European Commission

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.

This document has been edited to include only call text for which the deadline has not passed as of June 10th, 2019.

(European Commission Decision C(2019)4575 of 2 July 2019)

Table of Contents

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.

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;
- 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

[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)

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.

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).

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)[2]. For this purpose the 'Guide on Enabling synergies between ESIF, H2020 and other research and innovation related Union programmes'[3] 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).

2 http://s3platform.jrc.ec.europa.eu/map
3 http://ec.europa.eu/regional_policy/sources/docgener/guides/synergy/synergies_en.pdf

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 FAIR[4] (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 Network[5], and (ii) in line with the WHO 'Joint statement on public disclosure of results from clinical trials'[6] 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 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/EU[7].

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 fields[8]. 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 2[9] (IMI2), the European and

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4 https://www.force11.org/group/fairgroup/fairprinciples

5 http://www.who.int/ictrp/network/en/

6 http://www.who.int/ictrp/results/jointstatement/en/

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

8 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)

9 http://www.imi.europa.eu/content/imi-2

Developing Countries Clinical Trials Partnership 2[10] (EDCTP2) and the Active and Assisted Living Joint Programme 2[11] (AAL2). Topics in this work programme also respond to the priorities of the European Innovation Partnership on Active and Healthy Ageing [12] (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

10 http://www.edctp.org/
11 http://www.aal-europe.eu/why-another-aal-programme/
12 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-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

[34] ETRIKS: https://www.etriks.org/, EMIF: http://www.emif.eu/, OPEN-PHACTS: https://www.openphacts.org/

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

Specific Challenge: Personalised Medicine is a very broad and multifaceted area where success relies on a well-functioning collaboration between several disciplines and different actors. While great advances have been made in some fields of medicine, in particular in stratification of cancer patients and in addressing rare diseases, most of today's healthcare protocols do not include personalised approaches apart from occasional division into broad age groups (children/adults/elderly), sex or ethnicity. Furthermore the prevention aspect of personalised medicine, i.e. identifying individuals prone to develop certain diseases, is largely isolated from treatment options. As is the case for a relatively nascent field there is a need for standardisation of approaches, including for sampling, data storage, interpretation and data exchange and also for clinical trials design and reimbursement models. European countries with their social model of healthcare along with (in several cases) centralised cost reimbursement, are ideally placed to lead the way for an integrated health management system. Many needs for coordination and support activities have been identified by ICPerMed[38], 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 ICPerMed with a grant to operate its secretariat until October 2020[39] . Wider internationalisation of ICPerMed can be underpinned by coordinating networking activities with third countries.

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

[38] http://icpermed.eu
[39] 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 CELAC [40] as a group of countries, and for the 2019 call on China.~~ For the 2020 call, the project should focus on countries in Africa[41], linking also into the EU-AU (African Union) policy dialogue and taking into account the new Africa-Europa Alliance for Sustainable investment and Jobs[42]. 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

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40 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

41 African Union Member States

42 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 EUnetHTA[43]. 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 EMA[44] and the HMA network[45], as well as the European legal framework[46]. 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.

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43 European Network for Health Technology Assessment: http://www.eunethta.eu/
44 European Medicines Agency: www.ema.europa.eu
45 Heads of Medicines Agencies: http://www.hma.eu/
46 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-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 performing[48] 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-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..

Proposal 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 beyond[49]. 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.

[49] 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-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 stage[50] clinical trial(s) to validate novel or refined healthcare interventions[51] 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-concept[52] of clinical safety and efficacy[53] 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 criteria[54] 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

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

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

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

53 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

54 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-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*[57] 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.

[57] *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-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[63] 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 investigations [64] for high-risk devices will be compulsory [65] and the requirements regarding the clinical evaluation[66] 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 developers[67] 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).

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63 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

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

65 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.

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

67 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[68] [69].

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

[68] https://blogs.scientificamerican.com/news-blog/embryonic-stem-cells-cause-cancer-i-2009-02-19/

[69] 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 (EMA[70]), the Heads of Medicines Agencies (HMA [71]) network, EUnetHTA [72] 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

[70] European Medicines Agency: http://www.ema.europa.eu/en

[71] 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/

[72] EUnetHTA Joint Action 3 is a European network of national/regional HTA bodies under the EU Third Health Programme http://www.eunethta.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-17-2020: Global Alliance for Chronic Diseases (GACD) - Prevention and/or early diagnosis of cancer

Specific Challenge: The Global Alliance for Chronic Diseases[90] (GACD) call will focus on implementation research proposals for the prevention[91] and/or early diagnosis of cancer in Low and Middle-Income Countries (LMIC) and/or in vulnerable populations [92] in High-Income Countries (HIC)[93].

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 million[94] 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 3.4[95], 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:

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90 http://www.gacd.org/
91 Tertiary prevention is excluded from the topic.
92 Proposals should demonstrate the vulnerability of the targeted population in HIC.
93 https://databank.worldbank.org/data/download/site-content/CLASS.xls
94 GLOBOCAN and CONCORD-3
95 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-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 Procurement[107].

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

[107] 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-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

[117] National Health Mission, Government of India: http://www.nhm.gov.in/nhm.html

[118] 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 vaccination[119].

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.[120] Seasonal influenza vaccination also remains significantly below the 75% coverage target for older age groups.[121]

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 2017[122] , which is more than three times the number of cases reported in 2016. During the same period 50 people in the EU died due to measles[123].

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 hesitancy [124] , "WHO/SAGE Working Group on Vaccine Hesitancy" [125] , WHO/Europe "Guide to tailoring immunization programmes (TIP)"[126].

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

119 http://www.ebiomedicine.com/article/S2352-3964(16)30398-X/fulltext
120 http://www.who.int/immunization/monitoring_surveillance/data/gs_eurprofile.pdf
121 http://ecdc.europa.eu/en/publications/Publications/Seasonal-influenza-vaccination-antiviral-use-europe.pdf
122 https://ecdc.europa.eu/sites/portal/files/documents/Monthly%20measles%20and%20rubella%20monitoring%20report%20-%20JAN%202018.pdf
123 https://ecdc.europa.eu/en/news-events/measles-cases-eu-treble-2017-outbreaks-still-ongoing
124 https://ecdc.europa.eu/en/immunisation-vaccines/vaccine-hesitancy
125 http://www.who.int/immunization/programmes_systems/vaccine_hesitancy/en/
126 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 2017 [127] , the EC Communication on strengthened cooperation against vaccine preventable disease (COM/2018/245) [128] and the Council Recommendation on strengthened cooperation against vaccine preventable diseases)[129].

Type of Action: Research and Innovation action

127 http://europa.eu/rapid/press-release_SPEECH-17-3165_en.htm
128 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A245%3AFIN
129 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) [130] 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 Resistance[131].

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.

130 https://ecdc.europa.eu/en/antimicrobial-resistance
131 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 diseases[132], 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

[132] 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 PREPARE [133] and COMBACTE [134] . 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 ECRIN[135]and BBMRI[136]. 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)"[137].

133 http://www.prepare-europe.eu/
134 https://www.combacte.com/
135 http://www.ecrin.org/
136 http://www.bbmri-eric.eu/
137 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-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 AMR[138].

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

138 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.

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

Specific Challenge: It is estimated that more than 50 million European citizens suffer from multimorbidity[154]. As the global population continues to grow and age, multimorbidity is increasingly prevalent in elderly[155] 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.

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

155 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-37-2020: Towards the new generation of clinical trials – trials methodology research [162]

Specific Challenge: Efficient and effective clinical trials[163] 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[164,165,166];
- Defining patient populations and patient enrolment strategies;
- Data management[167].

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 privacy[168].

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 interventions [169] . In order to draw meaningful conclusions following state of the art of

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162 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.

163 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

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

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

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

167 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

168 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

169 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) for combinatorial interventions, seehttps://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 Agency[170] (EMA) and the Commission Expert Group on Clinical Trials[171] 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[172,173], 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 Control [174] 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 2017 [175] . Details of the lump sum funding pilot scheme are published on the Funding & Tenders Portal [176] together with the specific Model Grant Agreement for Lump Sums[177] applicable.

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170 https://www.ema.europa.eu/

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

172 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”

173 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.

174 https://ecdc.europa.eu/en/home

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

176 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home

177 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-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 Health[180] *and the EU chemical and other sectoral policies. Where appropriate, this priority will build on existing results from projects funded*

[180] 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 Initiative[181].

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 Economy[182]*, the Bioeconomy Strategy*[183]*, the Integrated Maritime Policy*[184]*, and the European Strategy for Marine and Maritime Research*[185]*. This priority will be implemented through several topics covered by different Societal Challenges and the Leadership in Enabling and Industrial Technologies (LEIT) pillar*[186]*.*

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.

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181 www.hbm4eu.eu/

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

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

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

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

186 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-29-2020: Innovative actions for improving urban health and wellbeing - addressing environment, climate and socioeconomic factors

Specific Challenge: The natural and built [194] 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 widening [195] . 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 EU[196] 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

194 Man-made structures, features, and facilities viewed collectively as an environment in which people live and work (https://en.oxforddictionaries.com/definition/built_environment)
195 http://www.health-inequalities.eu/about-hi/health-inequalities-in-the-eu/
196 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 cohesion[197].

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 policies[198]).

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:

197 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF
198 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 considered[199]:

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

[199] 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 Economy[200] . Selected projects under this topic as well as projects selected under other topics in Horizon 2020 supporting the Plastics Strategy [201] 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.

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

201 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 Economy[202] and of the Bioeconomy Strategy[203].

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.

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"[208] *as updated in the Communication "On enabling the digital transformation of health and care in the Digital Single Market"*[209].

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[210]*". 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 limitations[211].

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.

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208 *Updated by the DSM mid-term review: http://europa.eu/rapid/press-release_IP-17-1232_en.htm*
209 COM(2018) 233 final of 25.04.2018
210 https://sustainabledevelopment.un.org/sdg3
211 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 issues[212] 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.

[212] 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 Market[213].

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 systems[214]. 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 citizens[215] and integration of services[216].

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

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

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

216 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 solutions[217] 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 scalability [218] 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 research[219]. The main focus should be on improving people-centeredness in Europe but solutions can originate from non-

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217 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 understand in a broad sense including governance, payment, information systems, roles and skills in attaining efficient health care organisations when introducing new technologies.

218 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.

219 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 projects[220].

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[221]".

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

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

221 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 Cloud[222].

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

[222] 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):[223]

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

[223] 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.

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				

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-37-2020 (RIA-LS)			6.00	07 Apr 2020
SC1-BHC-06-2020 (RIA)			40.00	07 Apr 2020
SC1-BHC-11-2020 (RIA)			60.00	
SC1-BHC-17-2020 (RIA)			20.00	
SC1-BHC-20A-2020 (PCP) SC1-BHC-20B-2020 (PPI)			25.00	
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	
SC1-BHC-08-2020 (RIA)			80.00	24 Sep 2019 (First Stage) 07 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	
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 FAIR [224] 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

[224] https://www.force11.org/group/fairgroup/fairprinciples

	(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.

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	
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,	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.

SC1-BHC-25-2019, SC1-BHC-29-2020, SC1-BHC-30-2019, SC1-DTH-13-2020	

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.

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'[225]*, 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-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 projects[226] 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,

[226] 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-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:

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.

Collaboration with Canada[229]

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 partners [230] , 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;

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229 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.

230 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 policy[231], 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 Canada[232].

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.

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231 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.

232 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 Japan[233] or Canada[234] .

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-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, pharmaceutics, 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-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 group[252];

- 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;

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252 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; (templates [253] 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 PIPPI [254] and EURIPHI[255].

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.

253 Reference to template to be added
254 https://cordis.europa.eu/project/rcn/219012/factsheet/en
255 https://cordis.europa.eu/project/rcn/219929/factsheet/en

MAFEIP [256] . Sufficient travel allowances for regular information days concerning the procedures and thematic networking events (e.g. related to relevant co-ordination and support actions including SC1-HCC-04-2018[257]) should be foreseen. A plan to implement the services should be included. In that context investigation of complementary procurement approaches (see e.g.[258]) 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-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 projects[277], 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 Regulation[278], the Network and Information Systems Directive[279] and the operation in a European digital single market. The deployment should build on the Commission Recommendation on the European EHR exchange format[280] 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

277 E.g. from the H2020 topics PHC 34 – 2014, HCO-14-2016, HCO-15-2016, SC1-DTH-08-2018

278 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

279 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

280 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 Network [281] 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

[281] 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 programmes[282] 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

[282] 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 countries[283] 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 Jobs[284] 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.

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283 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

284 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 standardisation[285] 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):[286]

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

[286] 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.

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.

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,

	proposals shall include at least one organisation as partner in the consortium from Japan[287] or Canada[288]
SC1-HCC-09-2020	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. 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

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.

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

[287] 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).

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

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 *[insert name(s) of type(s) of action* 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.

Call - Trusted digital solutions and Cybersecurity in Health and Care

H2020-SC1-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 Pilots[289]

The Digitising European Industry initiative includes the launch of a set of initiatives supporting the building of the digital industrial platforms of the future[290]. 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

289 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.

290 COM(2016) 180 final, 19 April 2016

experimental environments that have been developed in these various initiatives when applicable[291].

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 Market[292].

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[291] 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.

[292] 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 party[293]). 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):

[293] 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-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 trough 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 cancer[295].

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:

[295] As reported by the World Health Organisation, see for example https://www.who.int/news-room/fact-sheets/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.

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

Opening date(s), deadline(s), indicative budget(s):[296]

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 [297]		14 Nov 2018
Opening: 09 Jul 2019				

296 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.

297 of which EUR 25.00 million from the 'Information and Communication Technologies' WP part.

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.

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

	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.

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.

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 actions[298]

1. Subscription fee: Human Frontier Science Programme Organisation

An annual subscription to the international Human Frontier Science Programme Organisation (HFSPO)[299] will allow EU non-G7 Member States to fully benefit from the Human Frontier Science Programme (HFSP) and provide increased visibility for European research, as well as contributing to the implementation of the Union's strategy for international cooperation[300] 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, 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 Health[301]; (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.and (v) to organise conferences, events and outreach activities. Should existing framework contracts prove unsuitable or insufficient to support the abovementioned activities, one or more calls for tender may be launched as appropriate.

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

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

Indicative timetable: Some 10 contracts expected for 2018 (indicative), 10 contracts for 2019 (indicative) and 10 contracts for 2020 (indicative)

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

300 COM(2012)497

301 The Scientific Panel for Health is mandated by Regulation (EU) No 1291/2013 establishing Horizon 2020

Indicative budget: EUR 3.50 million from the 2018 budget and EUR 3.50 million from the 2019 budget and EUR 2.00 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 4.00 million from the 2020 budget

4. Grant to the Global Alliance for Chronic Diseases[302]

The European Commission will make a contribution towards activities of the Global Alliance for Chronic Diseases (GACD). This will enable the European Commission to take part in GACD, which brings together leading health research funding agencies of key countries (currently Australia, UK, Canada, China, India, Mexico, USA, Brazil, Japan, Thailand, Argentina and South Africa) to coordinate research activities addressing on a global scale the prevention and treatment of chronic, non-communicable diseases such as cardiovascular diseases, diabetes, mental health and cancer. Recommendations of GACD are expected to have a fundamental value for future orientation of public health research policy. This will also contribute to the implementation of the Union's strategy for international cooperation[303] 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

302 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

303 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 Emergencies[304]

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), research grants may be awarded in line with specific provisions of the Financial Regulation[305&306], that allow the awarding of grants without 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.

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 FAIR [307] principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

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304 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.

305 Article 189.1 of the Financial Regulation 2018/1046 "Grants shall be awarded following a publication of calls for proposals except in the cases referred to in Article 195."

306 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[…]"

307 https://www.force11.org/group/fairgroup/fairprinciples

Type of Action: RIA - Grants awarded without a Call for Proposals (Article 189.1 and 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 10.00 million from the 2020 budget

7. InnovFin Infectious Diseases (InnovFin ID)[308]

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 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.

[308] The indicative budget complements the allocation in 2018, 2019 and 2020 from the Part on Access to risk finance

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)[309]

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 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 cooperation[310] 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 K[311]:

- The proposal of the action must clearly detail the objectives and the results to be obtained and include at least the following elements:

309 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

310 COM(2012)497

311 Due to specific character of the action other conditions of General Annex K do not apply

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;
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 3.3 [312] , "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;

[312] https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals

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)[313]

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 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. This action will also contribute to the implementation of the Union's strategy for international cooperation[314] 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 K[315]:

313 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

314 COM(2012)497

315 Due to specific character of the action other conditions of General Annex K do not apply

 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;

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;

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;

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 3.3 [316], "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;

316 https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals

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 50.00 million from the 2020 budget

10. Presidency events – Innovation for better ageing[317]

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

317 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

Budget[318]

	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
	from 08.020301	*445.00*	*565.00*	*498.00*
H2020-SC1-DTH-2018-2020		100.00	107.50	92.00
	from 09.040301	*100.00*	*107.50*	*92.00*
H2020-SC1-FA-DTS-2018-2020		36.00	35.00[319]	70.00
	from 09.040301	*36.00*	*35.00*	*70.00*
Contribution from this part to call H2020-EIC-FTI-2018-2020 under Part 17 of the work programme		17.42	17.42	17.42
	from 08.020301	*14.84*	*14.84*	*14.84*
	from 09.040301	*2.58*	*2.58*	*2.58*
Contribution from this part to call H2020-DT-2018-2020 under Part 5.i of the work programme				15.00
	from 09.040301			*15.00*
Other actions				
Subscription		5.16	5.26	5.30
	from 08.020301	*5.16*	*5.26*	*5.30*

318 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.

319 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.

Public Procurement		3.50	3.50	2.00
	from 09.040301	*2.00*	*2.00*	*0.50*
	from 08.020301	*1.50*	*1.50*	*1.50*
Expert Contracts		3.67	3.50	4.00
	from 08.020301	*2.17*	*2.00*	*2.00*
	from 09.040301	*1.50*	*1.50*	*2.00*
Grant to Identified beneficiary		0.24	30.00	50.20
	from 08.020301	*0.24*	*30.00*	*50.20*
RIA - Grants awarded without a Call for Proposals (Article 189.1 and Article 195 (b) of the Financial Regulation)		10.00	10.00	10.00
	from 08.020301	*10.00*	*10.00*	*10.00*
Financial Instrument		30.00	10.00	20.00
	from 08.020301	*30.00*	*10.00*	*20.00*
Estimated total budget		650.99	787.18	783.92