principles of Green Public Procurement as appropriate, see http://ec.europa.eu/environment/gpp/index_en.htm

- 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, notably taking into account levels of acceptance with users and professionals as well as health economics considerations.
- 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 MAFEIP²⁴² 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.

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

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

²⁴² See www.mafeip.eu

- Growing awareness and successful use of public procurement to boost ICT innovation applied to integrated care and active and healthy ageing, implemented across the whole chain of care 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: Public Procurement of Innovative solutions

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

SC1-DTH-06-2020: Accelerating the uptake of computer simulations for testing medicines and medical devices

Specific Challenge: The development of medical devices and pharmaceutical products are associated with high costs. A new pharmaceutical product and its introduction into the market is estimated to cost today over 2 billion EUR, from which nearly 75% is spent at the late stages of the drug development process in the various phases of the clinical trials.

As biomedical knowledge increases and bioinformatics capability likewise grows, there is hope that greater predictive power may be obtained from individualised computer simulations used in in-silico medicine research, such as predictive toxicology and pharmacokinetics.

The adoption of individualised computer models and simulations to develop and assess drugs and devices, their translation into the clinic and penetration on the market of ICT solutions, depend on the trust of users (healthcare professionals and patients), the industry and investors and the competent authorities and regulatory bodies. The users need proofs of validation in the real clinical contexts.

The specific challenge of this call is accelerating the uptake of individualised computer simulations in the regulatory evaluation of medicines and/or medical devices to become closer to the market. Applicants will provide proofs of validation of computer modelling solutions that gain the trust of regulatory bodies for innovation, in order to, in collaboration with academic and industrial experts, develop the framework of standards, protocols and shared resources required to evaluate the safety and the efficacy of medical devices and/or medicines at the end of the drug development process.

Scope: Proposals will develop innovative scientific and technological computer modelling solutions for testing medicines and/or medical devices. The proposed computer modelling solutions will be the result of a multidisciplinary effort (e.g. within the fields of computational modelling, chemo/bio-informatics, systems biology, pharmacology, -omics (genomics, epigenomics, metabolomics), tissue mechanics, biology, pharmaceuticals, medicine, physiology, toxicology, social science aspects such as gender) and should also explore and inform of the reasons for failure should the drug or medical device be found not efficient or safe and will suggest improvements. To help adopt such in-silico methods, measures for validation (human trials, animal studies, in vivo and in vitro validation, including the use of biobanks if appropriate) of the in-silico results should be included in the proposed projects. The benefit for human health, environment and animal welfare should be analysed and quantified. Engagement with regulators and consideration of the regulatory framework issues for computer simulations are highly recommended. Participation of SMEs is encouraged.

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

- Accelerating the adoption of computer simulations for testing medicines and/or medical devices, their translation into the clinic and the market.
- Increasing the trust of users (healthcare professionals and patients), investors and stakeholders at industry and academia to adopt computer simulations for testing medicines or medical devices as a substitution or complement of current clinical trials when appropriate.

- Contributing to redesigning current drug clinical trials by integrating in-silico methods for testing medicines or medical devices and creating a unique, digitised, personalised testing environment.
- Engagement with regulators and consideration of the regulatory framework for computer modelling solutions.
- Contributing to reducing the size and the duration of the human clinical trials and/or contributing to significantly reducing animal testing in clinical trials.
- Contributing to increased efficacy and patient safety in clinical trials.
- Contributing to reducing development costs and/or shorter time-to-market for new drugs or new medical devices.
- Contributing to setting standards for computer modelling solutions for testing.
- Contributing to the European Cloud Initiative, notably by providing open, reusable data and in silico models for clinical trials.

Type of Action: Research and Innovation action

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

SC1-DTH-07-2018: 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 new initiatives on digital health and care within the Digital Single Market policy²⁴³, the European Commission aims at leveraging the potential of big data and high performance computing for the emergence of new personalised prevention and treatments for European citizens. The European Cloud Initiative will facilitate the access of researchers to the newest data managing technologies, High Performance Computing facilities to process data and to a European Open Science Cloud list of ICT services while ensuring the appropriate data safety and protection.

²⁴³ See http://europa.eu/rapid/press-release_IP-17-1232_en.htm

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 in order to reduce the burden of non-communicable diseases, 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, as well as with Centres of Excellences for computing applications in the area of biomedicine and bio-molecular research²⁴⁴ as appropriate. They should demonstrate access to the sufficient and relevant clinical data needed for advanced validations. The work should build on – and contribute to reusable data and computer models. 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: The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- 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;

²⁴⁴ <https://ec.europa.eu/programmes/horizon2020/en/news/overview-eu-funded-centres-excellence-computing-applications>

- Contribution to the emergence of a European Data Infrastructure for personalised medicine in the context of the DSM, notably by providing reusable data and computer models for personalised prevention and health treatments;
- 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: Prototyping a European interoperable Electronic Health Record (EHR) exchange

Specific Challenge: Large amounts of valuable health data are generated and collected during and between citizens' medical examinations across Europe. However, opportunities to reuse these data for research and better healthcare are often missed because health data continue to be confined in data silos, often not matching semantic standards, quality needs 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 and harmonisation (including common clinical models, tools and agreed approaches), privacy and security (including data access and data integrity) and communication (towards citizens, patients and healthcare providers) to allow citizen/patient empowerment, advance medical science and improve health for everyone. Infrastructures are nowadays mature enough to host extensible and secure EHR services that can extend the healthcare continuum across borders and possibly embrace social care as well as healthcare-related data storage services such as fitness/wellbeing.

Scope: The focus is on developing and testing an extensible, secure and interoperable platform in compliance with the General Data Protection Regulation²⁴⁵ and the Network and Information Systems directive²⁴⁶. The work should include the development of a European prototype implementation with embedded security and large scale testing and validation in a set of use cases with demonstrated relevance for citizens' health and with involvement of citizens, hospitals, medical doctors, pharmacies and health professionals across Europe. Health authorities should be involved in the relevant parts of the proposed work.

This action is expected to prototype a (i) citizen-centered implementation of a platform that can be integrated in a federated platform structure, easy-to-use and secure, constantly accessible and portable within any other Member States of the EU and (ii) a data-driven platform to help the scientific community to benefit from user generated data (health, care,

²⁴⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation): <http://eur-lex.europa.eu/eli/reg/2016/679/oj>

²⁴⁶ Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union: <http://eur-lex.europa.eu/eli/dir/2016/1148/oj>

and health-related) going beyond the currently established level of implementation. Social Sciences and Humanities should thereby be considered appropriately.

The proposal should demonstrate its ability to providing a harmonised/standardised and interoperable platform with demonstrated relevant functionalities at the different user levels including, but not limited to:

- Ingest appropriate and relevant data and information sets in real time or in batch mode, including multilingual text and binary data;
- Expandable to new fields and datasets, extensible so as to be able to integrate subsequent types of 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 services, such as in a cloud-based platform;
- 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;
- Operate in a secure environment;
- Provide citizen health data and health information import capabilities through a secured API;
- Provide appropriate export and/or access/use functionalities for citizens' health data and health information;
- Ensure citizens' opt-in processes are properly undertaken in order to allow the secondary use of data for scientific purposes and promoted health;
- 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 citizens/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;
- Ensure compliance with the Medical Devices Regulation as appropriate and regarding the specific requirements, such as the need for a unique device identification and proof of cybersecurity;

- Consider legal aspects related to data contributions and use, such as portability, data donorship, based on existing regulations on national and EU level;
- Compliance or harmonisation with requirements of respective national legislation as appropriate, especially in terms of data protection and regarding electronic patient consent.

This prototype should be primarily focused on citizens' health data generated by the citizens themselves, healthcare professionals or sourced from relevant healthcare organisations. It should include relevant components to enable further medical purposes and health research. This prototype should also be extensible so as to be able to integrate subsequent types of data such as quantified-self data or Omics data.

The consortium should cover a wide range of relevant stakeholders with multi-disciplinary expertise in technology, health and care, legal aspects, interoperability and user engagement. Involvement of Industry and health organisations is encouraged in the most appropriate phases of the project. as well as a balanced European collaboration.

The design of the prototype should be user driven as to ensure the early buy-in of final users (from citizens to healthcare professionals and scientists). It should demonstrate tested and validated functionality in exchange of realistic and fit for the purpose EHR datasets exchange bi-directionally between: 1. hospitals, 2. medical doctor practitioners and hospitals, 3. hospitals and citizen, 4. medical doctor practitioner and citizen 5. Cross-border hospitals and 6. Citizen and research database.

Additionally, a targeted communication and education campaign with key information and tools should be produced to explain the functioning and purpose of the infrastructure (from empowerment of the citizen and promotion of health to the contribution to research) and incentives should be provided to users to accelerate the take-up and sustainability of the platform. The Connecting Europe facilities²⁴⁷ and the activities of the eHealth network²⁴⁸ should be taken into account to avoid duplication.

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

- Interoperable and secure electronic health data use across Europe for citizens and for promoting health,
- Improved health services and health conditions, enhanced quality and safety;

²⁴⁷ The CEF eHealth initiative:
<https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/CEF+Digital+Home>

²⁴⁸ The eHealth Network activities: https://ec.europa.eu/health/ehealth/policy/network_en

- Improved efficiency in terms of health economics such as on timeliness of intervention or measures taken, preventive actions/recommendations;
- Extended healthcare continuum across borders, actors and confinements;
- Improved collection and re-use of data and information sets for citizens' health and related research;
- Open, extensible and harmonisation-based EHR solution for app developers;
- Easy and safe for citizens to donate their health data for research;
- Contribution to the creation of the digital single market providing a scalable, extensible interoperable platform;
- Support integration with services under the Connecting Europe Facility.

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-09-2019: 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 should 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;
- Support integration with existing cross-border ePrescription services, such as implemented under the Connecting Europe Facility²⁴⁹;
- 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);

²⁴⁹ <https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/CEF+Digital+Home>

- 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 European eHealth services, such as implemented under the CEF.

It is expected that Members of the Consortium should include a wide range of relevant stakeholders and experts including inter alia Pharmacists, National Competent Authorities, IT Integrators, producers of ePrescribing, clinical record systems. It should 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 should 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.

The Commission considers that proposals requesting a contribution from the EU of between EUR 5 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: The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- 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, open for integration with existing cross-border ePrescription and electronic health record services, such as under CEF²⁵⁰ or H2020
- Better address adverse events/effects and safety issues by enhanced development of standard vocabulary for the related reporting;
- 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;

²⁵⁰ <https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/CEF+Digital+Home>

- 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: Digital health and care services²⁵¹

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 including health promotion and disease prevention.

Scope: Support the health and care service provider to procure the development, testing and implementation 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 and collaboration across institutions. Key challenges that could be addressed are patient empowerment, self-management, patient safety, patient involvement, chronic disease management, diagnosing, home-care logistics, hospital logistics, skills and independent living. These challenges could be addressed by applicable ICT domains e.g., telemedicine, mHealth, IoT, shared open source IT-based platforms, etc. as will be defined in the market consultation process. This should result in early adoption and demonstration of the potential for scaling-up the services and positive impact with evidence of appropriate incentives of various actors.

Proposals should deliver and:

- be driven by clearly identified user needs guiding the procurers of the buyers group²⁵²;
- be driven by public and/or private procurers from each country participating (at national, regional or local level) that have responsibilities and budget control in the relevant area of supply of health and care services;
- demonstrate strong commitment of end-users and their communities in the co-creation process;

²⁵¹ For the year 2020 no budget is allocated to the topic SC1-DTH-10-2019-2020. **Instead the topic SC1-DTH-14-2020 - Pre-commercial Procurement for Digital Health and Care Solutions has been opened in 2020.** The new topic SC1-DTH-14-2020 is an update of the previous topic SC1-DTH-10-2019-2020 and represents the recent developments in related actions.

²⁵² Proposals are encouraged to follow the principles of Green Public Procurement as appropriate, see http://ec.europa.eu/environment/gpp/index_en.htm

- 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) and;
- identify and understand the implications for training (including aspects of organisational, digital health literacy and new collaborative innovation principles and practises), management, and retention of healthcare staff under this topic.

The procurers, hospital clusters, care services providers 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 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. MAFEIP²⁵³. Sufficient travel allowances for regular information days concerning the procedures and thematic networking events (e.g. related to relevant co-ordination support actions) should be safeguarded. A plan how to implement the services would be an asset if the outcome of the project is successful. Approaches towards value based procurement are encouraged.

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

²⁵³ Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing – MAFEIP: <http://mafeip.eu>

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

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

- Established path to innovation, evidence of benefits of disruptive technologies that can support the development of sustainable business models, improved user and market engagement, strengthened procurement community, evidence of healthy innovation ecosystem including researchers, users, eHealth and other solution providers and procurers. Evidence in key performance areas i.e., quality in health and care, sustainability of the delivery system and economic value.
- Increased opportunities for solution uptake across wider international procurement markets by aiming at interoperable solutions that are validated through field testing by participating procurers in multiple countries across Europe and contribution to standardisation where relevant.

Type of Action: Pre-Commercial Procurement

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

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

Specific Challenge: Senior people 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 social 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 (health and social) 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 the Digital Single Market, and applicable to a very wide range of patient pathways. These approaches aim to enable people to remain independent as long as possible and prevent hospitalisation.

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 of services with patient and citizen feedback.
- 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 should cover in priority: work time management, quality of data/information exchange and multi-disciplinary coordination.

Outcome indicators should contribute to the assessment of the action 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.

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: 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.

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-14-2020: Pre-commercial Procurement for Digital Health and Care Solutions

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

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

Proposals should deliver and:

- be driven by clearly identified user needs guiding the procurers of the buyers group²⁵⁴;
- 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;

²⁵⁴ Proposals are encouraged to follow the principles of Green Public Procurement as appropriate, see http://ec.europa.eu/environment/gpp/index_en.htm

- demonstrate strong commitment of end-users and their communities in the co-creation process;
- as applicable contribute to the use of interoperable solutions based on open platforms and take into account existing best practices and standardisation initiatives;
- validate the benefits (both clinical and financial) of ICT-based services in comparison to traditional healthcare services;
- provide robust safeguards to ensure compliance with ethical standards, patients' rights and privacy protection;
- include clear time-lines, a well-structured work-plan aligned to the objectives of the different phases and according particular importance to the role played by the preparatory phase; (templates²⁵⁵ made available by the Commission are strongly recommended to be used in particular as concerns the call for tender) and;
- address training aspects, digital health literacy and new collaborative innovation principles and practises, management, and retention of healthcare staff under this topic.
- build on expertise from and align with other relevant actions such as PIPPI²⁵⁶ and EURIPHI²⁵⁷.

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

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

The proposals should include the methodology foreseen to measure progress and validation process applicable in the tendering phase, towards the key performance areas of quality of care, sustainability and economic value within the selected key area of intervention, see e.g.

²⁵⁵ Reference to template to be added

²⁵⁶ <https://cordis.europa.eu/project/rcn/219012/factsheet/en>

²⁵⁷ <https://cordis.europa.eu/project/rcn/219929/factsheet/en>

MAFEIP²⁵⁸. Sufficient travel allowances for regular information days concerning the procedures and thematic networking events (e.g. related to relevant co-ordination and support actions including SC1-HCC-04-2018²⁵⁹) should be foreseen. A plan to implement the services should be included. In that context investigation of complementary procurement approaches (see e.g.²⁶⁰) including value based procurement are encouraged.

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

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

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

- Established path to innovation, evidence of benefits of disruptive technologies that can support the development of sustainable business models, improved user and market engagement, strengthened procurement community, evidence of healthy innovation ecosystem including researchers, users, eHealth and other solution providers and procurers. Evidence in key performance areas i.e., quality in health and care, sustainability of the delivery system and economic value.
- Increased opportunities for solution uptake across wider international procurement markets by aiming at interoperable solutions that are validated through field testing by participating procurers in multiple countries across Europe and contribution to standardisation where relevant.

Type of Action: Pre-Commercial Procurement

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

SC1-HCC-01-2018: 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.

²⁵⁸ Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing – MAFEIP: <http://mafeip.eu>

²⁵⁹ EC Horizon 2020 SC1-HCC-04-2018: Digital health and care services – support for strategy and (early) adoption, pp. 95-98, http://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-health_en.pdf, funded project: PIPPI: <https://cordis.europa.eu/project/rcn/219012/factsheet/en>

²⁶⁰ Targeted consultation on the draft Guidance on Public Procurement of Innovation, https://ec.europa.eu/growth/content/targeted-consultation-draft-guidance-public-procurement-innovation_en, EC DG GROW, 04/10/2017

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 and integrated 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 should be achieved by bringing stakeholders together (including researchers from the social sciences and the humanities), synthesising innovation from European projects, analysing and aligning (emerging) national certification and labelling schemes and facilitating development and exchange of best practices.

This CSA should aim to support the establishment of a European reference framework for age-friendly housing and should 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, certification and regulation & standardisation bodies, building and ICT industry), the scheme should 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 relevant European and international 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 should take into account outcomes of the ongoing work around a 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.

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

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

- 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: 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 universAAL²⁶¹ and FIWARE²⁶²- 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 care²⁶³.

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.

²⁶¹ <http://www.universaal.info/>

²⁶² <https://www.fiware.org/>

²⁶³ http://ec.europa.eu/newsroom/document.cfm?doc_id=40787

The Commission considers that proposals requesting a contribution from the EU of up to EUR 1.5 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: 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: 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. In line with the strategy for EU international cooperation in research and

innovation (COM(2012)497), international cooperation is encouraged, in particular with the US, Canada, Japan, South Korea and China.

Scope: The action should 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 should 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 should also ensure that relevant stakeholders are engaged during the process through regional and international workshops and a set of communication and dissemination actions.

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

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

- 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 competitiveness 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: Digital health and care services – support for strategy and (early) adoption

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 and, eventually, on (large scale) deployment of eHealth systems and new care delivery models. The network should support existing ecosystems, create capacities, promote, co-ordinate, collaborate with other innovation accelerators and investors, and focus on adoption and scale of health innovation European wide. To facilitate sufficient knowledge brokerage all appropriate actors in the innovation chain and systems should be engaged

The consortium should represent a well-designed network of procurers and demand side actors e.g., European regions, national care authorities, NGOs, patient and consumer organisations that have proven experience in the field and the capacity to engage and consult objectively all relevant actors. The consortium should also connect to investors, National Promotional Banks and Economic Development Agencies.

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

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 of users 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 eHealth²⁶⁴, Inspire²⁶⁵ and EAFIP²⁶⁶ should be taken on-board. Networking with supply and consumer market actors, investors and business accelerators should be well established (e.g. eHealth hub²⁶⁷ [5] , EIT-KIC²⁶⁸ , EIP-AHA²⁶⁹ , AAL²⁷⁰ , ENoLL²⁷¹ , National Promotional Banks, Economic Development Agencies). The progress in Blueprint Digital Transformation of

²⁶⁴ European Procurers Platform - eHealth - Transforming the market for eHealth Solutions <http://innovationinhospitals.com/>

²⁶⁵ International Network Supporting Procurement of Innovation via Resources and Education, <http://inspirecampus.eu/>

²⁶⁶ European Assistance for Innovation Procurement (EAFIP) <http://eafip.eu/>

²⁶⁷ 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>

²⁶⁸ European Institute of Innovation & Technology - Health, <https://eit.europa.eu/eit-community/eit-health>

²⁶⁹ European Innovation Partnership on Active and Healthy Ageing, http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing

²⁷⁰ <http://www.aal-europe.eu/>

²⁷¹ European Network of Living Labs <http://openlivinglabs.eu/>

health and care²⁷² and EU-US MoU on health IT innovation eco-systems²⁷³ should be incorporated.

The proposal should include parallel activities building up on the competences and capacities of the network including but not limited to:

1) Co-ordinate the development of a multi-collaborative growth policy & strategy of the European health & care procurers and other demand side actors in the quadruple helix²⁷⁴ systemic context. The knowledge brokerage should facilitate easy migration 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 key areas of interventions in knowledge brokerage settings to get validated and accepted in health & care delivery services integrating data strategy as a fuel of novel digital health services;
- linking research institutions, university hospitals in the context of thematic CoP;
- education of new collaborative innovation principles and practises;
- building upon national initiatives, however, taking into account the Lisbon treaty²⁷⁵ and
- developing the existing or building up repositories of methodologies and set-ups of CoPs

2) Tailored assistance for procurers, regions, cities, national authorities and users to foster sustainable adoption e.g., by developing case specific innovation/business models, giving legal aid, addressing regulation, managing risks, sharing best practises, training and education, access to finance, addressing procurement events etc., interlinking with innovation acceleration of digital health and care industries, other actors.

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

²⁷² Blueprint Digital Transformation of health and care: <http://ec.europa.eu/research/conferences/2016/aha-summit/index.cfm?pg=blueprint>

²⁷³ 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

²⁷⁴ Open Innovation, Open Science, Open to the World – a vision for Europe, EC, 2016, p.12

²⁷⁵ Treaty of Lisbon amending the treaty on European Union and the treaty establishing the European Community (2007/C 306/01), see notably Articles 2C(k), 2E(a), 5a, 136a (section on Public Health), 188c(b)
<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12007L/TXT&from=en>

Nonetheless, this does not preclude submission and selection of a proposal requesting other amounts or duration.

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

- 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: Support to a Digital Health and Care Innovation initiative in the context of Digital Single Market strategy

Specific Challenge: The Communication on the mid-term review of the implementation of the Digital Single Market Strategy (COM(2017)228) identified three priorities on digital transformation of health and care (DTHC): citizens' access to their data; data infrastructure; interaction between citizens and healthcare providers for better health management. That document indicated that specific measures would be elaborated in a dedicated Communication to be adopted in the months to follow.

Progressing significantly at EU scale on the referred priorities requires aligning the efforts of many relevant players across Europe, namely their efforts on research and innovation, in line with activities supported by H2020, as well as efforts on deployment, political coordination, stakeholder awareness and mobilisation, etc. Such coordinated European action on is already supported through various frameworks including the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA), the eHealth network of Member State representatives, the eHealth stakeholders group, the health and care activities under the Digitising European Industry platform and other. It is also the focus of actions under European programs including H2020 (notably its societal challenge 1), the Active and Assisted Living Joint Programme, the IMI and ECSEL Joint Undertakings and the Knowledge and Innovation Community on Health from the European Institute of Technology.

Scope: The action should address the activities indicated below, in close coordination with European Commission services, while considering the coordination activities and programs

mentioned above, relevant projects and actions supported by the EU, and other relevant initiatives.

1) Delivery on the third DTHC priority of the DSM (focusing on user-centred integrated care), which should represent approximately 75% of the total effort of the action. This will concentrate on supporting and extrapolating the lessons from practical experiences across Europe that are particularly impactful, successful and replicable. The focus will be on large scale deployment of digital solutions for chronic diseases and integrated care (that absorb the majority of healthcare budgets and where there is a big scope for improvement) and patient-centred care, considering a limited set of implementation scenarios which seem particularly impactful. The experiences to be considered may cover public and non-public initiatives, including from the reference sites and other participants of the EIP on AHA, as well as relevant European projects (finished or not) on integrated care. Three tasks will be undertaken:

1.1. Support the identified initiatives and projects, assessing their impact, analysing their strengths and weaknesses, and providing advice for further deployment, including on available funding from public (EU or other) and private sources as well as other types of assistance. In all cases, and notably for EU funding and assistance, the aim should be to maximise their leverage effect and demonstrable impact.

1.2. Replicate the lessons from the selected initiatives and projects, through a common framework for assessing impact (with particular consideration to the MAFEIP²⁷⁶), twinning activities, and collaboration actions between relevant initiatives and stakeholders. The later may include a variety of instruments including pre-commercial and innovation procurement. Success and failure factors will be analysed and compared in view to assess their potential replicability. This work should build on the H2020 support action funded under SC1-HCO-17-2017²⁷⁷, and any other relevant efforts to link initiatives in the scope of the third DTHC priority of the DSM.

1.3. Scale up the deployment across Europe of DTHC solutions, analysing, elaborating on and promoting enabling factors and "building blocks", which may lead to European reference frameworks. These may relate e.g. to mHealth, smart homes, smart hospitals, legislation and practices on data management, recognition of professions and professional acts, reimbursement schemes, health technology assessment, incentive and penalty schemes, performance and outcome-based approaches, subsidy schemes, interoperability and standards, skills and literacy measures, etc. This work will build up on the scale-up strategy of the EIP on AHA and any other efforts to scale at European level initiatives in the scope of the third DTHC priority of the DSM.

2) Collaboration platforms on key aspects of the three DTHC priorities of the DSM, which should represent approximately 20% of the total effort of the action. This requires to identify relevant stakeholders and initiatives across Europe and engage them to collaborate, jointly

²⁷⁶ See www.mafeip.eu

²⁷⁷ See <http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-hco-17-2017.html>

analyse key challenges and solutions, elaborate common strategic agendas and commitments for action in three areas:

2.1. Citizens' access and management of data relevant to their health and wellbeing (first DTHC priority). This will address public and private initiatives allowing active citizen involvement with regard to data relevant to their health (access, manage, sharing, donating, etc). It will be important to reach out to relevant stakeholders, e.g. health authorities, patient and healthcare provider associations, data protection authorities, data platforms, etc. Account should be taken of schemes to share data, including across borders, such as the health Digital Service Infrastructure under the Connecting Europe Facility (CEF²⁷⁸), and other relevant ongoing projects and actions funded by the EU (e.g. topic SC1-DTH-08-2018).

2.2. Aggregated demand for infrastructure capacity to handle health data (capture, transfer, process, store, etc) by researchers, developers of products and services and other players involved in the secondary use of data (second DTHC priority). The focus will be on the interaction between the referred demand and the supply for generic data infrastructure capacity, considering in particular the initiatives on EuroHPC (high performance computing), European Open Science Cloud (EOSC) as well as future related activities supported by the H2020 and the (CEF) programs. Special attention should be paid to security, privacy and identification aspects. Account should be also taken of the most relevant ongoing projects and actions funded by the EU (under H2020, CEF, structural funds, etc) focusing on health data.

2.3. Interaction between citizens and healthcare providers (third DTHC priority), including feedback from patients and on health outcomes, exploitation of real world data, and other aspects meant to improve quality of care and health management in general. This will refer to various initiatives already existing in this area.

3) Vision of EU coordination and support on DTHC beyond 2020, which should represent approximately 5% of the total effort of the action. Considering inputs gathered through the implementation of the two other work packages and additional feedback from relevant stakeholders, advise on future EU support on DTHC goals, including possible financial support under the next Multi-annual Financial Framework (e.g. support for research and innovation, cohesion, strategic investment), as well as legislative, policy, or other types of intervention.

The proposal should include partners with demonstrated experience of delivering on the areas mentioned above, who are widely acknowledged for their expertise and results, while providing a broad representation of constituencies relevant to DTHC, as well as of regions across Europe.

Beyond the profile and credentials of their partners, the proposal should demonstrate capacity to reach out to and effectively engage relevant stakeholders across Europe, influence their policies and practices as well as stimulate cooperation amongst them.

²⁷⁸ <https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/CEF+Digital+Home>

Moreover, the proposal should be able to credibly deliver on the expected impacts identified below. This will require relevant expertise on a variety of domains and an appropriate level of resources convincingly allocated to the action.

The Commission considers that proposals requesting a contribution from the EU up to 4 M€ over two 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: The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- Effective support to and engagement of stakeholders active on the third DTHC priority of the DSM, resulting in tangible impact from the beginning of the action and sustainably throughout its duration.
- Functional collaboration platforms on key aspects of the three DTHC priorities of the DSM and instrumental contribution to the implementation of EU policy on DTHC in the context of the DSM.
- Actionable strategic vision for EU policy on DTHC beyond 2020, including appropriate mobilisation of EU instruments.

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-06-2020: Coordination and Support to better data and secure cross-border digital infrastructures building on European capacities for genomics and personalised medicine

Specific Challenge: Personalised medicine uses data generated by new technologies to better understand the individual characteristics in order to deliver the right care to the right person at the right time. This approach has substantial potential for tackling major health challenges, such as cancer and rare diseases, helping to deliver better and more effective health outcomes. In order to seize this potential, there is a need to support the large scale pooling of expertise and of genomic and other health data, as well as to identify common standards for the generation, analysis and sharing of this data.

Coordination and support is needed to develop cross-border solutions for sharing expertise and linking genomic and other health data. This should be achieved by identifying relevant initiatives and projects, discerning best practice emerging from clinical implementation and engaging with relevant stakeholders. It is critical to identify common standards for data quality, security, interoperability, privacy, ethical guidelines and governance models underpinning the establishment of sustainable cross-border digital infrastructures and networks for genomics and personalised medicine in Europe.

Scope: This action should aim to support the identification of common standards, cross-border digital infrastructures and coordination mechanisms to advance personalised medicine in Europe. It should build on existing initiatives, projects and resources at national, regional and European level.

This CSA should consolidate knowledge from existing initiatives and projects to identify the most appropriate practices, standards and governance models for establishing cross-border digital infrastructures supporting genomics research and personalised medicine in Europe.

In a coordinated effort with national initiatives, Research & Innovation projects, and other stakeholders (among them national authorities, health institutions, standardisation bodies, ICT industry), the action should develop coordination mechanisms for sharing expertise and for securely linking genomic and other health data (eg electronic health records, registries, including rare disease registries etc), respecting legal (including but not limited to similarities and differences in EU Member states and associated countries, standardisation, type approval etc.) and ethics requirements. This CSA should identify and facilitate the exchange of best practices between relevant R&I projects, initiatives and other stakeholders. It should provide an overview of relevant standards for data quality, security, interoperability, privacy and ethics. It should identify critical elements of a system of transparent governance of a digital infrastructure enabling the cross-border linking of genomic and other health data in Europe. It should also develop a quality risk management concept for sustainability and further development.

For grants awarded under this topic, beneficiaries may provide support to third parties as described in General Annex K of the Work Programme either in form of grants or prizes. The respective options of Article 15 of the Model Grant Agreement will be applied.

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

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

- Agreed standards and mechanisms for the cross-border linking and analysis of genomic and other health data with potential for wide-spread adoption across Europe.
- Adequate basis for developing a cross-border digital infrastructure for linking genomic and other health data in Europe.
- Best possible and secure use of genomic and other health data for personalized medicine.
- Adequate basis for investment decisions in personalized medicine (both private and public) based on expected returns.
- Support Europe's global leadership in personalized 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-HCC-07-2020: Support for European eHealth Interoperability roadmap for deployment

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

Scope: Considering and building on outcomes of related activities and projects²⁷⁹, the focus is to support deployment and monitoring of eHealth interoperability meaning real life interoperable digital platforms and solutions for use by citizens, researchers, health services and the workforce across borders in the EU Digital Single Market. The support should comprise a coherent package of activities that will improve the deployment of interoperable eHealth solutions and platforms, with a significant number of citizens in several Member States accessing and providing their own health data in platforms. The deployment should consider interoperability of (electronic) Health Records across national borders, the empowered European citizen, compliance with the General Data Protection Regulation²⁸⁰, the Network and Information Systems Directive²⁸¹ and the operation in a European digital single market. The deployment should build on the Commission Recommendation on the European EHR exchange format²⁸² and be guided by strong and systemic contributions for better data and better computational approaches to advance disease prevention and personalised medicine. Emphasis should be given to specific fields of high societal relevance and high prevalence. Omics type of information associated to the use and exchange of health datasets

²⁷⁹ E.g. from the H2020 topics PHC 34 – 2014, HCO-14-2016, HCO-15-2016, SC1-DTH-08-2018

²⁸⁰ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation): <http://eur-lex.europa.eu/eli/reg/2016/679/oj>

²⁸¹ Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union: <http://eur-lex.europa.eu/eli/dir/2016/1148/oj>

²⁸² <https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format>

should be strongly considered with special regard to analysis and corresponding further health-related data. Relevant activities of the eHealth Network²⁸³ should be taken into account. For all relevant data (e.g. from hospitals, doctors or user-generated) ethics and legal issues should be considered appropriately.

For grants awarded under this topic, beneficiaries may provide support to third parties as described in General Annex K of the Work Programme either in form of grants or prizes. The respective options of Article 15 of the Model Grant Agreement will be applied.

The Commission considers that proposals requesting a contribution from the EU of up to EUR 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: The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

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

Type of Action: Coordination and support action

²⁸³ https://ec.europa.eu/health/ehealth/policy/network_en

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

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

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

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

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

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

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

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

Financial support for upscaling measures and large-scale deployment should be considered in the tasks to be defined for the Coordination and Support Action. These should include

twinning programmes²⁸⁴ and capacity building for local and regional authorities. This action should create a clear and coherent set of recommendations or guidelines for public health authorities in Europe together with a strategy to support their implementation. Proposals are also expected to set up a cooperation mechanism facilitating regular exchanges between the demand (both public and private procurers) and supply (including SMEs and start-ups) sides to identify the difficulties innovators may experience in scaling up solutions across borders in the EU and define measures to improve cross-border deployment of these solutions.

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

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

For grants awarded under this topic, beneficiaries may provide support to third parties as described in General Annex K of the Work Programme either in form of grants or prizes. The respective options of Article 15 of the Model Grant Agreement will be applied.

The Commission considers that proposals requesting a contribution from the EU of up 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: The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

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

Type of Action: Coordination and support action

²⁸⁴ Twinning activities such as under the European Innovation Partnership on Active and Healthy Ageing (EIP AHA).

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

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

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

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

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

Scope: The aim is to support the coordination of a registry of relevant existing e-Health solutions describing their services and potential for low and lower middle income African countries²⁸⁵ or regions together with a roadmap and strategic implementation plans building on the requirements of end-user communities and policy makers in the target countries. The action should take into account national and regional policies and (best) practices regarding health and care services and health infrastructures and also include lessons learned from existing eHealth policies and programmes at all levels of the health system. It should take into account the new Africa-Europa Alliance for Sustainable investment and Jobs²⁸⁶ as relevant.

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

²⁸⁵ Low and lower middle income countries as defined by the World Bank in September 2016 (<https://datahelpdesk.worldbank.org/knowledgebase/articles/906519>):

Low income countries: Benin, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Eritrea, Gambia, Guinea (Conakry), Guinea (Bissau), Madagascar, Malawi, Mali, Mozambique, Niger, Rwanda, Senegal, Sierra Leone, Somalia, South Sudan, Tanzania, Togo, Uganda, Zimbabwe

Lower middle income countries: Angola, Cabo Verde, Cameroon, Congo (Brazzaville), Cote d'Ivoire, Djibouti, Egypt, Ghana, Kenya, Lesotho, Mauritania, Mauritius, Morocco, Nigeria, Sao Tome and Principe, Sudan, eSwatini (Swaziland), Tunisia, Zambia

²⁸⁶ <https://www.africa-eu-partnership.org/en/stay-informed/news/european-commission-unveils-new-africa-europe-alliance-sustainable-investment-and>

The action should make use of and contribute to standardisation²⁸⁷ as appropriate. Proposals should comply with and contribute to the development of the relevant legislation, in particular on ethics and data protection of health data. Socio-economic and gender issues should be addressed appropriately.

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

For grants awarded under this topic, beneficiaries may provide support to third parties as described in General Annex K of the Work Programme either in form of grants or prizes. The respective options of Article 15 of the Model Grant Agreement will be applied.

The Commission considers that proposals requesting a contribution from the EU of between EUR 1.5 and 2 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. At least one consortium partner must come from low and lower middle income countries in Africa.

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

- Higher level of international cooperation and networking in eHealth programmes and policies between European countries or regions and low and middle income African countries, focusing on areas that are beneficial to the target countries / regions and their citizens in eHealth;
- Increased opportunities for e-health innovators, patients, medical staff and health system stakeholders in Europe and Africa;
- Better accessibility of eHealth Services.

Type of Action: Coordination and support action

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):²⁸⁸

²⁸⁷ refer to DG DEVCO Staff Working Document on Digitalisation for Development (Council regulation November 2017) and the relevant WHO guidelines on eHealth

²⁸⁸ The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.

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Topics (Type of Action)	Budgets (EUR million)			Deadlines
	2018	2019	2020	
Opening: 07 Nov 2017				
SC1-DTH-03-2018 (RIA)	25.00			25 Apr 2018
SC1-DTH-07-2018 (RIA)	35.00			
SC1-DTH-08-2018 (RIA)	30.00			
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)	4.00			
Opening: 26 Jul 2018				
SC1-DTH-10-2019-2020 (PCP)		22.00		14 Nov 2018
Opening: 16 Oct 2018				
SC1-DTH-01-2019 (RIA)		35.00		24 Apr 2019
SC1-DTH-05-2019 (PPI)		10.00		
SC1-DTH-09-2019 (IA)		19.00		
SC1-DTH-11-2019 (IA)		20.00		
SC1-HCC-02-2019 (CSA)		1.50		
Opening: 09 Jul 2019				
SC1-HCC-06-2020 (CSA)			4.00	13 Nov 2019
SC1-HCC-07-2020 (CSA)			3.00	
Opening: 19 Nov 2019				
SC1-DTH-02-2020 (RIA)			32.00	22 Apr 2020
SC1-DTH-04-2020 (RIA)			8.00	

The Director-General responsible may delay the deadline(s) by up to two months.

All deadlines are at 17.00.00 Brussels local time.

The budget amounts for the 2020 budget are subject to the availability of the appropriations provided for in the draft budget for 2020 after the adoption of the budget 2020 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

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SC1-DTH-06-2020 (RIA)			32.00	
SC1-DTH-14-2020 (PCP)			9.00	
SC1-HCC-08-2020 (CSA)			2.00	
SC1-HCC-09-2020 (CSA)			2.00	
Overall indicative budget	100.00	107.50	92.00	

In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects supported under the following topics: SC1-DTH-01-2019, SC1-DTH-02-2020, SC1-DTH-03-2018, SC1-DTH-05-2019, SC1-DTH-06-2020, SC1-DTH-07-2018, SC1-DTH-08-2018, SC1-DTH-09-2019, SC1-DTH-10-2019-2020, SC1-DTH-11-2019, SC1-DTH-14-2020, SC1-HCC-01-2018, SC1-HCC-02-2019, SC1-HCC-03-2018, SC1-HCC-04-2018, SC1-HCC-05-2018, SC1-HCC-06-2020.

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- 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. The following exceptions apply:

SC1-HCC-03-2018	Due to the specific objectives of the call, in addition to the minimum number of participants as set out in the Rules of Participation, proposals shall include at least one participant from the country or region targeted by the action 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.
SC1-DTH-04-2020	Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes,

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	proposals shall include at least one organisation as partner in the consortium from Japan ²⁸⁹ or Canada ²⁹⁰
SC1-HCC-09-2020	<p>Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals submitted to SC1-HCC-09-2020 shall include at least one partner from low or lower middle income countries in Africa.</p> <p>Low income countries: Benin, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Eritrea, Gambia, Guinea (Conakry), Guinea (Bissau), Madagascar, Malawi, Mali, Mozambique, Niger, Rwanda, Senegal, Sierra Leone, Somalia, South Sudan, Tanzania, Togo, Uganda, Zimbabwe</p> <p>Lower middle income countries: Angola, Cabo Verde, Cameroon, Congo (Brazzaville), Cote d'Ivoire, Djibouti, Egypt, Ghana, Kenya, Lesotho, Mauritania, Mauritius, Morocco, Nigeria, Sao Tome and Principe, Sudan, eSwatini (Swaziland), Tunisia, Zambia</p>

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

SC1-DTH-01-2019, SC1-DTH-02-2020, SC1-DTH-04-2020, SC1-DTH-06-2020	The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
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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](#) published on the Funding & Tenders Portal.

Grant Conditions:

SC1-DTH-10-2019-2020, SC1-DTH-14-	The funding rate for PCP actions is limited to 90% of the total eligible costs to leverage co-financing from the procurers in this
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²⁸⁹ Funding is expected to be made available in Japan by the Ministry of Internal Affairs and Communication (MIC) and/or the National Institute of Information and Communications Technology (NICT).

²⁹⁰ Funding is expected to be made available in Canada by the Canadian Institutes of Health Research (CIHR)

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2020	specific case.
SC1-DTH-05-2019	The funding rate for PPI actions is limited to 35% of the total eligible costs to leverage co-financing from the procurers in this specific case.
SC1-HCC-06-2020, SC1-HCC-07-2020, SC1-HCC-08-2020, SC1-HCC-09-2020	For grants awarded under this topic [for <i>[insert name(s) of type(s) of action</i> beneficiaries may provide support to third parties as described in part K of the General Annexes of the Work Programme either in form of grants or prizes. The respective options of Article 15 of the Model Grant Agreement will be applied.

Consortium agreement:

SC1-DTH-01-2019, SC1-DTH-02-2020, SC1-DTH-03-2018, SC1-DTH-04-2020, SC1-DTH-05-2019, SC1-DTH-06-2020, SC1-DTH-07-2018, SC1-DTH-08-2018, SC1-DTH-09-2019, SC1-DTH-10-2019- 2020, SC1-DTH-11- 2019, SC1-DTH-14- 2020, SC1-HCC-01- 2018, SC1-HCC-02- 2019, SC1-HCC-03- 2018, SC1-HCC-04- 2018, SC1-HCC-05- 2018, SC1-HCC-06- 2020, SC1-HCC-07- 2020, SC1-HCC-08- 2020, SC1-HCC-09- 2020	Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.
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Call - Trusted digital solutions and Cybersecurity in Health and Care

H2020-SCI-FA-DTS-2018-2020

This call aims at multidisciplinary technologies and solutions in health and care with a focus on Artificial Intelligence, High Performance Computing and 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'. In addition to the topics published in the Societal Challenge 1 part of the H2020 Work Programme, an action on AI for the smart hospital of the future (topic DT-ICT-12-2020) is supported.

Focus Area on Digitising and transforming European industry and services

Platforms and Pilots²⁹¹

The Digitising European Industry initiative includes the launch of a set of initiatives supporting the building of the digital industrial platforms of the future²⁹². European industry needs to come to agreements on functions and interfaces for those platforms, reference architectures and interaction protocols that have the potential to create markets and market opportunities leading to ecosystems and standards.

Proposals are expected to make a significant step forward in platform building, interoperability between existing platforms, integration of relevant digital technologies such as IoT, AI, photonics, robotics, cloud and Big Data, and validation via pilots and experimentation facilities. Starting from suitable reference architectures, platform interfaces are defined, tested via piloting, supported via ecosystem building to prepare their roll-out, and evolved into standards.

Various platform development activities exist at EU or national level, e.g. the Reference Architectural Model Industrie 4.0 (RAMI 4.0) and the Industrial Data Space. To develop the next-generation digital platforms, proposals need to bring various initiatives together and act as linking pins. Proposals should build on existing platforms, pilot sites, testbeds, and

²⁹¹ In the Societal Challenge 1 Work Programme 2018-2020 only the topic DT-TDS-01-2019 is related to the Platforms and Pilots call. The topics DT-TDS-04-2020 and DT-TDS-05-2020 are not related to the Platforms and Pilots call. Therefore, the text specified for Platforms and Pilots is not relevant for DT-TDS-04-2020 and DT-TDS-05-2020.

²⁹² COM(2016) 180 final, 19 April 2016

experimental environments that have been developed in these various initiatives when applicable²⁹³.

Proposals need to address all of the following four activities, namely platform building, large-scale piloting, ecosystem building, and standardisation.

In platform building, proposals need to develop next-generation digital platforms, which build on the state-of-the-art, reuse what is available, and integrate different technologies, such as IoT, AI, robotics, cloud and Big Data. Platforms should aim at openness and interoperability between platforms to avoid lock-in, preventing dominant positions of individual players, and comply with standards and regulation. Proposals need to target solutions for SMEs and mid-caps, taking into account interoperability with emerging and future solutions. This may require the mapping of reference architecture models for integrating existing sectorial platforms. The interfaces of the platform need to be described via open specifications and reference implementations need to be developed. A major aim is to offer platform functionalities that can be generically reused in multiple contexts to support various types of applications and services.

In large-scale piloting, pilots are set up that make use of the digital platforms, develop prototype applications on top of the platforms, and validate the platforms in both reduced, controlled environments and in real-life use cases. Pilots may adapt platforms to specific application needs and validate their relevance for such needs, in order to foster take-up and large scale deployment. The pilots should cover innovative application scenarios with high socio-economic impact. Demonstration of cooperation between large-scale pilots in different domains and combination of services from different sectors/domains are welcome. The key need is to deliver interoperable solutions that provide an experience that customers or businesses require, to test them in complex regulatory environments, and to give guidance for secure and safe implementation.

In ecosystem building, the take-up of digital platforms is fostered by expanding the ecosystem of players involved and through opportunities for entrepreneurs by promoting new market openings allowing also smaller and newer players to capture value. For instance, small and innovative ICT players can develop services/applications with a clear societal and economic value, on top of the digital platforms. Moreover, additional small-scale pilots can be conducted by SMEs, validating the digital platforms and prototype applications. Experiments running on top of the pilots, under specific scenarios, will allow for the validation and acceptance by any actors in the ecosystem and users in particular.

In standardisation, contributions should be made to suitable standardisation bodies or pre-normative activities, as outlined in the Communication on Priorities of ICT Standardisation for the Digital Single Market²⁹⁴.

²⁹³ Relevant ongoing initiatives at EU level include the set of Large Scale Pilots called for under the Internet of Things Focus Area in 2016 (IoT-01-2016) and the Factories of the Future projects under FoF-11-2016.

²⁹⁴ COM(2016) 176 final, 19 April 2016

Projects for grants awarded under topics DT-ICT-07-2018-2019, DT-ICT-08-2019, DT-ICT-09-2020, DT-ICT-10-2019, DT-ICT-11-2019, DT-ICT-12-2020 (located in the 'Information and Communication Technologies' part of the Work Programme) and DT-TDS-01-2019 (located in the SC1-Health, demographic change and wellbeing part of the Work programme) should support a critical mass of large-scale piloting and ecosystem building activities. For these grants, beneficiaries may strengthen these activities by providing financial support to third parties in line with the conditions set out in General Annex K of the Work Programme. Consortia need to define the selection process of organisations, for which financial support will be granted (typically in the order of EUR 50 000 – 150 000 per third party²⁹⁵). Maximum 20% of the EU funding can be allocated to this purpose. The financial support to third parties can only be provided in the form of grants. The respective options of Article 15.1 and Article 15.3 of the Model Grant Agreement will be applied.

Proposals should contain an outline business case and industrial exploitation strategy. They also need to define clear business models and justify how the results support those business models.

Expected Impact

Projects are expected to have a high impact on citizens, industry, businesses or public services. In particular:

- Increased prospects for future digital industrial platforms by validation of technological choices, sustainability and reproducibility, of architecture models, standards, and interoperability, as well as of verification of non-functional characteristics such as security and privacy.
- Strengthened links with other, bottom-up programmes and initiatives, supported by regional, national and European policies and funds.
- Increased number of services and applications operated by European companies, especially small businesses and entrepreneurs.
- Significant and measureable contribution to standards or pre-normative activities.
- Increased number of platforms, applications, business processes and innovative business models validated via large-scale piloting.
- Emergence of sustainable ecosystems around digital platforms.

Proposals should describe how the proposed work will contribute to the impact criteria above, in addition to the expected impacts under the specific topic addressed, and provide KPIs, the baseline and targets to measure impact.

Proposals are invited against the following topic(s):

²⁹⁵ In line with Article 23 (7) of the Rules for Participation the amounts referred to in Article 137 of the Financial Regulation may be exceeded when this is necessary to achieve the objectives of the action.

DT-TDS-01-2019: Smart and healthy living at home

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.

Pilots in the selected areas should clearly cover the supply and demand sides. For further expanding with other users, developers of additional applications, replication of the pilot through new sites, and complementary assessment of the acceptability of the use cases where appropriate, the actions in this topic may involve financial support to third parties as outlined in the chapeau 'Platforms and Pilots'.

A clear methodology and impact indicators for socio-economic impact assessment from using the platform should be included, where possible using the MAFEIP²⁹⁶ 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. Regulatory aspects and legal aspects of data ownership should be addressed. Relevant ethics and gender issues should be taken into account.

Proposals should address one of the two following areas:

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

²⁹⁶ See www.mafeip.eu

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.

2. 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.

For this topic, the four activities and impact criteria described in the chapeau 'Platforms and Pilots' have to be applied. Pilot projects are expected to contribute to the consolidation and coherence work that will be implemented by the CSA supporting the activities defined under "DT-ICT-13-2019: Digital Platforms/Pilots Horizontal Activities". This requires that they contribute to clustering their results of horizontal nature (interoperability approach, standards, security and privacy approaches, business validation and sustainability, methodologies, metrics, etc.).

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. At least one proposal should be funded for each of the above-mentioned areas

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;
- Demonstrate links and build synergies with Member States' and regional initiatives in this area;
- Improved and evidence-based efficiency of health and care systems with demonstrated added-value of 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, and trust in connected data spaces.

Type of Action: Innovation action

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

Proposals are invited against the following topic(s):

DT-TDS-04-2020: AI for Genomics and Personalised Medicine

Specific Challenge: Several national and regional initiatives already support the pooling of genomic and other health data to advance research and personalised medicine. The next step is to make use of the existing infrastructures and initiatives for the successful exploitation of genomic data to facilitate personalised medicine.

The challenge is to demonstrate the potential and benefits of AI technologies for identifying new knowledge, support clinical research and decision making by linking Europe's relevant genomic repositories, while ensuring full compliance with data protection legislation and ethical principles.

Scope: Proposals should demonstrate the potential and benefits of AI technologies for advancing research and personalised medicine through the linking of relevant genomics data and repositories, according to adequate organisational, regulatory, security, ethical and technical requirements.

Proposals should develop and test AI solutions for linking genomics repositories across the EU, including banks of "-omics" and health related data, biobanks and other registries (including e.g. rare disease registries), with the view of supporting clinical research and decision making. By combining sequenced genomic data and other medical data, physicians and researchers can understand better diseases at a personal level and can determine the most appropriate treatment for a particular person. The focus should be to reduce the burden of diseases for which a treatment exists and to apply such treatments in a more targeted way, to identify new evidences on the predictive value of the AI solutions and to enhance the diagnostic capacity e.g. for rare or low prevalence and complex diseases.

Proposals should demonstrate a potential to build a large-scale distributed repository of relevant genomic data and other -omics and medical data that will enable to advance validation of the new clinically impactful insights supported through AI solutions. Proposals should ensure compliance with the relevant privacy, cybersecurity, ethical and legal rules. Sex and gender aspects should be considered appropriately. The European Open Science Cloud Initiative (EOSC) may facilitate the access of researchers to the newest data managing technologies, High Performance Computing facilities to process and analyse data and to a European Open Science Cloud list of ICT services while ensuring the appropriate data safety and protection. Proposals should address technical specifications and standards for the secure access and exchange of cross-border genomic and other health data, and collaborate with actions selected under the topic SC1-HCC-06-2020 as relevant for achieving progress towards the expected impacts.

The Commission considers that proposals requesting from the EU up to EUR 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: The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

- Supporting the development and testing of AI technologies on genomics and other linked –omics and health data repositories for identifying new knowledge, support clinical research and decision making, leading to more reliable and meaningful outcomes for advancing research and personalised medicine.
- Promoting the sharing of data and infrastructure for prevention and personalised medicine research, concretely a European network on genomics, seeking to link it with ongoing '-omics' and human cell mapping initiatives.
- Effectiveness of AI technologies for genomics and personalised medicine.
- Measuring patient-based value healthcare outcomes for impact assessment on how genomics, personalised medicine and patient outcomes can help to implement value-based healthcare in Europe.
- Contributing to developing technical specifications for secure access and cross-border exchange of genomic and other –omics and health datasets in Europe for research purposes.
- Facilitating interoperability of relevant registries (including e.g. rare disease registries) and databases in support of genomics and personalised medicine research.
- Supporting the pooling of health data and resources across the EU, and demonstrate the benefits for advancing research, disease prevention and personalised medicine.
- Contributing to standards for genomic data generation, analysis, privacy and sharing of genomic and associated clinical and other phenotype data, including self-reported data, data from wearables, omics, and imaging.
- Contributing to the European Cloud Initiative, notably by providing open, reusable data for prevention, genomics and personalised medicine research.
- Increasing the trust of users (healthcare professionals and patients) and other stakeholders on AI solutions to process and link genomics data with other –omics and health related data for better decision-making and value-based patient health outcomes.

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.

DT-TDS-05-2020: AI for Health Imaging

Specific Challenge: Artificial Intelligence (AI) offers substantial opportunities for healthcare, supporting better diagnosis, treatment, prevention and personalised care. Analysis of health images is one of the most promising fields for applying AI in healthcare, contributing to better prediction, diagnosis and treatment of diseases. In order to develop and test reliable AI applications in the field, access to large-volume of high- quality data is needed.

Scope: This action should contribute to testing and developing AI tools and analytics focused on the prevention, prediction and treatment of the most common forms of cancer while providing solutions to securely share health images across Europe.

Proposals should set up and contribute to populate a large interoperable repository of health images, enabling the development, testing and validation of AI-based health imaging solutions to improve diagnosis, disease prediction and follow-up of the most common forms of cancer²⁹⁷.

The repository should include high quality, interoperable, anonymised or pseudo-anonymised data sets of annotated cases, based on data donorship, and should comply with relevant ethics, security requirements and data protection legislation. Gender aspects should be considered appropriately. It should ensure data quality and interoperability based on common standards and open Application Programming Interfaces (APIs).

Proposers should specify measures for validating AI-based solutions for health images, such as the effectiveness of clinical decision making. There should be rigorous, peer-reviewed scientific evidence establishing their safety, validity, reproducibility, usability, reliability and usefulness for better health outcomes. It is critical to show how AI-based solutions will deal with and inform about possible failures, inaccuracies and errors. Adequate performance metrics, monitoring and evaluation criteria and procedures should be put in place. The reasoning behind AI-based conclusions and recommendations should be explained so that users can understand their situation and be able to consent or challenge any proposed course of action.

The consortium should build on relevant national and EU activities and bring together: 1) expertise to set up the infrastructure, ensuring the appropriate sharing of data quality and interoperability, 2) AI developers/expertise to experiment its content while ensuring compliance with relevant legislations

The Commission considers that proposals requesting from the EUR 8 -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: The proposal should provide appropriate indicators to measure its progress and specific impact in the following areas:

²⁹⁷ As reported by the World Health Organisation, see for example <https://www.who.int/news-room/factsheets/detail/cancer>

- Contributing towards the creation of a EU-wide repository of health images dedicated to the most common forms of cancer, enabling experimentation of AI-based solutions to improve diagnosis, treatment and follow-up and contribute to a more precise and personalised management of cancer.
- Contributing to developing technical, organisational and ethical standards for AI for health imaging
- Promoting access to anonymised health image data sets to be made more openly reusable across the EU for training AI applications.
- Increasing trust in AI solutions among users (healthcare professionals and patients), investors and stakeholders at industry and academia.

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.

Focus Area on Boosting the effectiveness of the Security Union

Proposals are invited against the following topic(s):

SU-TDS-02-2018: Toolkit for assessing and reducing cyber risks in hospitals and care centres to protect privacy/data/infrastructures

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 including hardware with embedded software, such as e.g. pacemakers, ...); solutions addressing the need for cybersecurity certification of products/devices and services in the health and care domain; 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.

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.

Proposals under this topic may be subject to security scrutiny if they could potentially lead to security-sensitive results that should be classified (see guide for classification).

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

- Improved security of Health and Care services, data and infrastructures;
- Less risk of data privacy breaches caused by cyberattacks;
- 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-03-2018: Raising awareness and developing training schemes on cybersecurity in hospitals

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. This may include proactive managerial and technological strategies to reduce vulnerabilities e.g. best practices to minimize the potential for becoming a victim of phishing and ransomware or strategies to respond to attacks,.... 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.

The Commission considers that proposals requesting a contribution from the EU of up to EUR 1 million would allow this specific challenge to be addressed appropriately.

Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Proposals under this topic may be subject to security scrutiny if they could potentially lead to security-sensitive results that should be classified (see guide for classification).

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

- Less human errors causing cybersecurity threats;
- Less risk of data privacy breaches;
- Reduced cybersecurity vulnerability of Health and Care services, data and infrastructures;
- Increased patient trust and safety.

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).²⁹⁸

Topics (Type of Action)	Budgets (EUR million)			Deadlines
	2018	2019	2020	
Opening: 07 Nov 2017				
SU-TDS-02-2018 (RIA)	35.00			25 Apr 2018
SU-TDS-03-2018 (CSA)	1.00			
Opening: 26 Jul 2018				
DT-TDS-01-2019 (IA)		60.00 ²⁹⁹		14 Nov 2018
Opening: 09 Jul 2019				

²⁹⁸ The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.

The Director-General responsible may delay the deadline(s) by up to two months.

All deadlines are at 17.00.00 Brussels local time.

The budget amounts for the 2020 budget are subject to the availability of the appropriations provided for in the draft budget for 2020 after the adoption of the budget 2020 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

²⁹⁹ of which EUR 25.00 million from the 'Information and Communication Technologies' WP part.

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DT-TDS-05-2020 (RIA)			35.00	13 Nov 2019
Opening: 19 Nov 2019				
DT-TDS-04-2020 (RIA)			35.00	22 Apr 2020
Overall indicative budget	36.00	60.00	70.00	

In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects supported under the following topics: DT-TDS-04-2020, DT-TDS-05-2020.

These topics will contribute to the Focus Areas on 'Digitising and transforming European industry and services': DT-TDS-01-2019, DT-TDS-04-2020, DT-TDS-05-2020.

Indicative timetable for evaluation and grant agreement signature:

For single stage procedure:

- Information on the outcome of the evaluation: Maximum 5 months from the final date for submission; and
- 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. The following exceptions apply:

DT-TDS-04-2020, DT-TDS-05-2020	The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
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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](#) published on the Funding & Tenders Portal.

Grant Conditions:

DT-TDS-01-2019	For grants awarded under this topic, Innovation Action beneficiaries may provide support to third parties as described in General Annex K of the Work Programme . The support to third
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	parties can only be provided in the form of grants. The respective options of Article 15.1 and Article 15.3 of the Model Grant Agreement will be applied.
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Consortium agreement:

DT-TDS-01-2019, DT-TDS-04-2020, DT-TDS-05-2020, SU-TDS-02-2018, SU-TDS-03-2018	Members of consortium are required to conclude a consortium agreement, in principle prior to the signature of the grant agreement.
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SME instrument & Fast-Track-to-Innovation

The respective calls for the EIC-SME instrument (H2020-EIC-SMEInst-2018-2020) and EIC-Fast-Track-to-Innovation (H2020-EIC-FTI-2018-2020) are found under the Horizon 2020 Work Programme Part – *Towards the next EU Framework Programme for Research and Innovation: European Innovation Council (EIC) Pilot* (part 17 of this work programme).

Other actions³⁰⁰

1. Subscription fee: Human Frontier Science Programme Organisation

An annual subscription to the international Human Frontier Science Programme Organisation (HFSP³⁰¹) 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 cooperation³⁰² in research and innovation.

Type of Action: Subscription

Indicative timetable: 2018, 2019 and 2020

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) and EUR 5.30 million from the 2020 budget

2. Studies, activities of the Scientific Panel for Health, support to the Horizon Europe Cancer Mission board, conferences, events and outreach activities

A number of specific contracts will be signed under existing framework contracts in order: (i) to support activities of the Scientific Panel for Health³⁰³; (ii) to support the dissemination and exploitation of project results; (iii) to contribute to the definition of future challenge priorities; (iv) to prepare guidelines on the analytical use cases of real world data (RWD) for healthcare, (v) to carry out preparatory activities for the Horizon Europe Mission on Cancer, including scientific, administrative and logistical support as well as support to the citizen engagement process, (vi) to carry out an evaluation of the EU AMR (AntiMicrobial Resistance) research strategy and (vii) 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

³⁰⁰ The budget amounts for the 2020 budget are subject to the availability of the appropriations provided for in the draft budget for 2020 after the adoption of the budget 2020 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

³⁰¹ The European Union is a member of the HFSP Organisation (HFSP³⁰¹) and has funded HFSP under previous Framework Programmes

³⁰² COM(2012)497

³⁰³ The Scientific Panel for Health is mandated by Regulation (EU) No 1291/2013 establishing Horizon 2020

Indicative timetable: Some 10 contracts expected for 2018 (indicative), 10 contracts for 2019 (indicative) and 10 contracts for 2020 (indicative)

Indicative budget: EUR 3.50 million from the 2018 budget and EUR 3.50 million from the 2019 budget and EUR 3.00 million from the 2020 budget

3. External expertise

This action will support the use of appointed independent experts for the monitoring of actions (grant agreement, grant decision, procurements, financial instruments), for ethics checks, and for the evaluation of the EDCTP2 annual work plans. A special allowance of EUR 450/day will be paid to the expert appointed in his/her personal capacity who acts independently and in the public interest.

Type of Action: Expert Contracts

Indicative timetable: 2018, 2019 and 2020

Indicative budget: EUR 3.50 million from the 2018 budget and EUR 3.50 million from the 2019 budget and EUR 3.00 million from the 2020 budget

4. Grant to the Global Alliance for Chronic Diseases³⁰⁴

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 cooperation³⁰⁵ in research and innovation.

Legal entities:

GACD Action, Gibbs Building, 215 Euston Road, London NW1 2BE, United Kingdom

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

Indicative timetable: Second quarter 2018

Indicative budget: EUR 0.24 million from the 2018 budget

³⁰⁴ This grant will be awarded without call for proposals in line with Article 190(1)(e) of the Rules of applications of Regulation (EU, Euratom) 966/2012, Regulation No 1268/2012 and Article 11(2) of the Rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)", Regulation (EU) No 1290/2013

³⁰⁵ COM(2012)497

5. Commission expert group for the impact assessment of the planned Commission communication on infectious diseases

An expert group will be established to perform an impact assessment for the preparation of the planned Commission communication on infectious diseases ('countering the threat from emerging and re-emerging infectious diseases: towards the establishment of the European Biomedical Outbreak Research initiative').

A special allowance of EUR 450/day will be paid to the experts appointed in their personal capacity who act independently and in the public interest for each full working day spent assisting the Commission, in terms of Article 21 of Decision C(2016)3301. This amount is considered to be proportionate to the specific tasks to be assigned to the experts, including the number of meetings to be attended and possible preparatory work. The group will consist of highly qualified, specialised, and independent experts selected on the basis of objective criteria, following an open call for expression of interest.

Type of Action: Expert Contracts

Indicative timetable: 2018

Indicative budget: EUR 0.17 million from the 2018 budget

6. Mobilisation of research funds in case of Public Health Emergencies³⁰⁶

In case of a public health emergency (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) and in particular, as part of the EU response to the COVID-19 pandemic, in accordance with Article 195(b) of the Financial Regulation 2018/1046³⁰⁷, grants may be awarded without a call for proposals in exceptional and duly substantiated emergencies. At that time, the Funding & Tenders Portal will open a dedicated section where research applications can be received. This will be communicated to the National Contact Points. The invitation to apply for funding may also be limited to targeted entities for activities (such as clinical trials) specifically linked to COVID-19. Entities will be targeted taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances ("extreme urgency" due the COVID-19 pandemic).

Additional funding may also be awarded in ongoing grant agreements to cover additional activities specifically linked to COVID-19, without a call for proposals according to the Financial Regulation 2018/1046, Article 195(b). These activities relate to the implementation for the "ERAvsCorona" action plan, supported by Member States, and aim to develop large, EU-wide COVID-19 clinical trials, or to support other related actions in the plan. Providing such additional funding to ongoing grants that can support pertinent short- and mid-term

³⁰⁶ Should there be no Public Health Emergency in 2018, 2019 or 2020, the indicative budget may be re-allocated to the action 'InnovFin Infectious Diseases' or to the Call H2020-SC1-BHC-2018-2020.

³⁰⁷ Article 195 (b) of the Financial Regulation 2018/1046 "Grants may be awarded without a call for proposals only in the following cases: [...] (b) in other exceptional and duly substantiated emergencies;

research efforts to confront the COVID-19 crisis will allow us to address the current situation with the appropriate urgency.

Beneficiaries in grants awarded under actions relating to Public Health Emergencies must make available their research data, at the latest within 30 days after it has been generated, through open access or, if agreed by the Commission, by giving access rights to those third parties that need the research data to address the public health emergency. Therefore, the relevant option of Article 29.3 will be applied. It is expected that quality-controlled data are shared in accordance with the FAIR³⁰⁸ principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

The standard eligibility and admissibility criteria, evaluation criteria, thresholds, weighting for award criteria, maximum rate of co-financing and conditions for providing financial support to third parties, are provided in the General Annexes.

Specific derogations and additional conditions may be announced or directly communicated to the potential applicants and to the beneficiaries which would like to receive additional funding to the grant agreements. Such conditions will include additional exploitation obligations to ensure that the resulting products will be available and accessible as soon as possible including an obligation to license on a non-exclusive basis and at fair and reasonable conditions, additional dissemination obligations and the right of the Commission to object to the transfer or licensing of the results. It may also include justified derogations from the standard limits to financial support to third parties. Where applicable, the relevant grant agreement options will be applied.

Type of Action: CSA, RIA and IA- Grants awarded without a Call for Proposals (Article 195 (b) of the Financial Regulation)

Indicative timetable: Will depend of the Public Health Emergency

Indicative budget: EUR 10.00 million from the 2018 budget and EUR 10.00 million from the 2019 budget and EUR 219.50 million from the 2020 budget

7. InnovFin Infectious Diseases (InnovFin ID)³⁰⁹

Infectious diseases (ID) are a major global threat to health. ID R&D is hampered by a funding gap and a lack of investment by industry. In addition, many existing ID treatments and vaccines are jeopardised by the emergence of antimicrobial resistance, which threatens the effective prevention and treatment of an ever-increasing range of infections. Combating ID is a public health priority for the EU.

InnovFin Infectious Diseases aims to finance pre-commercial stage investments in the field of ID, i.e. the project produces innovative vaccines, drugs, medical and diagnostic devices or novel research infrastructures for combatting infectious diseases. Projects developing

³⁰⁸ <https://www.force11.org/group/fairgroup/fairprinciples>

³⁰⁹ The indicative budget complements the allocation in 2018, 2019 and 2020 from the Part on Access to risk finance

innovative vaccines, drugs, medical and diagnostic devices must have gone successfully through the preclinical stage and preferably through early stage clinical development and now require clinical validation or be ready for later stage clinical trials in order to be eligible for InnovFin ID. Projects on research infrastructures must refer to facilities, resources and related services to be used by the scientific community to conduct top-level research and must be novel e.g. not replicate what already exists, in order to be eligible for InnovFin ID. The InnovFin ID Operation must have proven public health impact and potentially have market prospects. It will make loans of between EUR 7.5 million and EUR 75 million to SMEs, midcaps, special project vehicles, research institutions and other legal entities for the purposes of corporate or project finance, and to large pharmaceutical companies for financing the development of pre-identified medical products on a risk-sharing basis. Other forms of finance may also be possible. Projects and/or the IP development (such as clinical trials) can be undertaken outside the EU or Associated Countries.

Expected impact: InnovFin Infectious Diseases will help in:

- increasing EU investments in ID research;
- de-risking investments and hence encouraging industry, in particular, to invest more heavily in this area;
- preparing for further roll-out to the market of new drugs, vaccines, diagnostics and medical technologies to combat ID;
- fostering the healthcare sector and hence creating jobs and growth in the EU.

Selection procedure: EIB checks the financial viability of each potential financing operation, while DG Research & Innovation, assisted by other Commission DGs, approves each operation against eligibility criteria set for the pilot. Eligible projects will be financed on a first-come, first served basis.

Type of Action: Financial Instrument

Indicative timetable: Third quarter of 2018, 2019 and 2020

Indicative budget: EUR 30.00 million from the 2018 budget and EUR 10.00 million from the 2019 budget and EUR 20.00 million from the 2020 budget

8. Grant to the Coalition for Epidemic Preparedness Innovations (CEPI)³¹⁰

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international non-profit association established under Norwegian Law. It was founded by the Governments of Norway, Germany, Japan, India, the Bill & Melinda Gates Foundation (BMGF) and the Wellcome Trust, and launched during the World Economic Forum in Davos 2017. Its

³¹⁰ This grant will be awarded without call for proposals in line with Article 190(1)(e) of the Rules of applications of Regulation (EU, Euratom) 966/2012, Regulation No 1268/2012 and Article 11(2) of the Rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)", Regulation (EU) No 1290/2013

objective is to finance and coordinate the development of new medical countermeasures to prevent and contain infectious disease epidemics, which are of particular concern to low-income countries. The H2020 funding will be used to enhance and expand CEPI's activities. This action will also contribute to the implementation of the Union's strategy for international cooperation³¹¹ in research and innovation and the EU's development policy, in particular attention will be given to the constraints national health systems face in low and middle income countries.

This type of action differs from the ERA-NET Cofund and the EJP Cofund actions. Therefore, the conditions in General Annexes C and D, as well as the specific award criteria in General Annex H, do not apply.

In accordance with Article 9.3(c) of the Regulation (EU) 1290/2013 the minimum condition shall be the participation of one legal entity established in a Member State or associated country.

The main purpose of this action is to provide financial support to third parties through calls for proposals, in the forms of grants, in line with the following conditions in General Annex K³¹²:

- The proposal of the action must clearly detail the objectives and the results to be obtained and include at least the following elements:
 1. A fixed and exhaustive list of the different types of activities for which a third party may receive financial support;
 2. The definition of the persons or categories of persons which may receive financial support;
 3. The criteria for awarding financial support;
 4. The criteria for calculating the exact amount of the financial support;
 5. The maximum amount of financial support for each third party.
- Additionally, the following conditions have to be fulfilled:
 1. The open calls must be published widely and must adhere to Horizon 2020 standards with respect to transparency, equal treatment, conflict of interest and confidentiality;
 2. All calls for third parties must be published on the Horizon 2020 Participants Portal and on the EU grant beneficiary's own web site;
 3. The calls must remain open for at least two months; if call deadlines are changed this must immediately be published on the call page and all registered applicants must be informed of this change;

³¹¹ COM(2012)497

³¹² Due to specific character of the action other conditions of General Annex K do not apply

4. Without delay, the outcome of the call must be published, including a description of the third party action, the date of the award, duration, and the legal name and country.
 - The beneficiary of the EU grant must ensure that the recipients of the financial support allow the Commission, the European Anti-fraud Office (OLAF) and the Court of Auditors to exercise their powers of control on documents, information, even stored on electronic media, or on the final recipient's premises.

The respective options of Articles 13.1 and 13.3 of the Mono Partner Model Specific Agreement will be applied.

In accordance with Article 23(7) of the Regulation No 1290/2013, Article 137(1)(c) of the Financial Regulation No 966/2012, Article 210a of the Rules of Application Regulation No 1268/2012, the maximum amount that can be paid to a third party may exceed EUR 60 000 (since this financial support is the primary aim of the action and necessary to achieve its objectives).

Eligible costs: Only the costs of providing financial support to third parties are eligible (if they comply with the general conditions and the specific conditions set out in the grant agreement) and the following categories of costs are not eligible:

- Direct personnel costs;
- Direct costs of subcontracting;
- Other direct costs;
- Indirect costs.

Funding rate: The EU contribution will be limited to a maximum of 70% of the total eligible costs of the action and it will take the form of a grant consisting of reimbursement of the eligible costs related to the action, in accordance with the conditions set out in the grant agreement.

Grant proposals will be evaluated by experts, on the basis of the award criteria 'Excellence', 'Impact' and 'Quality and efficiency of the implementation', in line with the Article 15 of the Horizon 2020 Rules for Participation Regulation No 1290/2013. In particular the following aspects will be taken into account:

- Under the "Excellence" criterion:
 1. Clarity and pertinence of the objectives;
 2. Soundness of the concept, and credibility of the proposed methodology;
 3. Appropriate consideration of interdisciplinary approaches and, where relevant, use of stakeholder knowledge and gender dimension in research and innovation content;
- Under the "Impact" criterion:

The extent to which the outputs of the action would contribute to each of the following expected impacts:

1. To develop medical countermeasures against prioritised pathogens with epidemic potential;
2. To help to prevent and contain epidemics;
3. To support the Sustainable development goals 3.3³¹³, “to combat communicable diseases” and 3.B “to support the research and development of vaccines for the communicable diseases that primarily affect developing countries, and provide access to affordable essential vaccines”.

Quality of the proposed measures to:

1. Exploit and disseminate the action results, and to manage research data where relevant;
 2. To communicate the action activities to different target audiences.
- Under the "Quality and efficiency of the implementation" criterion:
 1. Quality and effectiveness of the work plan, including extent to which the resources assigned are in line with their objectives and deliverables;
 2. Appropriateness of the management structures and procedures, including risk and innovation management.

Model grant agreement: Mono-Partner Model Framework Partnership Agreement and Mono-Partner Model Specific Agreement

Legal entities:

Coalition for Epidemic Preparedness Innovations, Marcus Thranes gate 2, 0473 Oslo, Norway

Type of Action: Grant to identified beneficiary - Co-fund actions

Indicative timetable: Second quarter of 2019

Indicative budget: EUR 30.00 million from the 2019 budget

9. Grant to the Coalition for Epidemic Preparedness Innovations (CEPI)³¹⁴

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international non-profit association established under Norwegian Law. Its objective is to finance and coordinate the development of new medical countermeasures to prevent and contain infectious diseases that

³¹³ <https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals>

³¹⁴ This grant will be awarded without call for proposals in line with Article 189.1 and Article 195 (e) of the Financial Regulation 2018/1046 and Article 11(2) of the Rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)", Regulation (EU) No 1290/2013

have epidemic potential before they become global health emergencies. The Commission in 2019 entered into a Framework Partnership with CEPI, creating a co-fund through which H2020 funding will be used to enhance and expand CEPI's activities. Under this Framework Partnership, the current action will support additional CEPI activities towards the development of medical countermeasures against pathogens with epidemic potential, and in particular the SARS-COV-2 agent causing the COVID-19 pandemic. This action will also contribute to the implementation of the Union's strategy for international cooperation³¹⁵ in research and innovation and the EU's development policy, in particular attention will be given to the constraints national health systems face in low and middle income countries.

This type of action differs from the ERA-NET Cofund and the EJP Cofund actions. Therefore, the conditions in General Annexes C and D, as well as the specific award criteria in General Annex H, do not apply.

In accordance with Article 9.3(c) of the Regulation (EU) 1290/2013 the minimum condition shall be the participation of one legal entity established in a Member State or associated country.

The main purpose of this action is to provide financial support to third parties primarily through calls for proposals³¹⁶, in the forms of grants, in line with the following conditions in General Annex K³¹⁷:

The proposal of the action must clearly detail the objectives and the results to be obtained and include at least the following elements:

1. A fixed and exhaustive list of the different types of activities for which a third party may receive financial support;
2. The definition of the persons or categories of persons which may receive financial support;
3. The criteria for awarding financial support;
4. The criteria for calculating the exact amount of the financial support;
5. The maximum amount of financial support for each third party.

Additionally, the following conditions have to be fulfilled:

1. The open calls must be published widely and must adhere to Horizon 2020 standards with respect to transparency, equal treatment, conflict of interest and confidentiality;
2. All calls for third parties must be published on the Horizon 2020 Funding & Tenders Portal and on the EU grant beneficiary's own web site;

³¹⁵ COM(2012)497

³¹⁶ Exceptions to the principle of open calls for proposals must be duly justified with reference to exceptional circumstances, such as emergency or monopoly situations, and will be subject to the approval of the Commission services.

³¹⁷ Due to specific character of the action other conditions of General Annex K do not apply

3. The calls must remain open for at least two months³¹⁸; if call deadlines are changed this must immediately be published on the call page and all registered applicants must be informed of this change;

4. Without delay, the outcome of the call must be published, including a description of the third party action, the date of the award, duration, and the legal name and country.

The beneficiary of the EU grant must ensure that the recipients of the financial support allow the Commission, the European Anti-fraud Office (OLAF) and the Court of Auditors to exercise their powers of control on documents, information, even stored on electronic media, or on the final recipient's premises.

The respective options of Articles 13.1 and 13.3 of the Mono Partner Model Specific Agreement will be applied.

In accordance with Article 23(7) of the Regulation No 1290/2013 and the Article 204 of the Financial Regulation No 2018/1046, the maximum amount that can be paid to a third party may exceed EUR 60 000 (since this financial support is the primary aim of the action and it is necessary to achieve its objectives).

Eligible costs: Only the costs of providing financial support to third parties are eligible (if they comply with the general conditions and the specific conditions set out in the grant agreement) and the following categories of costs are not eligible:

Direct personnel costs;

Direct costs of subcontracting;

Other direct costs;

Indirect costs.

Funding rate: The EU contribution will be limited to a maximum of 70% of the total eligible costs of the action and it will take the form of a grant consisting of reimbursement of the eligible costs related to the action, in accordance with the conditions set out in the grant agreement.

Grant proposal will be evaluated by experts, on the basis of the award criteria 'Excellence', 'Impact' and 'Quality and efficiency of the implementation', in line with the Article 15 of the Horizon 2020 Rules for Participation Regulation No 1290/2013. In particular the following aspects will be taken into account:

Under the "Excellence" criterion:

1. Clarity and pertinence of the objectives;

2. Soundness of the concept, and credibility of the proposed methodology;

³¹⁸ Exceptions must be duly justified with reference to exceptional circumstances such as emergency and will be subject to the approval of the Commission services.

3. Appropriate consideration of interdisciplinary approaches and, where relevant, use of stakeholder knowledge and gender dimension in research and innovation content;

Under the "Impact" criterion:

The extent to which the outputs of the action would contribute to each of the following expected impacts:

1. To develop medical countermeasures against prioritised pathogens with epidemic potential;
2. To help to prevent and contain epidemics;
3. To support the Sustainable development goals 3.3³¹⁹, "to combat communicable diseases" and 3.B "to support the research and development of vaccines for the communicable diseases that primarily affect developing countries, and provide access to affordable essential vaccines".

Quality of the proposed measures to:

1. Exploit and disseminate the action results, and to manage research data where relevant;
2. To communicate the action activities to different target audiences.

Under the "Quality and efficiency of the implementation" criterion:

1. Quality and effectiveness of the work plan, including extent to which the resources assigned are in line with their objectives and deliverables;
2. Appropriateness of the management structures and procedures, including risk and innovation management.

Model grant agreement: Mono Partner Model Specific Agreement

Legal entities:

Coalition for Epidemic Preparedness Innovations, Marcus Thranes gate 2, 0473 Oslo, Norway

Type of Action: Grant to identified beneficiary - Co-fund actions

Indicative timetable: Third quarter 2020

Indicative budget: EUR 100.00 million from the 2020 budget

³¹⁹ <https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals>

10. Presidency events – Innovation for better ageing³²⁰

A maximum of EUR 200,000 will be allocated to the Croatian Presidency for the organisation of a conference focusing on innovation for a better ageing.

Legal entities:

University of Zagreb School of Medicine (UZSM), Šalata 3, HR-10 000 Zagreb

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

Indicative timetable: First quarter 2020

Indicative budget: EUR 0.20 million from the 2020 budget

11. Continued Support for the European registry for human embryonic stem cell lines³²¹

A contribution for 5 years was made under Other Action 5 of the Work Programme 2016-2017 Health, demographic change and well-being and Grant Agreement No 726320 - hPSCreg to Berlin- Brandenburg Centre for Regenerative Therapies – BCRT Charité to ensure the continued registration of human Pluripotent Stem Cell (hPSC) lines in a European registry. The Grant Agreement started on 01/01/2017 and is ending on 31/12/2021.

It is now intended that Fraunhofer-IBMT (Institut für Biomedizinische Technik), part of the Fraunhofer Society, will replace BCRT Charité. In order to address such organizational changes, allow contractual amendment and continue work carried out under the Grant Agreement it therefore is necessary to identify the new beneficiary carrying out the work under Grant Agreement No 726320 – hPSCreg.

Legal entities:

FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V., HANSASTRASSE 27C, 80686, Muenchen, Germany

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

Indicative timetable: 2nd quarter of 2020

³²⁰ This grant will be awarded without call for proposals in line with Article 189.1 and Article 195 (e) of the Financial Regulation 2018/1046 and Article 11(2) of the Rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)", Regulation (EU) No 1290/2013

³²¹ This grant will be awarded without call for proposals in line with Article 195(e) of the Financial Regulation, Regulation (EU, Euratom) No 1046/2018 and Article 11(2) of the Rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)", Regulation (EU) No 1290/2013

Budget³²²

	Budget line(s)	2018 Budget (EUR million)	2019 Budget (EUR million)	2020 Budget (EUR million)
Calls				
H2020-SC1-BHC-2018-2020		445.00	565.00	498.00
	<i>from 08.020301</i>	<i>445.00</i>	<i>565.00</i>	<i>498.00</i>
H2020-SC1-DTH-2018-2020		100.00	107.50	92.00
	<i>from 09.040301</i>	<i>100.00</i>	<i>107.50</i>	<i>92.00</i>
H2020-SC1-FA-DTS-2018-2020		36.00	35.00 ³²³	70.00
	<i>from 09.040301</i>	<i>36.00</i>	<i>35.00</i>	<i>70.00</i>
Contribution from this part to call H2020-EIC-FTI-2018-2020 under Part 17 of the work programme		17.42	17.42	17.42
	<i>from 08.020301</i>	<i>14.84</i>	<i>14.84</i>	<i>14.84</i>
	<i>from 09.040301</i>	<i>2.58</i>	<i>2.58</i>	<i>2.58</i>
Contribution from this part to call H2020-DT-2018-2020 under Part 5.i of the work programme				15.00
	<i>from 09.040301</i>			<i>15.00</i>
Other actions				
Subscription		5.16	5.26	5.30
	<i>from 08.020301</i>	<i>5.16</i>	<i>5.26</i>	<i>5.30</i>

³²² The budget figures given in this table are rounded to two decimal places.

The budget amounts for the 2020 budget are subject to the availability of the appropriations provided for in the draft budget for 2020 after the adoption of the budget 2020 by the budgetary authority or, if the budget is not adopted, as provided for in the system of provisional twelfths.

³²³ To which EUR 25.00 million from the 'Information and Communication Technologies' WP part will be added making a total of EUR 60.00 million for this call.

Horizon 2020 - Work Programme 2018-2020
Health, demographic change and wellbeing

Public Procurement		3.50	3.50	3.00
	<i>from 08.020301</i>	<i>1.50</i>	<i>1.50</i>	<i>2.50</i>
	<i>from 09.040301</i>	<i>2.00</i>	<i>2.00</i>	<i>0.50</i>
Expert Contracts		3.67	3.50	3.00
	<i>from 09.040301</i>	<i>1.50</i>	<i>1.50</i>	<i>2.00</i>
	<i>from 08.020301</i>	<i>2.17</i>	<i>2.00</i>	<i>1.00</i>
Grant to Identified beneficiary		0.24	30.00	100.20
	<i>from 08.020301</i>	<i>0.24</i>	<i>30.00</i>	<i>100.20</i>
CSA, RIA and IA- Grants awarded without a Call for Proposals (Article 195 (b) of the Financial Regulation)		10.00	10.00	219.50
	<i>from 08.020301</i>	<i>10.00</i>	<i>10.00</i>	<i>163.50</i>
	<i>from 09.040301</i>			<i>56.00</i>
Financial Instrument		30.00	10.00	20.00
	<i>from 08.020301</i>	<i>30.00</i>	<i>10.00</i>	<i>20.00</i>
Estimated total budget		650.99	787.18	1043.42