



EN

Horizon Europe

Work Programme 2021-2022

4. Health

(European Commission Decision C(2021)4200 of 15 June 2021)



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Introduction

The Union and the world are challenged by the COVID-19 pandemic. While it has uncovered vulnerabilities in our social and economic systems, it has also provided new impetus, visibility and recognition of the critical role that health care systems and health professionals play in responding to the needs of people, serving society and underpinning the economy. It also underlined the power of research and innovation in uncovering the knowledge and developing the technologies to respond rapidly and effectively to public health emergencies. In addition to the direct suffering that COVID-19 is causing to symptomatic patients and their families, including long-term COVID-19 symptoms in survivors, the social distancing measures and lockdowns are causing major disruptions in social and economic life aggravating inequalities, loneliness and neglect, but also increasing existential fears, anxieties and distress, with serious negative impact on mental health and well-being. Population groups who are at risk of COVID-19, such as people suffering from co-morbidities and the elderly, are affected by these measures disproportionately but also young people entering and establishing their adult life. There is thus an urgent need for research and innovation to understand the long-term effects of both COVID-19 and the social distancing measures on people's health and well-being, and in turn develop effective responses for a solid recovery of the Union. Research conducted during the pandemic and following its sequels is pivotal to inform preparedness for potential similar events in the future. The pandemic has also demonstrated the downside of globalisation in which the dependence on global value chains can quickly result in shortages of critical supplies, such as essential medicines or other health technologies.

To help repair the economic and social damage caused by the coronavirus pandemic, the European Commission, the European Parliament and EU Member States leaders have agreed on a Recovery Plan for Europe that will lead the way out of the crisis and lay the foundations for a modern and more sustainable Union. The Health cluster will put the focus of this work programme mainly to this endeavour, which will benefit from financial resources from this Multiannual Financial Framework and from NextGenerationEU (NGEU), the Union's financing instrument to boost the recovery. It requires research and innovation supporting the recovery of people and communities from COVID-19 but also for making society more resilient and national health systems better prepared to any future public health emergency. The Recovery Plan aims the Union to building back better, which also entails supporting the twin digital and green transitions by unlocking the full potential of data-enabled research and innovation for digitised health systems and a competitive and secure data-economy, including on the basis of European Electronic Health Records as well as the establishment of the European Health Data Space. The digital transformation of health and care will certainly help to increase the capacity of health care systems to deliver more personalised and effective health care with less resource wasting. It will contribute but is not sufficient for making the Union the first climate-neutral continent by 2050, with zero pollution and zero waste. Additional efforts are needed to make also the delivery of health care, the design of health technologies and their manufacturing more sustainable by reducing energy consumption,

waste, pollution and the release of harmful substances, including pharmaceuticals, into the environment.

Even though research and innovation has the power to uncovering the knowledge and developing the technologies to serve societal well-being, economic prosperity and environmental sustainability, it only can succeed through cooperation of the best research teams with the prospective users of such knowledge and technologies. It is thus of outmost importance to involve those users - like patients and healthy citizens, health care professionals providers and payers, public health authorities and regulators, researchers or innovators from academia and industry - early in the knowledge generation or technology development process, including through patient/citizen engagement, community involvement or other forms of social innovation approaches, such that research and innovation activities are adjusted to the users' particular expectations, needs, constraints and potential. Any cooperation would benefit from adequate intellectual property management strategies. Beyond cooperating along the value chain of knowledge and know-how production and valorisation or within the knowledge triangle (research-education-innovation), it is in the EU's strategic interest to also reach out and cooperate with other countries outside the EU and on other continents. This applies in particular for multi-lateral cooperation on (global) health issues with countries associated to Horizon Europe but also with other partner countries and regions in the world. 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 funded under the Health cluster.

Nevertheless, the pandemic shows also the importance of effective coordination among EU Member States in the area of health. The European Commission is building a strong European Health Union, in which all EU Member States prepare and respond together to health crises, in synergy with national activities in the area of crisis preparedness and response; medical supplies are available, affordable and innovative, and countries work together to improve prevention, diagnosis, treatment and aftercare for any diseases, including cancer. Stronger common preparedness and response will rely on greater input from the Union's agencies and bodies, including any future EU Health Emergency Preparedness and Response Authority (EU-HERA) for which the HERA incubator foresees preparatory actions¹. Likewise, some research and innovation actions under the Health Cluster should deliver relevant complementary inputs to the announced "Europe's Beating Cancer Plan"², contributing to actions covering the entire cancer care pathway, including prevention, early detection, diagnosis, treatment, cancer data monitoring, as well as quality of life of cancer patients and survivors.

Horizon Europe is the research and innovation support programme in a system of European and national funding programmes that share policy objectives. Through the programme,

¹ HERA Incubator: Anticipating together the threat of COVID-19 variants, COM (2021) 78 Final, 17.2.2021

² <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan>

special attention is given to ensuring cooperation between universities, scientific communities and industry, including small and medium-sized enterprises, and citizens and their representatives, in order to bridge gaps between territories, generations and regional cultures, especially caring for the needs of the young in shaping Europe's future. Moreover, accelerating the performance and boosting the use and impact of research and innovation also requires it to make use of complementary capacities, such as European research, innovation and space infrastructures and services, or to develop complementary activities in synergy with other European Union funding programmes. Applicants could consider and actively seek complementarities and synergies with, and where appropriate possibilities for further funding of additional activities not covered by their proposal from EU, national or regional programmes such as: EU4Health, Digital Europe Programme, European Regional Development Fund (ERDF), European Social Fund (ESF+), Structural Reform Support Programme (SRSP), Just Transition Fund (JTF), European Maritime and Fisheries Fund (EMFF), European Agricultural Fund for Rural Development (EAFRD) or InvestEU. This could involve dedicated calls (EU synergies calls), meaning that actions that have been awarded a grant under such a call could have the possibility to also receive funding under other EU programmes, including relevant shared management funds. Additionally, to encourage multi-actors approaches and to be more effective in achieving impact, applicants could consider synergies with other relevant initiatives funded under the Horizon Europe programme, including the Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT). The innovation ecosystems created and nurtured by the EIT-KICs can in particular contribute to building communities or platforms for coordination and support actions, sharing knowledge or disseminating and fostering the exploitation of the project results (the proposals are also encouraged to explore other forms and means of service provisions distinct to the EIT-KICs, in particular EIT-KIC Health and EIT-KIC Digital).

All could help to support the development of skills and capacities in research or health systems, as well as accelerating the take-up and use of scientific evidences, new technologies and best practices in health care and by health systems, industries and markets, at national or regional level.

As examples, the EU4Health programme could help to ensure that the best use is made of research results and facilitate the uptake, scaling-up and deployment of health innovations in healthcare systems and clinical practice. Thereby unlocking the potential of innovation in health, and improving efficiency by avoiding the duplication of activities and optimising the use of financial resources.

The ERDF focuses, amongst others, on the development and strengthening of regional and local research and innovation ecosystems and smart economic transformation, in line with regional/national smart specialisation strategies. It can support investment in research infrastructure, activities for applied research and innovation, including industrial research, experimental development and feasibility studies, building research and innovation capacities and uptake of advanced technologies and roll-out of innovative solutions from the Framework Programmes for research and innovation through the ERDF.

The EU's Recovery and Resilience Facility (RRF) offers support to Member States in financing reforms and investments that improve their resilience and their growth potential, mitigate the economic and social impacts from the COVID-19 crisis, including in the area of health, and support the green and digital transition. For project ideas that go beyond the remit of an R&I proposal and directly contribute to the objectives of the RRF it is advisable to check access to funding available at national level in line with the Member States' recovery and resilience plans for a fast and targeted support.

Notwithstanding the synergies mentioned above, the work programme 2021-2022 of cluster 1 'Health' captures synergies with other clusters based on the challenges and areas of intervention of each destination. Further synergies are encouraged with regard to complementary funding opportunities provided by topics in other clusters and other pillars of Horizon Europe, notably in the European Research Infrastructure work programme (under pillar I)³ and the European Innovation Council work programme (under pillar III)⁴. Additional synergies could also be explored at project-level, i.e. between the portfolio of projects funded either under the same topic or by establishing a portfolio of projects funded under different topics (of the health cluster, of the other clusters 2-6, or of the pillars I/III of Horizon Europe). In particular, applicants to calls of the health cluster are encouraged to consider, where relevant, the services offered by the current and future EU-funded European Research Infrastructures, including the European Open Science Cloud.^{5,6} Moreover, if projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, they must make use of European space technologies and services provided by Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).⁷

³ The work programme 2021-2022 of the European Research Infrastructure programme includes the following calls supporting European research infrastructures and services that are or may be relevant for health research and innovation: FAIR and open data sharing in support of European preparedness for infectious diseases; FAIR and open data sharing in support of cancer research; Research Infrastructure services for rapid research responses to infectious disease epidemics; Research Infrastructures services to support research addressing cancer; Enabling research infrastructure services for better use of imaging data to address challenges in thematic research areas; Implementing digital services to empower neuroscience research for health and brain inspired technology via EBRAINS; Research Infrastructures services for sustainable and inclusive Global Value Chain and Europe recovery from socio-economic crises.

⁴ The work programme 2021-2022 of the European Innovation Council (EIC) includes the following calls focused on strategic challenges aimed at supporting breakthrough technologies and innovations with the potential to scale up internationally and for European companies to become market leaders: EIC Pathfinder Challenges: Awareness inside, Tools to measure and stimulate activity in brain tissue, Emerging technologies in cell and gene therapy, Engineered living materials; EIC Transition Challenges: Medical technology and devices: from lab to patient; EIC Accelerator Challenges: Strategic digital and health technologies.

⁵ 2018 Roadmap of the European Strategy Forum on Research Infrastructures (ESFRI) with the ESFRI research infrastructures list (pp 15-17), https://ec.europa.eu/info/sites/info/files/research_and_innovation/esfri-roadmap-2018.pdf; European Research Infrastructures, Commission website: https://ec.europa.eu/info/research-and-innovation/strategy/european-research-infrastructures_en; List of entities legally established as European Research Infrastructure Consortium (ERIC) <https://www.eric-forum.eu/the-eric-landscape/>.

⁶ European Open Science Cloud (EOSC) <https://www.eosc-portal.eu/>; [European COVID-19 Data Platform](https://www.eosc-portal.eu/) / COVID-19 Data Portal <https://www.covid19dataportal.org/>

⁷ European space technology based earth observation, positioning, navigation and timing services provided by: Copernicus, the European Union's Earth observation programme

The work programme 2021-2022 of cluster 1 ‘Health’ is directed towards two Key Strategic Orientations (KSOs) for research and innovation set by Horizon Europe’s strategic plan 2021-2024, notably to creating a more resilient, inclusive and democratic European society (KSO-D) and promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains (KSO-A). It aims to mainly contribute to four impact areas of the strategic plan: Good health and high-quality accessible health care; A resilient EU prepared for emerging threats; High quality digital services for all; and A competitive and secure data-economy. More specifically, cluster 1 aims to contribute to six expected impacts as set out by the strategic plan, which are the following six destinations of this work programme:

Destination 1 - Staying healthy in a rapidly changing society: Citizens of all ages stay healthy and independent in a rapidly changing society thanks to healthier lifestyles and behaviours, healthier diets, healthier environments, improved evidence-based health policies, and more effective solutions for health promotion and disease prevention.

Destination 2 - Living and working in a health-promoting environment: Living and working environments are health-promoting and sustainable thanks to better understanding of environmental, occupational, social and economic determinants of health.

Destination 3 - Tackling diseases and reducing disease burden: Health care providers are able to better tackle and manage diseases (infectious diseases, including poverty-related and neglected diseases, non-communicable and rare diseases) and reduce the disease burden on patients effectively thanks to better understanding and treatment of diseases, more effective and innovative health technologies, better ability and preparedness to manage epidemic outbreaks and improved patient safety.

Destination 4 - Ensuring access to innovative, sustainable and high-quality health care: Health care systems provide equal access to innovative, sustainable and high-quality health care thanks to the development and uptake of safe, cost-effective and people-centred solutions, with a focus on population health, health systems resilience, as well as improved evidence-based health policies.

Destination 5 - Unlocking the full potential of new tools, technologies and digital solutions for a healthy society: Health technologies, new tools and digital solutions are applied effectively thanks to their inclusive, secure and ethical development, delivery, integration and deployment in health policies and health care systems.

Destination 6 - Maintaining an innovative, sustainable and globally competitive health-related industry: EU health industry is innovative, sustainable and globally competitive thanks to improved up-take of breakthrough technologies and innovations, which makes the EU with its Member States more resilient and less dependent from imports with regard to the access to and supply of critical health technologies.

<https://www.copernicus.eu/en/copernicus-services>; Galileo, the European Global Satellite Navigation System (GNSS) <https://www.gsc-europa.eu/galileo/services/galileo-initial-services>; and the European Geostationary Navigation Overlay Service (EGNOS) <https://www.gsa.europa.eu/egnosc/services>.

Destination 1 – Staying healthy in a rapidly changing society

Calls for proposals under this destination are directed towards the Key Strategic Orientation KSO-D *‘Creating a more resilient, inclusive and democratic European society’* of Horizon Europe’s Strategic Plan 2021-2024. Research and innovation supported under this destination should contribute to the impact area *‘Good health and high-quality accessible health care’* and in particular to the following expected impact, set out in the Strategic Plan for the health cluster: *‘citizens of all ages stay healthy and independent in a rapidly changing society thanks to healthier lifestyles and behaviours, healthier diets, healthier environments, improved evidence-based health policies, and more effective solutions for health promotion and disease prevention’*. In addition, research and innovation supported under this destination could also contribute to the following impact areas: *‘High quality digital services for all’*, *‘Sustainable food systems from farm to fork on land and sea’*, and *‘Climate change mitigation and adaptation’*.

People’s health care needs are different, depending on their age, stage of life and socio-economic background. Their physical and mental health and well-being can be influenced by their individual situation as well as the broader societal context they are living in. Furthermore, health education and behaviour are important factors. Currently, more than 790 000 deaths per year in Europe are due to risk factors such as smoking, drinking, physical inactivity, and obesity. Upbringing, income, education levels, social and gender aspects also have an impact on health risks and how disease can be prevented. Moreover, people’s health can be impacted by a rapidly changing society, making it challenging to keep pace and find its way through new technological tools and societal changes, which both are increasing demands on the individual’s resilience. In order to leave no one behind, to reduce health inequalities and to support healthy and active lives for all, it is crucial to provide suitable and tailor-made solutions, including for people with specific needs.

In this work programme, destination 1 will focus on major societal challenges that are part of the European Commission’s political priorities, notably diet and health (obesity), ageing and demographic change, mental health, digital empowerment in health literacy, and personalised prevention. Research and innovation supported under this destination will provide new evidences, methodologies and tools for understanding the transition from health to disease. This will allow designing better strategies and personalised tools for preventing diseases and promoting health, including through social innovation approaches. Specific measures will also be developed to educate and empower citizens of all ages and throughout their life, to play an active role in the self-management of their own health and self-care, to the benefit of an active and healthy ageing. In 2022, it will also call for proposals for improving the availability and use of artificial intelligence (AI) tools to predict the risk for onset and progression of chronic diseases. Key to achieving the expected impacts is the availability and accessibility of health data from multiple sources, including real-world health data, which will require appropriate support by research and data infrastructures, AI-based solutions, and robust and transparent methodologies for analysis and reporting.

Dialogue and coordination between stakeholders and policy makers as well as integration across different settings will be needed to develop more effective cross-sectoral solutions for health promotion and disease prevention and deliver improved evidence-based health for all.

In view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic but also between other projects funded under another topic, cluster or pillar of Horizon Europe (but also with ongoing projects funded under Horizon 2020). In particular, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health and EIT-KIC Health (under pillar III of Horizon Europe), or in areas cutting across the health and other clusters (under pillar II of Horizon Europe). For instance, with cluster 2 “*Culture, Creativity and Inclusive Society*” such as on health inequalities, on other inequalities affecting health, or on citizens’ behaviour and engagement; with cluster 4 “*Digital, Industry and Space*” such as on digital tools, telemedicine or smart homes; with cluster 5 “*Climate, Energy and Mobility*” such as on urban health or on mitigating the impact of road traffic accidents and related injuries; with cluster 6 “*Food, Bioeconomy, Natural Resources, Agriculture and Environment*” such as on the role of nutrition for health (incl. human microbiome, mal- and over-nutrition, safe food), personalised diets (incl. food habits in general and childhood obesity in particular) and the impact of food-related environmental stressors on human health (incl. marketing and consumer habits).⁸

Expected impacts:

Proposals for topics under this destination should set out a credible pathway to contributing to staying healthy in a rapidly changing society, and more specifically to one or several of the following impacts:

- Citizens adopt healthier lifestyles and behaviours, make healthier choices and maintain longer a healthy, independent and active life with a reduced disease burden, including at old ages or in other vulnerable stages of life.
- Citizens are able and empowered to manage better their own physical and mental health and well-being, monitor their health, and interact with their doctors and health care providers.
- Citizens’ trust in knowledge-based health interventions and in guidance from health authorities is strengthened, including through improved health literacy (including at young ages), resulting in increased engagement in and adherence to effective strategies for health promotion, diseases prevention and treatment, including increased vaccination rates and patient safety.

⁸ Strategic Plan 2021-2024 of Horizon Europe, Annex I, Table 2.

*Horizon Europe - Work Programme 2021-2022
Health*

Health policies and actions for health promotion and disease prevention are knowledge-based, people-centred and thus targeted and tailored to citizens' needs, and designed to reduce health inequalities.

The following call(s) in this work programme contribute to this destination:

Call	Budgets (EUR million)		Deadline(s)
	2021	2022	
HORIZON-HLTH-2021-STAYHLTH-01	69.00		21 Sep 2021
HORIZON-HLTH-2022-STAYHLTH-01-two-stage		170.00	01 Feb 2022 (First Stage) 06 Sep 2022 (Second Stage)
HORIZON-HLTH-2022-STAYHLTH-02		50.00	21 Apr 2022
Overall indicative budget	69.00	220.00	

Call - Staying Healthy (2021)

HORIZON-HLTH-2021-STAYHLTH-01

Conditions for the Call

Indicative budget(s)⁹

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁰	Number of projects expected to be funded
		2021		
Opening: 22 Jun 2021 Deadline(s): 21 Sep 2021				
HORIZON-HLTH-2021-STAYHLTH-01-02	RIA	60.00 ¹¹	Around 10.00	6
HORIZON-HLTH-2021-STAYHLTH-01-03	CSA	3.00	Around 3.00	1
HORIZON-HLTH-2021-STAYHLTH-01-04	CSA	3.00	Around 3.00	1
HORIZON-HLTH-2021-STAYHLTH-01-05	CSA	3.00	Around 3.00	1
Overall indicative budget		69.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.

⁹ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹⁰ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹¹ Of which EUR 36.00 million from the 'NGEU' Fund Source.

<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2021-STAYHLTH-01-02: Towards a molecular and neurobiological understanding of mental health and mental illness for the benefit of citizens and patients

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several impacts of destination 1 “*Staying healthy in a rapidly changing society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to one or several of the following expected outcomes:

- Researchers, health care professionals and developers of medical interventions have a much better understanding of how genetic, epigenetic and environmental risk and resilience factors interact to drive or prevent the transition from mental health to mental illness throughout the life course. Developers of medical interventions make use of this understanding to develop novel classes of medications and non-pharmaceutical interventions for the prevention and treatment of mental illnesses (including relapse prevention).
- Mental health professionals have access to different types of validated biomarkers for making more accurate diagnoses (beyond current symptom-based criteria) and for optimising and personalising preventive and therapeutic treatment decisions. As a result, patients receive more targeted therapies and relapse less frequently. They experience less stigma due to more accurate and objective diagnoses and increased public awareness about the molecular and neurobiological basis of mental health and mental illness.

- Citizens have the possibility to undergo laboratory testing for assessing their mental health and their predisposition to mental illnesses, and are given timely evidence-based guidance on personalised preventive measures that underpin their active engagement and adherence to effective strategies for promoting their mental health.
- Public health authorities and policy makers have access to comprehensive clinical trial data on the effectiveness of different types of pharmacological and non-pharmacological strategies for the promotion of mental health and prevention of mental illnesses, helping them draft evidence-based clinical guidelines and best practices as well as design tailor-made prevention policies and campaigns.

Scope: Mental illnesses represent a huge and growing burden for Europe, both at individual and societal level. There is an enormous stigma and they often remain undetected as diagnoses largely depend on symptom-based criteria without any biological markers linked to causative mechanisms. Currently available medications are primarily used by trial and error (rather than in a targeted and personalised manner) and they are all very similar in their mechanisms of action with rather little breakthrough innovation in the last few decades. There is further a lack of evidence base on the optimal use of different pharmacological and non-pharmacological prevention strategies. A deeper molecular and neurobiological understanding of the interplay between genetic, epigenetic and environmental risk and resilience factors, including neural circuit alterations, is critical for the development of objective biomarkers and evidence-based interventions that will significantly improve mental health outcomes.

Accordingly, the proposed research is expected to deliver on several of the following:

- Significantly advance the molecular and neurobiological understanding of how genetic, epigenetic and environmental risk and resilience factors (such as psychosocial experiences, diet, sleep, natural and artificial light, use or abuse of drugs, infections and other exposures) interact to drive or prevent the transition from mental health to mental illness¹² throughout the life course as well as how such molecular and neurobiological changes could be reversed. The use of computational modelling and/or artificial intelligence tools is encouraged for the analysis of big, complex and heterogeneous data¹³.
- Develop relevant predictive models through federated analysis of large European cohorts of psychiatric disorders and investigate the biological and neural basis of pathogenetic mechanisms and symptoms shared by different disorders. If relevant to the disorders studied, develop neurobiologically-grounded models of cognition and social behaviour and apply these models and their simulation potential to the understanding and improved

¹² This may include any mental and behavioural disorder(s) according to ICD-10 Chapter V (<https://icd.who.int/browse10/2019/en#/V>) except dementia. Neurological disorders are outside the scope of this topic. Psychiatric disorders to be studied may be acute, chronic or relapsing-remitting in nature and applicants are encouraged to also study the molecular/neurobiological changes brought about by interventions and associated with remission.

¹³ Data needs to meet the FAIR principles: findable, accessible, interoperable and reusable.

management of mental health conditions associated with behavioural or emotional dysfunction.

- Identify, validate and document different types or combinations of biomarkers for all of the following purposes:
 - o development of robust quantitative, clinical measures of mental health;
 - o identification of signatures, for example genetic and epigenetic blueprints, conferring susceptibility to and protection against mental illnesses;
 - o establishment of more objective diagnostic and monitoring criteria (complementing current symptom-based criteria) to improve patient outcomes and reduce the stigma associated with mental illness;
 - o prediction of treatment response and risk of relapse for better, more scientifically-guided and targeted use of currently available preventive and therapeutic interventions for different population groups.

For biomarker discovery, applicants are encouraged to take stock of advances in disciplines such as for instance neuropsychology, neurophysiology, neuroendocrinology, neuroimaging, electrophysiological monitoring, e-health/m-health, -omics (genomics, epigenomics, transcriptomics, proteomics, metabolomics, lipidomics, exposomics, microbiomics including the role of the microbiota-gut-brain axis), optogenetics, nanomedicine, stem cell biology, neuroimmunology and immunopsychiatry.

- Discover new disease pathways and drug targets (including pathways involved in maintaining mental health) to boost the development of new (or repurposed) classes of safer and more effective medications¹⁴ for the prevention and treatment of mental illnesses (including relapse prevention).
- Establish the molecular and neurobiological effects as well as cognitive and psychological consequences of both pharmacological and non-pharmacological prevention strategies (for example: neurostimulation, neurofeedback, psychotherapy and other psychological/behavioural interventions, light therapy, diet, exercise, lifestyle, mindfulness or a combination of them) and assess their efficacy and side effects as part of clinical trials (also determining windows of opportunity when preventive actions are most effective throughout the life course).

Proposals may cover different stages in the continuum of the innovation cycle (from basic and translational research to the validation of findings in real-world settings) and should ensure strong involvement of end-users, including citizens and patients. Sex and gender differences and the effects of age should be duly taken into account. International cooperation is encouraged and the proposed research is expected to be multidisciplinary, including through

¹⁴ Going beyond monoaminergic neurotransmitter systems by targeting novel pathways and addressing also the challenge of getting drugs pass through the blood-brain barrier.

the involvement of medical sciences, psychological sciences, social sciences and the humanities.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-HLTH-2021-STAYHLTH-01-03: Healthy Citizens 2.0 - Supporting digital empowerment and health literacy of citizens

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 3.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 3.00 million.
<i>Type of Action</i>	Coordination and Support Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several impacts of destination 1 “*Staying healthy in a rapidly changing society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- European citizens are educated, motivated and empowered to use digital tools for monitoring and managing their own physical, mental and social health and well-being. As a result, they take on a more active role in achieving their health potential and in adopting healthy lifestyles at home, in the community and at work, and they also interact better with their doctors and carers (receiving and providing feedback). Citizens are more health literate, are more autonomous and active, participate more in social life, have better employment opportunities, take on a more active role in achieving their health potential and in turn have a higher quality of life.
- Member States actively contribute to health literacy efforts, monitor and evaluate them.
- Health care and social services are better integrated, affordable, open to diversity and inclusion: they comply with precautionary protections concerning sensitive health data,

consider the needs of end users (citizens, formal and informal carers) and innovation carriers (SMEs, hospitals) and favour tools of social innovation.

- Health promotion and disease prevention are enhanced by the awareness of healthier lifestyle behaviours, and overall there are better health outcomes throughout the life-course. There is a greater involvement of non-health sectors (including environment, food, safety and occupational health) and this has a direct impact on the determinants of health. Overall, there is a boost in the transition from treatment to prevention and this contributes to the reengineering of prevention into health care.

Scope: Digital technologies are a driving force for empowering citizens in taking on an active role in the management of their own health and well-being as well as for supporting innovations for coordinated person-centred care models.

There is a growing body of evidence demonstrating the value of digital health interventions and solutions for health promotion, disease prevention and treatment. However, in parallel, it is vital to ensure that online-based patient-centred programmes do not leave behind the very people they are primarily designed to empower. Moreover, citizen's digital health literacy is essential for the successful transformation of health care systems.

Accordingly, the proposed activities should address all of the following:

- Map health literacy research in the EU (and beyond).
- Develop a comprehensive and inclusive European strategy in improving (digital) health literacy for the benefit of all citizens focusing on health promotion, disease prevention, treatment and (self-)care as well as on monitoring its impact on the quality of life, wellbeing, productivity and the economy, taking into account geographic, social and economic determinants of inequities in digital health literacy.
- Help patients navigate the health care systems, interact with their doctors and carers as well as better manage their own health at home, in the community and at work.
- Create a network of champions in digital health literacy across the EU (and beyond) to foster exchange and uptake of best practices.
- Set concrete targets as well as areas for improvement on health literacy levels across Europe.
- Develop monitoring mechanisms and indicators to assess health literacy levels and their evolution across Member States.
- Include stakeholders from all relevant sectors (including but not limited to education, innovation, health care, Medtech, media) and involve also citizens in the co-creation, design, planning, implementation and evaluation of the strategy, including through social innovation tools and approaches.

In all instances, gender as well as demographic, geographic and socio-economic aspects should be duly taken into account.

HORIZON-HLTH-2021-STAYHLTH-01-04: A roadmap for personalised prevention

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 3.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 3.00 million.
<i>Type of Action</i>	Coordination and Support Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several impacts of destination 1 “*Staying healthy in a rapidly changing society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Researchers, research funders and policy-makers implement a Strategic Research and Innovation Agenda.
- Policy makers, public health services, industrial stakeholders and citizen associations across Europe work together with a coordinated, harmonised and comprehensive research approach towards personalised prevention for all.
- Public health services, health systems and citizen associations are aware and adopt personalised prevention strategies.
- Insurers and public authorities take evidence-based policy decisions for implementing personalised prevention strategies for all.

Scope: The progress in medicine over the past decades has been impressive. Nevertheless, many promising advancements have not yet been taken up in health care. Thanks to personalised approaches and the development of targeted interventions, several health conditions that were until recently very serious or even fatal, can now be cured, attenuated or turned into a chronic health condition. However, more could be achieved if we could identify individuals at higher risk of developing a particular condition early on and before symptoms occur. In this regard, it is worth noting that two thirds of chronic diseases are thought to be preventable.

Personalised prevention therefore holds many promises and would allow for a paradigm shift in the provision and management of health care if efforts are co-ordinated and concentrated at the European and global levels. A number of successful individual preventive approaches are already deployed, for example in the field of cancer. However, more insight is needed on the

underlying human biology, taking stock of the rich data accumulated from the biomedical sciences. Furthermore, successful strategies will require holistic approaches, taking into account behavioural and life style factors. Most importantly, better co-ordination is essential to foster and accelerate the development and adoption of personalised prevention strategies for the years to come. It will also be important to assess the value of prevention in terms of savings in the health system.

Proposals should address all of the following:

- Identification and networking of key stakeholders for the co-creation of strategies for personalised prevention.
- Literature mapping, research gap analysis and mapping of existing research programmes for personalised prevention in Europe and beyond.
- Identification of existing bottlenecks, analysis of evidences and examples of successful implementation of personalised prevention approaches and assessment of their transferability.
- Analysis of how personalised prevention can be delivered most effectively, efficiently and cost-effective.
- Robust, professional communication strategy to maximise the impact of the findings and the uptake of personalised prevention strategies.
- A Strategic Research and Innovation Agenda on personalised prevention throughout the life course to inform research funders and other prospective partners of the expected future European partnership on personalised medicine.

Proposals should engage with related research initiatives (e.g. ICPeMed) and provide input to prospective partners of the expected future European partnership on personalised medicine.

Proposals should encourage a patient-centred approach that empowers patients, promotes a culture of dialogue and openness between health professionals, patients and their families, and unleashes the potential of social innovation.

HORIZON-HLTH-2021-STAYHLTH-01-05: Mobilising a network of National Contact Points (NCPs) for the Health Cluster

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 3.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 3.00 million.

<i>Type of Action</i>	Coordination and Support Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>The following additional eligibility criteria apply: Applicants must be Horizon Europe national support structures (e.g. NCP) responsible for Health and officially nominated to the Commission, from a Member State or Associated Country.</p> <p>Only in case and as long as Horizon Europe structures would not yet be officially nominated, national support structures responsible for Health (SC1) nominated for Horizon 2020 would be eligible.</p>
<i>Procedure</i>	<p>The procedure is described in General Annex F. The following exceptions apply:</p> <p>The granting authority can fund a maximum of one project.</p>

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to all of the expected impacts of destination 1 “*Staying healthy in a rapidly changing society*”, as well as the expected impacts of all other destinations of the health cluster. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- An improved and professionalised NCP service across Europe, thereby helping simplify access to Horizon Europe calls, lowering the entry barriers for newcomers, and raising the average quality of proposals submitted.
- A more consistent level of NCP support services across Europe.
- The network of National Focal Points (NFPs)¹⁵ supporting the implementation of the EU Health programmes and the Enterprise Europe Network (EENs)¹⁶ providing support for small and medium-sized enterprises will be closely collaborating with the network of National Contact Points (NCPs) for the Health Cluster based on identified complementarities and synergies.

Scope: Proposals should aim to facilitate trans-national co-operation between National Contact Points (NCPs) with a view to identifying and sharing good practices and raising the general standard of support to programme applicants.

The network will organise NCP Information Days, NCP trainings, brokerage events for potential participants and provide appropriate tools and instruments to support NCPs and researchers. Activities will support researchers of the social sciences and humanities to connect into all Clusters of Horizon Europe. To achieve its expected outcomes and objectives,

¹⁵ https://ec.europa.eu/chafea/health/national-focal-points/index_en.htm

¹⁶ <https://een.ec.europa.eu/>

the NCP network could cooperate with but should not duplicate actions foreseen in other thematic and horizontal Horizon Europe NCP networks.

Proposals should include a work package to implement matchmaking activities to link up potential participants from widening countries with emerging consortia in the domain of the Health Cluster. Matchmaking should take place by means of online tools, brokerage events, info days and bilateral meetings between project initiators and candidate participants from widening countries. Other matchmaking instruments may be used as appropriate. Where relevant, synergies should be sought with the Enterprise Europe Network to organise matchmaking activities in accordance with Annex IV of the NCP Minimum Standards and Guiding Principles.

The proposed structure and activities of the HE Health NCP network, should be closely interlinked with and associated to (at national and regional level) with those of the National Focal Points (NFPs) supporting the EU Health programmes. It is important to facilitate cooperation, identify and use synergies between the work of these two NCP and NFP networks - but also with other NCPs/NFPs responsible for different EU programmes providing funding available for health-related actions. This cooperation would not only improve the quality of the relevant actions funded by Horizon Europe and EU4Health but also the overall EU-level public health impact of all health-related actions using any EU funding.

Special attention should be given to enhancing the competence of NCPs, including helping less experienced NCPs rapidly acquire the know-how built up in other countries.

The consortium should have a good representation of experienced and less experienced NCPs.

The proposal should cover the whole duration of Horizon Europe plus one year.

Call - Staying healthy (Two stage - 2022)

HORIZON-HLTH-2022-STAYHLTH-01-two-stage

Conditions for the Call

Indicative budget(s)¹⁷

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project	Number of projects expected
		2022		

¹⁷ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

**Horizon Europe - Work Programme 2021-2022
Health**

			(EUR million) ¹⁸	to be funded
Opening: 06 Oct 2021 Deadline(s): 01 Feb 2022 (First Stage), 06 Sep 2022 (Second Stage)				
HORIZON-HLTH-2022-STAYHLTH-01-01-two-stage	RIA	50.00 ¹⁹	Around 7.00	7
HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage	RIA	60.00 ²⁰	Around 6.00	10
HORIZON-HLTH-2022-STAYHLTH-01-05-two-stage	RIA	60.00 ²¹	Around 10.00	6
Overall indicative budget		170.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

¹⁸ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹⁹ Of which EUR 30.00 million from the 'NGEU' Fund Source.

²⁰ Of which EUR 36.00 million from the 'NGEU' Fund Source.

²¹ Of which EUR 36.00 million from the 'NGEU' Fund Source.

HORIZON-HLTH-2022-STAYHLTH-01-01-two-stage: Boosting mental health in Europe in times of change

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 7.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 50.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several impacts of destination 1 “*Staying healthy in a rapidly changing society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Health care professionals, national/regional public authorities and other relevant actors in key settings (e.g. schools, workplaces, etc.):
 - Have access to and apply evidence-based, innovative, cost-effective/cost-neutral, large-scale, comprehensive strategies and interventions for the promotion of mental health and the prevention of mental ill health, targeting the most vulnerable populations;
 - Adopt clinical guidelines, best practices, implementation strategies and policy recommendations (as applicable to them) to mitigate the mental health burden and help cope with the (combined) effects of a transforming Europe (e.g. the socio-economic consequences of the COVID-19 pandemic, climate change, environmental degradation, energy transition, demographic and migration factors, digitalisation, and exponential technological advancements);
- The scientific community together with the public authorities anticipate new and emerging risks to mental health associated with a transforming Europe, contributing to better and inclusive public mental health preparedness.
- Citizens have access to and make use of new tools and services to take informed decisions about their wellbeing and mental health care needs (including for self-management and self-care).
- Citizens feel less stigmatised and marginalised due to their mental ill health.

Scope: Against the backdrop of a transforming Europe and in the midst of a global pandemic, the EU is committed to lead the transition to a healthier planet and a new digital world. The health and wellbeing of its citizens is a prerequisite to achieve this aspiration.

On the one hand, extreme weather and environmental disasters have risen dramatically over the last decade. Links between these events and serious mental health problems, including anxiety, depression, post-traumatic disorder and suicide, have been reported. Moreover, several new words such as “eco-anxiety”, “ecoparalysis” and “ecological grief” have been coined to express the acute and/or chronic effects on mental health caused by climate and environmental changes.

On the other hand, digital technologies and the achievement of the Digital Single Market – one of the EU’s key priorities – are transforming our economy, our industries as well as our culture and lifestyle. Digitalisation, including digitally-enabled technologies such as robotics and artificial intelligence, are penetrating much faster into societies than in the past and affect us all. Accordingly, the “Fourth Industrial Revolution” is changing the way we work (e.g. workplaces, working practices and patterns, the workforce and its skills, and how we perceive work) as well as the way we live. The exponential incorporation of digital technologies in our daily lives has already caused profound changes in the way we communicate and is likely to have significant impact (both positive and negative) on mental health and intellectual/cognitive ability, in particular of the youth. Digital platforms can provide mental health support as well as increase social inclusiveness. However, digital technologies also introduce new risks, such as continuous connectivity, cyberbullying and exposure to inappropriate or fake content.

Accordingly, the proposed research should aim to deliver in all three dimensions listed below, focusing on one or several of the (combined) effects of a transforming Europe highlighted in the “Expected Outcomes”²².

1. Provide a comprehensive knowledge base of how a transforming Europe can influence mental health in a fast-evolving society, especially in the most vulnerable populations, by consolidating data from relevant sources and/or acquiring new data, and by reviewing existing methodologies.
2. Develop and implement (pilot and/or scale-up) interventions, which promote wellbeing and prevent mental illness to help cope with and mitigate the stress of a changing society, including digitalisation, climate change and/or other factors highlighted in the “Expected Outcomes”.⁸ The interventions should target relevant settings (e.g. workplaces, schools) and the most vulnerable populations (e.g. children and adolescents, the elderly, people with pre-existing health conditions and co-morbidities and other high-risk groups such as socio-economic disadvantaged groups, migrants, etc.). Integration of care and coordination among different settings from communities to health care is desirable. The effectiveness of the interventions should be evaluated, inter alia, in terms of health outcomes, (comparative) cost-effectiveness, implementation facilitators and barriers. Depending on the aspects covered by the proposed research, desired outputs may include, but are not limited to:

²² For instance, the socio-economic consequences of the COVID-19 pandemic, climate change, environmental degradation, energy transition, demographic and migration factors, digitalisation, and exponential technological advancements.

- o Evidence-based guidelines for health care professionals on the promotion of mental wellbeing and prevention of mental illness related to ICT and climate and environment change (including screening methods).
 - o Evidenced-based pedagogical practices for education professionals to foster mental health promotion in schools (including higher education) and/or via eLearning.
 - o Consultation during school time to educate students (e.g. on coping with change) and to detect early students at risk.
 - o Educational material and campaigns targeting the most vulnerable groups, (e.g. children and the elderly), disseminated via the most appropriate and effective media and communication channels, to improve health literacy, skills, attitudes and self-awareness leading to a better (self-)management of wellbeing and/or mental ill health.
 - o Studies on occupational mental health in the workplace, in particular in small and medium-sized enterprises, e.g.: i) understanding the impact of a 24-hour digital economy on workers' well-being, also in terms of managerial control mechanisms, work-life balance and privacy and developing/piloting new methods to protect and support workers' well-being in this respect; ii) designing information and training campaigns for workers to integrate the already visible impacts of digitalisation-induced changes into the professional risk assessment processes; iii) developing return-to-work programmes, also exploring innovative collaboration between mental health services, (life-long) education, and employment sectors. This will ensure appropriate support to better integrate individuals affected by mental ill health in the workforce and the society.
3. Inform policy-makers and regulators on: i) the prevalence and burden of mental ill health related to a transforming European society (e.g. digital technologies, climate change, etc); and/or ii) the effects of a transforming European society (e.g. digitalisation, climate change and transition to “green jobs”) on occupational mental health; and/or iii) the (comparative) cost-effectiveness of public mental health interventions/policy choices.

Research should be multidisciplinary, including medical sciences, social sciences, the humanities, and the arts, if relevant. It is important to consider aspects such as (associated) behavioural patterns, stigma and novel social dynamics as well as different socioeconomic, cultural and geographical contexts. In all instances, sex and gender-related issues must be taken into account. All data should be disaggregated by sex, age and other relevant variables, such as by measures of socioeconomic status (i.e. take into account the socioeconomic gradient in mental health). International collaboration is encouraged.

Proposals should involve end-users (including civil society organisations) and/or strategic partners in the design and during the course of the project. Possible end-users and strategic partners could include local or regional authorities, community services, employers, schools/universities, cultural institutions, insurance companies, civil society organisations,

communities, among others. Proposals should adopt a patient-centred approach that empowers patients, promotes a culture of dialogue and openness between health professionals, patients and their families, and unleashes the potential of social innovation.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage: Trustworthy artificial intelligence (AI) tools to predict the risk of chronic non-communicable diseases and/or their progression

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 1 “*Staying healthy in a rapidly changing society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes.

- Clinicians, medical professionals and citizens have access to and use validated AI tools for disease risk assessment. Hence, citizens are better informed for managing their own health.
- Health care professionals utilise robust, trustworthy and privacy-preserving AI tools that help them to assess and predict the risk for and/or progression of chronic non-communicable diseases. Hence, citizens benefit from improved health outcomes.
- Health care professionals develop evidence-based recommendations and guidelines for the implementation of AI-based personalised prevention strategies. Hence, citizens benefit from optimized health care measures superior to the standard-of-care.

- Health care professionals employ quantitative indicators in order to identify and follow-up on individuals with high risk for the development and/or risk for the progression of chronic non-communicable diseases.

Scope: It is widely recognised that health systems must put more emphasis on prevention and adopt a person-centred approach. Artificial intelligence (AI) along with the increased availability of health data hold great potential to pave the way for personalised prevention and enable progress towards risk prediction and early detection of chronic non-communicable diseases.

This topic will support multidisciplinary research, build on broad stakeholder engagement and support proposals developing novel robust and trustworthy²³ AI tools to enable timely personalised prevention approaches for chronic non-communicable diseases/disorders. The topic does not exclude any diseases/disorders.

Proposals are expected to develop and test AI tools for assessing and predicting the risk of developing a disease and/or the risk of disease progression once it is diagnosed, taking into account the individuals' (or groups) genotypes, phenotypes, life-style, occupational/environmental stressors and/or socio-economic and behavioural characteristics, as necessary. Sex and gender aspects should be considered, wherever relevant.

The AI tools may include a broad range of technological solutions on their own and/or in combination with other relevant state-of-the-art technologies (i.e. AI algorithms, mobile apps and sensors, robotics, e-health tools, telemedicine etc.)

Proposals should implement proof-of-concept studies to test and validate the performance of their AI tools in the real-world setting and compare their performance to the established practice.

The applicants should ensure that the AI tools developed are driven by relevant end-users/citizens/health care professionals needs. Therefore, the proposals are expected to introduce concrete measures for the involvement of the end-users throughout the AI development process and not only in the last phases of development. SME(s) participation is encouraged with the aim to strengthen the scientific and technological basis of SME(s) and valorise their innovations for the people's benefit.

Proposals should address all of the following:

- Leverage existing high-quality health-relevant data from multiple sources (i.e. cohorts, electronic health records and registries, taking into account the individual's genotypic/phenotypic, medical, life-style, socio-economic, behavioural data etc.) and/or generation of new high-quality health data necessary for the rigorous development of the AI disease-risk tools.

²³ Ethics Guidelines for Trustworthy AI, published by the European Commission's High Level Expert Group on Artificial Intelligence, <https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines#Top>.

- Develop the adequate performance metrics to assess the technical robustness of the developed AI tools for risk assessment of disease and/or disease progression and in particular their accuracy, reliability, reproducibility and generalisability. Proposals should assess the possible inherent bias introduced to the AI tools originating from the data quality used for their development.
- Develop the criteria to assess the effectiveness of the AI tools for disease risk assessment in terms of improving health outcomes and enabling personalised prevention strategies.
- Implement proof of concept and/or feasibility studies to validate the AI tools for risk assessment of disease and/or disease progression in a relevant end-users environment and/or real-world setting and assess their performance in comparison to the standard-of-care.

Proposals should adhere to the FAIR²⁴ data principles and apply good practices for GDPR-compliant personal data protection. Proposals are encouraged to implement international standards and best practices used in the development of AI solutions.

Integration of ethics and health humanities perspectives to ensure an ethical approach to the development of AI solutions. In relation to the use and interpretation of data, special attention should be paid to systematically assess for gender and ethnic bias and/or discrimination when developing and using data-driven AI tools.

To ensure citizens' trust, wide uptake by user communities and scalability of the solutions across clinical contexts, actions should promote the highest standards of transparency and openness of the AI tool, going well beyond documentation and extending to aspects such as assumptions, architecture, code and underlying data.

Applicants are highly encouraged to deliver a plan for the regulatory acceptability of their technologies and to interact at an early stage with the regulatory bodies, whenever relevant.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

²⁴ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

HORIZON-HLTH-2022-STAYHLTH-01-05-two-stage: Prevention of obesity throughout the life course

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several impacts of destination 1 “*Staying healthy in a rapidly changing society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Researchers, developers of medical interventions, and health care professionals have a much better understanding of basic biological pathways (genetic and epigenetic blueprints) conferring susceptibility to and protecting against overweight/obesity, i.e. how genetic, epigenetic, environmental, socio-economic and lifestyle factors interact to drive or prevent the transition from normal weight to overweight/obesity throughout the life course.
- Health care professionals, national/regional/local public authorities and other relevant actors (e.g. schools, canteens, hospitals, work places, shopping malls, sport centres):
 - o Have access to, adopt and implement evidence-based clinical guidelines, best practices, coordinated, pan-European, multidisciplinary preventive strategies, policy recommendations and/or new policies to fight overweight/obesity and their co-morbidities throughout the life course.
 - o Have access to and make use of a robust outcomes framework and tool-kit for standardised collection of economic and cost data related to the prevention and treatment of overweight/obesity and its co-morbidities at population level across European regions and countries.
 - o Adopt and implement tailor-made prevention campaigns to tackle overweight/obesity, including campaigns for improving integration of health

education into academic learning and raising awareness of health care providers and citizens.

- Citizens have access to and make use of new tools and services to make informed decisions about lifestyle choices that will prevent them from becoming overweight/obese.

Scope: Obesity is one of the most serious public health challenges of the 21st century. Although health has improved in the EU over the last decades, the prevalence of obesity has tripled in many countries of the EU. It is known that once individuals become overweight or obese, they are at risk of developing related diseases (diabetes, cardiovascular diseases, cancer). Overweight and obesity are largely preventable. In the current pandemic, the issue of overweight/obesity has become even more prominent, highlighting the need for prevention of overweight/obesity.

Increased efforts in research and innovation are critical for developing and testing the impact of tools, initiatives, interventions, strategies, programmes, policies and their implementation to prevent overweight/obesity. The use of best practices, harmonisation guidelines and/or standard operating procedures, developed at various levels (from local to national) in the EU and beyond, will be the foundation for new research.

Cultural diversity, urban/rural dichotomy, socio-economic status, age groups, sex and gender differences should be investigated, where relevant. Strong collaborations across sectors and with other European projects dealing with issues such as agriculture, aquaculture, food, environment, etc. are welcome. Proposals should engage citizens, civil society organisations (e.g. employers/employee organisations, charities), authorities (e.g. municipalities and health authorities) and institutions (schools, canteens, hospitals, work places, shopping malls, sport centres), local producers, etc. in the development of their actions to ensure acceptability and deployment. Proposals should aim to develop scientifically robust and transparent methodologies, building on achievements from previous research activities.

Proposals should address several of the following research bottlenecks:

- A comprehensive understanding of biological pathways (genetic, epigenetic, molecular, microbiome, and/or neuroimmune) conferring susceptibility to and protecting against uncontrolled "weight gain".
- Identification of socio-economic and lifestyle factors influencing consumer behaviour and their association to overweight/obesity prevention.
- Identification of pre-obesity biomarkers (genetic, laboratory, imaging, etc.) and their association to lifestyle and environmental interventions aiming at obesity prevention and tailored to specific target populations.
- Mapping existing implementation research activities to prevent overweight/obesity, outcome analyses and identification of best practices.

- Conducting a thorough meta-review of information from available scientific literature and identification of the relationship between the risk for overweight/obesity and the biology of obesity, lifestyle habits, exposures, susceptibility to co-morbidities and/or all of their combinations.
- Developing recommendations and guidelines for what constitutes an appropriate healthy diet for different age and health groups.
- Understanding the causal links between overweight/obesity and sedentary behaviour, quality and quantity and types of food/drinks, physical activity, and personality traits.
- Designing a creative and engaging programme to reach the optimal balance between diets and physical activity for the prevention of overweight/obesity.
- Analysing obesity stigma, stress and work-life balance, circadian rhythm disruption, mental health (including psychological problems), screen-time dependency, drugs and side effect of drugs, for the prevention of overweight/obesity.
- Addressing inequality aspects of overweight/obesity at multiple levels, taking into account vulnerable groups, gender and socio-economic factors.
- Setting up pilots to assess the effectiveness of obesity management strategies, including cost-effectiveness, and analyse the impact of inactions, taking into account co-morbidities and value-based care system.
- Developing a system for monitoring population indicators relevant to overweight/obesity by extending European Core Health Indicators.

Proposals should adopt a patient-centred approach that empowers patients, promotes a culture of dialogue and openness between health professionals, patients and their families, and unleashes the potential of social innovation.

Proposals could consider the involvement of the European Commission's Joint Research Centre (JRC) whose contribution could consist of providing added-value regarding aspects of healthier school environments, effectiveness of policies influencing food preferences as well as improving the food offer and food environment.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant

agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

Call - Staying healthy (Single stage, 2022)

HORIZON-HLTH-2022-STAYHLTH-02

Conditions for the Call

Indicative budget(s)²⁵

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ²⁶	Number of projects expected to be funded
		2022		
Opening: 06 Oct 2021 Deadline(s): 21 Apr 2022				
HORIZON-HLTH-2022-STAYHLTH-02-01	RIA	50.00	Around 7.00	7
Overall indicative budget		50.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General

²⁵ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

²⁶ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

	Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-STAYHLTH-02-01: Personalised blueprint of chronic inflammation in health-to-disease transition

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 7.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 50.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 1 “*Staying healthy in a rapidly changing society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to several of the following expected outcomes:

- Researchers and medical professionals understand the chronic inflammation factors triggering the health-to-disease transition and subsequently provide optimal counselling to citizens for improving their health.
- Health care professionals have access to and employ objective health indicators of chronic inflammation for monitoring the health status, establishing personalised prevention measures and improving the health outcomes for citizens.
- Health care professionals have the scientific evidence and understanding of health-to-disease transition to develop and use improved guidelines for personalised prevention strategies to tackle chronic diseases.
- Citizens are better informed to actively manage their own health, have the tools to maintain their healthy status, improve their health and reduce their risk for developing chronic diseases.

Scope: Personalised approaches for disease prevention seek to determine the predisposition to disease and deliver timely and targeted prevention measures. Understanding the risk factors

that trigger the health-to-disease transition is essential for delivering personalized prevention measures or reducing the burden of chronic diseases.

A large body of clinical evidence has accumulated over the past decade demonstrating that chronic inflammation is a process implicated in chronic diseases/disorders. Inflammatory response is a physiological process helping the body to heal against harmful entities, but when dysregulated it could lead to unresolved chronic local or systemic inflammation. The later in combination with the person's genotype, phenotype, medical history, nutritional and well-being status, life-style and/or occupational/environmental/life stressors is likely to be involved in driving the health-to-disease transition, leading to the onset of chronic diseases.

Proposals should be of multidisciplinary nature involving all relevant stakeholders and may cover several different stages in the continuum of the innovation path (from translational research to validation of the findings in human studies etc.), as relevant.

Proposals are expected to develop and implement data-driven, personalised approaches to identify the drivers of chronic inflammation that may determine the transition from health to pre-symptomatic and early stages of chronic diseases/disorders. The topic does not exclude any diseases/disorders. The human studies and human data utilised/generated should be compatible to an age range as representative as possible to the pre-disease phase and onset of the disease to be studied, in order to boost the fast translation of the research results into proof-of-concept studies.

Proposals should develop personalised diagnosis and/or prevention strategies linked to chronic systemic/local inflammation and assess the effects of different types of interventions and/or their combinations i.e. pharmacological, non-pharmacological, nutritional supplements, diet and life-style modifications, as relevant. Sex and gender differences should be investigated, wherever relevant.

The proposals should address several of the following areas:

- Integrate state-of-the-art knowledge and data from suitable human studies (i.e. medical/clinical, well-being, life-style etc.) to identify actionable factors linking chronic systemic and/or local inflammation to the health-to-disease transition. Take stock of omics (i.e. genomics, metabolomics, nutrigenomics, microbiomics etc.), of dynamic measurements of the health and well-being status, and of data-driven analytical tools in order to identify biomarkers and other health indicators linked to the health-to-disease transition.
- Understand at the systems-level the human biology and physiology underlying chronic inflammation in connection to the tissues/organ dysregulation, organ cross-talk and homeostasis breakdown triggering the health-to-disease transition, taking into account the person's genotype, phenotype, medical history, nutritional and well-being status, life-style and/or occupational/environmental/life stressors.
- Develop and deploy robust sensors, devices and/or mobile apps and other innovative technologies to monitor dynamically the individual's health status and to identify

objective indicators of chronic inflammation correlative to the health-to-disease transition.

- Implement proof-of-concept human studies to assess the beneficial effect of diverse prevention and/or interventions strategies with the aim to demonstrate improved health outcomes.
- Test suitable interventions with the aim to demonstrate the reduction and/or reversion of the pre-disease state linked to chronic systemic and/or local inflammation.

Proposals should adopt a patient-centred approach to inform and empower patients, promote a culture of dialogue and openness between health professionals, patients and their families, and unleash the potential for social innovation.

The proposals should adhere to the FAIR²⁷ data principles and adopt wherever relevant, data standards and data sharing/access good practices developed by existing European health research infrastructures.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

²⁷ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

Destination 2. Living and working in a health-promoting environment

Calls for proposals under this destination are directed towards the Key Strategic Orientation KSO-D *'Creating a more resilient, inclusive and democratic European society'* of Horizon Europe's Strategic Plan 2021-2024. Research and innovation supported under this destination should contribute to the impact area *'A resilient EU prepared for emerging threats'* and in particular to the following expected impact, set out in the Strategic Plan for the health cluster: *'living and working environments are health-promoting and sustainable thanks to better understanding of environmental, occupational, social and economic determinants of health'*. In addition, research and innovation supported under this destination could also contribute to the following impact areas: *'Good health and high quality accessible health care'*, *'Climate change mitigation and adaptation'*, and *'Clean and healthy air, water and soil'*.

The environment we live and work in is a major determinant of our health and well-being. It has direct or indirect beneficial or adverse impact on our health and well-being. Environmental factors are estimated to account for almost 20% of all deaths in Europe. Opinion surveys have shown that European citizens are concerned about the impact of pollution on their health. The impacting factors on both physical and mental health and well-being are not all identified nor their effects comprehensively understood and accounted for to support evidence-based policy- and decision-making. Furthermore, agreed methodologies to estimate health-related costs of exposure to environmental stressors are lacking.

Therefore, Destination 2 aims at filling knowledge gaps in the understanding of the impacts on our health and well-being of those environmental, occupational and socio-economic risk factors that have the most significant or widespread societal impacts. In this work programme, Destination 2 focuses on indoor and outdoor air pollution, chemicals, non-ionizing radiation (electromagnetic fields), urbanisation, climate and other environmental changes, socio-economic inequalities, and changing working environments. Furthermore, under this work programme a topic is dedicated to the creation of a European partnership for the assessment of risks from chemicals, which should establish the EU as an internationally recognised driver of innovative chemical risk assessment for an optimal protection of human health and the environment. The results will support the EU's environment and health policies and overarching policy frameworks such as the European Green Deal, the Chemical Strategy for Sustainability, the 8th Environment Action Programme, the EU Strategic Framework on Health and Safety at Work as well as the WHO European Environment and Health Process (EHP).

Strong collaborations across sectors and with other Horizon Europe clusters dealing with issues such as agriculture, food, environment, climate, mobility, security, urban planning, social inclusion and gender will be needed to ensure that maximal societal benefits are reached. Thus, in view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, the

development and adoption of best practices, or joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic but also between other projects funded under another topic, cluster or pillar of Horizon Europe (but also with ongoing projects funded under Horizon 2020). In particular, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health and EIT-KIC Health (under pillar III of Horizon Europe), or in areas cutting across the health and other clusters (under pillar II of Horizon Europe).

All topics are open to international collaboration to address global environment and health challenges.

Expected impacts:

Proposals for topics under this destination should set out a credible pathway to contributing to living and working in a health-promoting environment, and more specifically to one or several of the following impacts:

- Policy-makers and regulators are aware and well informed about environmental, socio-economic and occupational risk factors as well as health-promoting factors across society;
- Environmental, occupational, social, economic, fiscal and health policies and practices at the EU, national and regional level are sustainable and based on solid scientific evidence. These include overarching policy frameworks such as the European Green Deal, the Chemical Strategy for Sustainability, the 8th Environment Action Programme, the EU Strategic Framework on Health and Safety at Work and the European Environment and Health Process led by the World Health Organization;
- The upstream determinants of disease - related to choices in energy generation, agricultural practices, industrial production, land use planning, built environment and construction - are known, understood and reduced;
- The health threats and burden resulting from hazardous chemicals and air, water and soil pollution and contamination is reduced, so that the related number of deaths and illnesses is substantially reduced by 2030;
- Living and working environments in European cities and regions are healthier, more inclusive, safer, resilient and sustainable;
- The adaptive capacity and resilience of populations and health systems in the EU to climate and environmental change-related health risks is strengthened;
- Citizens' health and well-being is protected and promoted, and premature deaths, diseases and inequalities related to environmental pollution and degradation are prevented;

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- Citizens understand better complex environment and health issues, and effective measures to address them and support related policies and regulations.

The following call(s) in this work programme contribute to this destination:

Call	Budgets (EUR million)		Deadline(s)
	2021	2022	
HORIZON-HLTH-2021-ENVHLTH-02	130.00		21 Sep 2021
HORIZON-HLTH-2021-ENVHLTH-03	200.00		21 Sep 2021
HORIZON-HLTH-2022-ENVHLTH-04		20.00	21 Apr 2022
Overall indicative budget	330.00	20.00	

Call - Environment and health (2021)

HORIZON-HLTH-2021-ENVHLTH-02

Conditions for the Call

Indicative budget(s)²⁸

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ²⁹	Number of projects expected to be funded
		2021		
Opening: 22 Jun 2021 Deadline(s): 21 Sep 2021				
HORIZON-HLTH-2021-ENVHLTH-02-01	RIA	30.00 ³⁰	Around 8.00	4
HORIZON-HLTH-2021-ENVHLTH-02-02	RIA	40.00 ³¹	Around 8.00	5
HORIZON-HLTH-2021-ENVHLTH-02-03	RIA	60.00 ³²	Around 10.00	6
Overall indicative budget		130.00		

General conditions relating to this call

<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.

²⁸ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

²⁹ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

³⁰ Of which EUR 18.00 million from the 'NGEU' Fund Source.

³¹ Of which EUR 24.00 million from the 'NGEU' Fund Source.

³² Of which EUR 36.00 million from the 'NGEU' Fund Source.

<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2021-ENVHLTH-02-01: Exposure to electromagnetic fields (EMF) and health

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 30.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 ‘*Living and working in a health-promoting environment*’. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Public authorities and regulators are supported with scientific evidence to implement the Council Recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) as well as Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields), in particular the implementation of article 1.4 of the Directive, as well as the most recent ICNIRP guidelines³³ for limiting exposure to electromagnetic fields;
- Public authorities improve their risk assessment, management and communication through access to FAIR³⁴ data and robust evidence on the exposure to EMF, in particular for the new generation radio-communication networks (e.g. 5G networks), and on the causal links between level and duration of exposures and health effects;

³³ HEALTH PHYS 118(5): 483–524; 2020

³⁴ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

- Public authorities and the scientific community take advantage of novel and robust methodologies, including models, for the assessment of health impact of exposures;
- Stakeholders consistently use quality criteria and standards (CEN/ISO³⁵) for the analytical methodologies in the assessment of exposure to EMF, including 5G, and their impact on human health and on the environment;
- Public authorities, employers and citizens rely on practical guidelines for exposure prevention and reduction;
- Citizens are effectively engaged and informed about the health impact of EMF exposures and risk-preventing behaviours.

Scope: Digital technologies and electronic communication services are a critical enabler for attaining the sustainability goals of the European Green Deal in many different sectors. The use of the new generation radio-communication networks, e.g. 5G (the fifth generation of mobile phone technology), promise higher data transfer rates and increased network capacity compared with previous generations. While digitalisation presents new opportunities, e.g. distance monitoring of air and water pollution and health outcomes, it also presents potential health risks. Europe needs a digital sector that puts sustainability at its heart: when deploying new technologies, the potential risks related to human health should also be assessed, in addition to the significant benefits.

There has been an exponential increase in the use of wireless personal communication devices (mobile phones, WiFi or Bluetooth-enabled devices etc.) by almost all citizens in private and professional settings and in the supporting infrastructures. The number of other applications using EMF has also increased such as security scanners, smart meters and medical equipment. This has resulted in an increase in man-made electromagnetic radiation in our surroundings.

The International Commission on Non-Ionizing Radiation Protection (ICNIRP) issues guidelines for limiting exposure to electric, magnetic and electromagnetic fields. EU member states are subject to Council Recommendation 1999/519/EC and the Directive 2013/35/EU, which follow basic rules on EMF exposure evaluation provided by ICNIRP guidelines. Nevertheless, there is some concern over the possible impact on health and safety from potentially higher exposure to EMF, e.g. arising from the deployment of 5G technology. Increased exposure may result from, for instance, the additional use of higher frequencies, and from the potential aggregation of different signals, especially in cities.

Research actions under this topic should provide forward-looking information on potential hazards and risks of existing and emerging EMF exposures through innovative monitoring techniques, experimental evidence and modelling and should include all of the following activities:

- Monitoring of exposures of the general population and specific groups at risk such as children and workers using innovative technologies;

³⁵ https://www.cencenelec.eu/news/brief_news/Pages/TN-2017-057.aspx

- Establishment of potentially new exposure patterns and comparison with existing patterns, e.g. those generated by the use of previous generations of mobile phone technologies. It should be documented how exposures to EMF changes over time due to the introduction of new technologies, including 5G, supporting infrastructure, radiofrequency bands, modulation techniques and applications;
- Investigating evidence of local and systemic biological effects and health impacts across the lifecycle using *in vitro* and *in vivo* approaches, respecting the 3Rs³⁶ principle, and taking into account combined exposures and changing patterns of device use;
- Delivering FAIR³⁷ data on the causal links between level and duration of exposures and potential health (biological) effects, including potential mechanisms, in living and working environments, considering also vulnerable groups, particularly children;
- Proposing new quality criteria and standards (CEN/ISO³⁸) for the analytical methodologies used for the assessment of exposure to EMF and their impact on human health and on the environment;
- Undertaking case studies on solutions for exposure reduction based on acquired evidence and deliver practical guidelines for exposure prevention along the stakeholder chain;
- Proposing and testing efficient communication methods and tools for engaging citizens in preventive actions and addressing their concerns.

Aspects such as gender, age, regional variations, socio-economics and culture should be considered, where appropriate.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-HLTH-2021-ENVHLTH-02-02: Indoor air quality and health

Specific conditions

³⁶ Replacement, reduction and refinement

³⁷ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

³⁸ https://www.cencenelec.eu/news/brief_news/Pages/TN-2017-057.aspx

<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 40.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 ‘*Living and working in a health-promoting environment*’. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Public authorities, consumer protection entities and patient associations have access to FAIR³⁹ data on air pollutants, including both chemical and microbiological determinants, and their main sources for relevant and representative indoor environments and settings in Europe;
- Society has access to user-friendly solutions to monitor indoor air quality, a knowledge base of risk factors associated to human health impacts related to the main indoor air determinants and guidelines for interventions to improve air quality;
- Policy-makers are provided with proposals for revised indoor air quality standards for the main determinants identified to support regulatory measures and improve regulatory monitoring;
- The Zero-Pollution Action Plan of the European Green Deal is supported by science-based evidence.

Scope: Air quality is primarily monitored in outdoor locations, often for regulatory targets compliance purposes. However, people spend the majority of their lives in indoor environments: e.g. at home, in the workplace, in schools and inside transport vehicles. Whereas improving outdoor air quality leads to general improvements of indoor air quality as well, certain sources of air pollution not covered by ambient air quality standards can dominate in some indoor environments. In the current pandemic situation, the issue of good indoor air quality has become even more prominent, encompassing issues such as the need of good ventilation of indoor spaces.

In addition to identifying determinants for indoor air quality, it is important to assess their health impacts in the levels reached indoors to facilitate setting of purposeful indoor air quality standards. The mere presence of a determinant may not mean harmful health effects and some (biological) determinants may even have beneficial health effects.

³⁹ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

Applicants should propose research actions that advance the understanding of the indoor air quality and related health and safety issues and should include all of the following activities:

- Identification and characterisation of sources and routes of exposure and dispersion of chemical and biological indoor air pollution, e.g. indoor air microbiome and allergens, viral pathogens, household chemicals, biocides in building materials, particulate matter, radon as well as emerging pollutants;
- Identification of differences and modes of interaction between indoor and outdoor air quality at relevant and representative locations;
- Development and deployment of technologies enabling cost-effective monitoring of indoor air quality (e.g. air quality sensors) and user-friendly alert systems;
- Development and deployment of effect-based test systems for the detection of synergistic effects of different biogenic particles and substances as well as additional chemical substances such as volatile organic compounds, including *in vitro* and *in vivo* approaches with respect to 3Rs⁴⁰;
- Identification of body burdens resulting from multipollutant (real-life scenario) indoor exposures and associated health effects, with specific focus on vulnerable population groups and sensitive life stages;
- Conducting dose-response studies to facilitate the setting of purposeful quality standards;
- Development of cost-effective, environment-friendly and scalable technologies to improve indoor air quality to reduce disease burdens;
- Preparation of guidelines and training materials for interventions, supporting health promotion and disease prevention in various sectors, e.g. construction and transport, and in various socio-economic settings;
- Delivery of FAIR⁴¹ data and databases structured to allow user-friendly access to information about exposures, sources and risk factors.

Aspects such as gender, regional variations, socio-economics and culture should be considered, where appropriate.

Proposals should ensure that chemical monitoring data are shared in IPCHEM⁴² through involvement with the European Commission's Joint Research Centre (JRC).

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve

⁴⁰ Replacement, reduction and refinement

⁴¹ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

⁴² <https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>

networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-HLTH-2021-ENVHLTH-02-03: Health impacts of climate change, costs and benefits of action and inaction

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 ‘*Living and working in a health-promoting environment*’. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Global and EU climate policies⁴³, the EU Observatory for Climate and Health⁴⁴, and the Green Deal activities are supported with up-to-date scientific evidence;
- Public authorities and surveillance organisations have access to predictive and early warning systems for direct and indirect health impacts caused by climate-change induced events and dispose of indicators for improved monitoring of policy actions;
- Public authorities, employers and risk managers draw benefit from user-friendly tools for integrated risk assessments and cost-benefit analysis of climate change mitigation and adaptation actions to support decisions across policy sectors;
- Public and private health authorities and care providers use guidelines and training materials produced to adapt and innovate health systems and practices to prevent and mitigate climate change related health risks in cost-efficient and effective ways.

Scope: The European Green Deal refocused the European Commission’s commitment of tackling climate and environment-related challenges. It also aims to protect, conserve and enhance the EU’s natural capital, and protect the health and well-being of citizens from

⁴³ New EU Strategy on Adaptation to Climate Change adopted on 24 February 2021 ([COM\(2021\)82](#))
⁴⁴ <https://climate-adapt.eea.europa.eu/observatory>

environment-related risks and impacts. In addition to aiming for climate neutrality by 2050, the Commission adopted a more ambitious EU strategy on adaptation to climate change on 24 February 2021. This is essential, as climate change will continue to create significant stress in Europe in spite of the mitigation efforts.

The World Health Organization estimates that climate change will cause at least 250 000 additional deaths per year globally between 2030 and 2050⁴⁵. Climate change, together with other natural and man-made health stressors, can influence human health and disease patterns in numerous ways. Some existing health threats will intensify and new health threats will emerge, with variable impact on different socio-economic groups. Climate changes induce events such as changes in biodiversity, disruption of ecosystems, habitats and land use, global warming and heat waves, changes in UV exposure or flooding. These events are influencing globally the incidence and spread of infectious diseases and increasing pollution, thereby causing new threats to human health.

The aim of this topic is the identification, monitoring and quantification of direct and indirect impacts on human health, including in occupational settings, and related risk factors correlated to climate change, especially in vulnerable population groups such as children or in groups at risk such as workers. Innovative surveillance tools are further required to ensure a timely response to emerging threats, to feed and strengthen early warning systems, and to enable the design, monitoring and evaluation of interventions. This may include mathematical modelling with big data and artificial intelligence (AI), remote sensing, citizen science and biomarkers of exposure or virulence.

Proposals must choose and address one of the following areas of research:

- Research on the relationships between changes in environmental hazards caused by climate change, the impacts on interrelated ecosystems and their influence on human health;
- Climate induced emergence and transmission of pathogens and spread of zoonotic pathogens using Eco-health⁴⁶ and One Health⁴⁷ approaches.

Proposals should include all of the following activities:

- Development of suitable indicators and monitoring mechanisms to assess the health-relevant outcomes of climate policies and actions;
- Development of predictive models and early warning systems for exposure and health impacts of climate change based on transparent assumptions and architecture;

⁴⁵ <https://www.who.int/news-room/fact-sheets/detail/climate-change-and-health>

⁴⁶ *Ecohealth* is a field of research, education, and practice that adopts systems approaches to promote the health of people, animals, and ecosystems in the context of social and ecological interactions.

⁴⁷ The *One Health* concept recognises that human health is tightly connected to the health of animals and the environment, for example that animal feed, human food, animal and human health, and environmental contamination are closely linked.

- Development of tools for health impact and cost-benefit assessment of climate-change adaptation and mitigation measures;
- Investigation of health co-benefits of adaptation and mitigation policy measures outside the health sector;
- Demonstration of the validity of tools and methods developed in the above listed activities in policy-relevant case studies;
- Determination of the societal implications of climate change on health systems, including occupational health, and development of adaptation measures;
- Development of training materials and guidelines to educate relevant actors in citizens' daily life on climate change health impacts and to facilitate adaptation of health systems and practices;
- Delivery of FAIR⁴⁸ data on positive and negative health impacts of climate change, including impact on groups at higher risk or vulnerability.

International cooperation is encouraged with the specific aim to support international climate policies. If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, they must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).⁴⁹

Aspects such as gender, age, regional variations, socio-economics and culture should be considered, where appropriate.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

Call - Partnerships in Health (2021)

HORIZON-HLTH-2021-ENVHLTH-03

⁴⁸ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability. This can include data from European data infrastructures and programmes such as Copernicus, European Space Agency and the GEO initiative.

⁴⁹ E.g. data and products provided by the Copernicus Climate Change Service <https://www.copernicus.eu/en>.

Conditions for the Call

Indicative budget(s)⁵⁰

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ⁵¹	Number of projects expected to be funded
		2021		
Opening: 22 Jun 2021 Deadline(s): 21 Sep 2021				
HORIZON-HLTH-2021-ENVHLTH-03-01	COFUND	200.00 ⁵²	Around 200.00	1
Overall indicative budget		200.00		

General conditions relating to this call

<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.

⁵⁰ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

⁵¹ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

⁵² Of which EUR 40.00 million from the 'NGEU' Fund Source.

<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.
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Proposals are invited against the following topic(s):

HORIZON-HLTH-2021-ENVHLTH-03-01: European partnership for the assessment of risks from chemicals (PARC)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 200.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 200.00 million.
<i>Type of Action</i>	Programme Co-fund Action
<i>Procedure</i>	The procedure is described in General Annex F. The following exceptions apply: The granting authority can fund a maximum of one project.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G. The following exceptions apply: Funding rate will be 50%. This is justified by the pooling of proposers' in-kind contributions and in-house activities.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 ‘*Living and working in a health-promoting environment*’. To that end, the proposal under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The EU is reinforced as an internationally recognised driver of innovation in chemicals risk assessment and thereby substantially contributing to the achievement of the Sustainable Development Goals related to chemicals;
- EU and national chemicals risk assessment and management authorities rely on a sustainable Europe-wide research and innovation platform for chemicals risk assessment, as identified in the Council Conclusions⁵³ of June 2019 ‘Towards a Sustainable Chemicals Policy Strategy of the Union’ and in the ‘Chemicals Strategy for Sustainability’⁵⁴, to provide joint new knowledge and innovate risk assessment processes;

⁵³ <https://www.consilium.europa.eu/en/press/press-releases/2019/06/26/council-conclusions-on-chemicals/>
⁵⁴ https://ec.europa.eu/environment/strategy/chemicals-strategy_en

- EU and national chemical risk assessment agencies and the scientific community enhance their collaboration and move towards ‘one substance – one assessment’ with shared evidence, tools and methodologies cutting across sectors;
- The Common European Green Deal Data Space is empowered, by providing it with reliable, relevant, curated and FAIR⁵⁵ data on chemicals in line with the European Strategy for Data⁵⁶;
- Synergies are established with relevant activities derived from other European Green Deal policy areas, such as the ‘Farm to Fork strategy’, the ‘Biodiversity Strategy for 2030’, the ‘8th Environment Action Programme’ and the ‘Zero Pollution Action Plan for Air, Water and Soil’, to understand and address their needs for research and innovation in chemicals risk assessment and ensure a better protection of the environment and human health from hazardous chemical exposures;
- Public authorities and industry engaged in developing a circular economy, including better waste management, as defined in the EU’s ‘Industrial Strategy’⁵⁷ and the ‘New Circular Economy Action Plan’⁵⁸, are supported with innovation in chemicals risk assessment.
- Workers are better protected from chemical risks as set out in the ‘EU Strategic Framework on Health and Safety at Work 2014-2020’⁵⁹ through better insight into exposures and health impacts and improved safety measures.

Scope: Chemicals risk assessors and managers are faced with data and knowledge gaps and lack of tools and methods, to speed up and prioritise risk assessments and capture risks from existing and emerging substances across regulatory domains. The lack of available or accessible information increases the risk of ‘regrettable’ substitutions and slows down the design of safer chemicals. A diverse landscape of regulatory frameworks and actors carrying out risk assessment of chemicals for their specific purpose has resulted in a fragmented approach. Risks to human and environmental health are still in certain cases considered separately, while in most cases they are inherently interrelated.

To enable risk assessors and risk managers to respond to current and future challenges, the Partnership⁶⁰ should stimulate research and innovation in chemicals risk assessment by developing a collaborative network with public research entities. A common research and innovation programme should be established by national and EU risk assessors and risk managers in consultation with relevant stakeholders (academia, industry, associations and others).

⁵⁵ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

⁵⁶ https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

⁵⁷ https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy_en

⁵⁸ <https://ec.europa.eu/environment/circular-economy/>

⁵⁹ <https://ec.europa.eu/social/main.jsp?catId=151>

⁶⁰ https://ec.europa.eu/info/files/european-partnership-chemicals-risk-assessment_en

Activities of the Partnership should be complementary and subsidiary to obligations under existing regulatory frameworks, and should coordinate with these as relevant. The Partnership should become a reference centre for research questions related to chemicals risk assessment, including those emerging from other Horizon Europe partnerships or missions. The Partnership is expected to establish relevant collaborations with other Horizon Europe partnerships and missions as set out in the working document on ‘Coherence and Synergies of candidate European partnerships under Horizon Europe’⁶¹ as well as to explore collaborations with other relevant activities at EU and international level. The Partnership should align with EU-wide initiatives on open access and FAIR data⁶².

The Partnership’s governance structure should engage upfront risk managers and risk assessors to coordinate, steer and frame the research and innovation activities, facilitate the use and uptake of the results in a regulatory context and contribute to a science based communication of the risk of chemicals. The Partnership’s governance and operational structures should also foster a dialogue on sustainability, beyond funding from EU research and innovation framework programmes, with political decision-makers and risk assessors.

Main blocks of activity:

1. Set-up and operate an EU-wide cross-disciplinary network to identify and agree on research and innovation needs and support research uptake into regulatory chemical risk assessment.

A dialogue and priority-setting process should be established, bringing together European regulatory entities and risk assessment agencies to develop a strategic research and innovation agenda for chemicals risk assessment in collaboration with the scientific community. This process should also facilitate access and uptake of new scientific knowledge that can contribute to regulatory science by policy-makers and risk assessors.

Relevant synergies should be fostered with other initiatives at national, EU or international level and targeted communication and dissemination should be implemented to ensure openness and transparency of this Partnership towards all concerned stakeholders. The Partnership should build on and extend the concept of National Hubs developed under the European Joint Programme on Human Biomonitoring, HBM4EU⁶³. Targeted citizen actions should be envisaged to increase their understanding of risks related to exposure to chemicals and reinforce their trust in risk assessment and risk management processes.

2. Carry out joint EU research and innovation activities on identified priorities to support the current regulatory risk assessment processes and respond to emerging challenges.

The Partnership should drive innovation in environmental and human exposure assessment. . New tools and methods for environmental and human exposure monitoring, including in

⁶¹ https://ec.europa.eu/info/horizon-europe/european-partnerships-horizon-europe_en#synergies

⁶² FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

⁶³ www.hbm4eu.eu

occupational settings, and to gather data on lifestyle and consumption behaviour, should be developed, validated and their harmonised use promoted. Biomarkers of effects in environment and in human should be developed as a proxy of environmental and health outcomes. Collaborations with existing programmes should be fostered; however, when required and relevant, the partnership can carry out monitoring and exposure assessment activities. This could entail monitoring of environmental media and human exposure to chemicals from various sources and exposure routes. For human biomonitoring, the Partnership should build on the results of HBM4EU and further exploit these as well as perform new studies for prioritised chemicals and regulatory questions. Moreover, human biomonitoring activities should be integrated in the wider exposure assessment and risk assessment contexts.

Toxicological or eco-toxicological studies to generate new data for chemical substances and mixtures relevant to public health (mechanistic, *in silico*, *in vitro* or *in vivo*), beyond the data required from industry under REACH or by other regulations, should be designed and performed, taking into account the Reduce-Refine-Replace (3Rs) principle and any regulatory requirements for their relevance. Novel methods for toxicological hazard assessment aligned with identified needs should be developed, and existing methods improved, including methods that can reliably screen (groups of) substances allowing to select the substances for which a full safety assessment is required. New Approach Methodologies (NAMs) should be integrated with classical experimental designs to improve hazard characterization and their regulatory acceptance promoted through validation or applicability studies.

The performance of current methodologies employed in regulatory risk assessment should be assessed to identify methodological knowledge gaps and R&I needs. Validation and standardisation of results and methods of the Partnership or from collaborating projects should be pursued, e.g. development of OECD Test Guidelines, to encourage their use in regulatory risk assessment. Integrated Approaches to Testing and Assessment (IATA), integrative exposure and exposure reconstruction models and practical approaches for regulatory risk assessment of single, aggregated or combined exposure should be developed and their regulatory uptake fostered. Causal associations between (combined) exposures to chemicals and health outcomes should be investigated.

3. Strengthen existing capacities and build EU-wide, transdisciplinary research and innovation platforms to support chemical risk assessment

A data policy in line with FAIR data principles, taking into account General Data Protection Regulation (GDPR) related challenges, should be developed and implemented in the Partnership for data management, harmonisation, interoperability and exchange. Building on accepted data formats and existing data platforms⁶⁴, solutions to collect, store, manage and permit access to new data generated by R&I activities in the partnership should be proposed. Access and linkage to existing data collections should be facilitated. Innovative methods for

⁶⁴ Examples of relevant EC data platforms:
IPCHEM <https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>,
eChemPortal: <https://www.echemportal.org/echemportal/>.

data analysis should be pursued, including uncertainty analysis, data mining, and machine learning.

Innovative approaches in chemical risk assessment should be investigated and, if validated, promoted including at least the following: 1) supporting the European Commission's work on defining the Safe-and-Sustainable-by-Design concept and implementation criteria and proposing a toolbox to support the application of these criteria; 2) investigating how to further support the initial pilot study on an EU Early Warning System launched by the European Commission in 2019; and 3) making models and modelling approaches accessible and compliant with FAIR principles via an open source repository.

The Partnership should, in cooperation with appropriate EU and National reference laboratory networks, identify, and, when needed, enhance existing networks and develop new networks. These networks should aim at standardising methods, making available Quality Assurance/Quality Control (QA/QC) schemes and promoting the uptake of new methods and tools through training and peer-to-peer learning. In addition, specific training should be undertaken for different groups of stakeholders, including own partners, to ensure a wide use of data, methods, tools and models promoted by the Partnership.

Partner composition, geographical coverage and funding conditions:

The Partnership is open to all EU Member States as well as countries associated to Horizon Europe and will remain open to those wanting to join during the Partnership's lifetime.

Beneficiaries should preferably be:

- National institutions in charge of chemical risk assessment and carrying out related research and innovation activities.
- Exceptionally, if the national risk assessors prefer not to participate as beneficiaries and manage a network of affiliated entities, other solutions can be envisaged but must be duly justified and, when to conditions for participating as affiliated entities exists, the national risk assessor may participate under such status.

To encourage national coordination, participation as beneficiary should be limited to two entities per country; the use of affiliated entities is thus strongly encouraged, when the conditions for participating as affiliated entity exist.

Affiliated entities are defined under the Horizon Europe Model Grant Agreement and, in this specific topic, should be:

- Academia and research organisations that are part of the national networks on research for chemicals risk assessment and have established links to the risk-assessing institutions.
- National risk assessors or government agencies in the exceptional case they will not be beneficiaries as mentioned above.

Depending on their individual legal and operational frameworks and in agreement with the relevant services of the European Commission (partner DGs), EU Agencies involved in chemicals risk assessment and/or producing knowledge on chemicals' safety may also join the Partnership, e.g. as beneficiaries.

Collaboration with the European Commission's Joint Research Centre (JRC) should be considered to facilitate the sharing of chemical monitoring data in IPCHEM⁶⁵, and in other areas of mutual interest, such as (bio)monitoring, novel approaches for risk assessment including non-animal approaches, safe and sustainable design of chemicals, training and capacity building.

The expected duration of the partnership is seven years.

The Horizon Europe contribution will be limited to a maximum of 50% of the total eligible costs of the action with a maximum of EUR 200 million of EU contribution.

Call - Environment and health (Single Stage - 2022)

HORIZON-HLTH-2022-ENVHLTH-04

Conditions for the Call

Indicative budget(s)⁶⁶

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ⁶⁷	Number of projects expected to be funded
		2022		
Opening: 06 Oct 2021 Deadline(s): 21 Apr 2022				
HORIZON-HLTH-2022-ENVHLTH-04-01	RIA	20.00 ⁶⁸	Around 4.00	5
Overall indicative budget		20.00		

⁶⁵ <https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>

⁶⁶ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

⁶⁷ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

⁶⁸ Of which EUR 12.00 million from the 'NGEU' Fund Source.

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-ENVHLTH-04-01: Methods for assessing health-related costs of environmental stressors

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 4.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 20.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 ‘*Living and working in a health-promoting environment*’. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- EU and national public authorities regularly use economic and health modelling in policy impact assessments and policy evaluation, and promote the use of these to other stakeholders;
- Stakeholders agree on the most relevant population health and quality of life metrics, including DALYs (Disability Adjusted Life Years) or QALYs (Quality Adjusted Life Years)⁶⁹, and economic metrics;
- The stakeholder community follows common guidelines and methodologies for integrative socio-economic assessments and cost-benefit analysis of environmental pollution in Europe.

Scope: Policy-makers face challenges when devising pollution mitigation measures and having to assess the health costs emerging from life-long exposures to environmental stressors or the benefits from clean environments. Deaths and disabilities resulting from pollution carry a quantifiable economic cost to society, but there are significant uncertainties in the cost estimates methodologies. There is also paucity of data to evaluate the economic benefits of clean environments.

Impact Pathway Analysis⁷⁰ and Health Impact Assessment (HIA)⁷¹ are methodologies, which can be useful in linking scientific knowledge with environmental economics for informing policy action in diverse sectors such as transport, energy, chemicals, occupational health etc.

Proposed research activities should mainly aim to improve the calculation of the socio-economic costs (and/or benefits) of health impacts during the life-course associated to environmental stressors, or combinations of these, advance methodological approaches and foster their acceptance as common good practice.

Proposals should consider all of the following activities:

- Systematic review and exploitation of latest evidence of exposure-response functions and causation resulting from published medical and scientific research accumulated data from the past 10-20 years, including results published based on EU-funded research projects;
- Identification of data gaps as regards environment and health risk factors and health-related tangible and intangible costs and recommendations on priorities for new data collections;
- Advancement of methodological rigor and consistency in accounting for morbidity and mortality, disabilities, linking valuation of statistical life and/or life-years with quality

⁶⁹ While introducing relevant changes, it should be ensured that metrics respect the UN Convention on the Rights of Persons with Disabilities.

⁷⁰ <http://arirabl.org/untitled/>

⁷¹ Health Impact Assessment (HIA) has been defined by WHO European Centre for Health Policy as a combination of procedures or methods by which a policy, programme or project may be judged as to the effects it may have on the health of a population.

adjustments within a unified framework, based on the most recent data available and adapted to the needs and circumstances in Europe;

- Application of experimental approaches addressing the potential link of quality of life and the burden of disease indicators with more integrative impact indicators (e.g. reflecting subjective well-being, health, work-life balance, education, housing, etc.) and identification of how national contexts can impact on health-related costs of the same environmental and occupational exposure;
- Enhancement of the understanding of the role of discounting and other methods for weighing present and future costs and benefits;
- Development of innovative tools, methods and models, and associated guidelines for health impact assessments and related cost-benefit analysis;
- Consultation of experts and stakeholders on tools, models, methods and assessments developed towards a shared agreement of these;
- Development of case studies involving public authorities comparing the costs of action and non-action in at least three EU or associated countries;
- Delivery of FAIR⁷² data and a user-friendly access to an open knowledge base including results, methodologies and data appropriate for use in public policies and budget allocations.

Projects could consider the involvement of the European Commission's Joint Research Centre (JRC) in the field of health impacts of environmental stressors.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

Whenever appropriate, the use of environmental data and products coming from the Copernicus⁷³ programme, specifically the Copernicus Atmosphere Monitoring Service (CAMS) and the Copernicus Climate Change Service (C3S), is encouraged.

⁷² FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.
⁷³ <https://www.copernicus.eu/en>

Destination 3. Tackling diseases and reducing disease burden

Calls for proposals under this destination are directed towards the Key Strategic Orientation KSO-D *‘Creating a more resilient, inclusive and democratic European society’* of Horizon Europe’s Strategic Plan 2021-2024. Research and innovation supported under this destination should contribute to the impact area *‘Good health and high-quality accessible healthcare’* and in particular to the following expected impact, set out in the Strategic Plan for the health cluster: *‘health care providers are able to better tackle and manage diseases (infectious diseases, including poverty-related and neglected diseases, non-communicable and rare diseases) and reduce the disease burden on patients effectively thanks to better understanding and treatment of diseases, more effective and innovative health technologies, better ability and preparedness to manage epidemic outbreaks and improved patient safety’*. In addition, research and innovation supported under this destination could also contribute to the following impact areas: *‘A resilient EU prepared for emerging threats’*, *‘Climate change mitigation and adaptation’*, and *‘High quality digital services for all’*.

Communicable and non-communicable diseases cause the greatest amounts of premature death and disability in the EU and worldwide. They pose a major health, societal and economic threat and burden. Many people are still suffering from these diseases and too often dying prematurely. Non-communicable diseases, including mental illnesses and neurodegenerative diseases, are responsible for up to 80% of EU health care costs⁷⁴. These costs are spent on the treatment of such diseases that to a large extent are preventable. Furthermore, only around 3% of the health care budgets are currently spent on preventive measures although there is a huge potential for prevention. Infectious diseases, including infections resistant to antimicrobials, remain a major threat to public health in the EU but also to global health security. Deaths caused by antimicrobial resistance (AMR) could exceed 10 million per year worldwide according to some predictions⁷⁵.

To further advance, there is an urgent need for research and innovation to develop new prevention measures, public health interventions, diagnostics, vaccines, therapies, alternatives to antimicrobials, as well as to improve existing prevention strategies to create tangible impacts, taking into account sex/gender-related issues. This will require international cooperation to pool the best expertise and know-how available worldwide, to access world-class research infrastructures and to leverage critical scales of investments on priority needs through a better alignment with other funders of international cooperation in health research and innovation. The continuation of international partnerships and cooperation with international organisations is particularly needed to combat infectious diseases, to address antimicrobial resistances, to respond to major unmet medical needs for global health security, including the global burden of non-communicable diseases, and to strengthen patient safety.

⁷⁴ Currently, around 50 million people in the EU are estimated to suffer from two or more chronic conditions, and most of these people are over 65. Every day, 22 500 people die in Europe from those diseases, counting of 87% of all deaths. They account for 550 000 premature deaths of people of working age with an estimated €115 billion economic loss per year (0.8% of GDP).

⁷⁵ AMR is estimated to be responsible for 25 000 deaths per year in the EU alone and 700 000 deaths per year globally. It has been estimated that AMR might cause more deaths than cancer by 2050.

In this work programme, destination 3 will focus on major societal challenges linked to the Commission's political priorities such as the fight against cancer and other non-communicable diseases, better diagnosis and treatment of rare diseases, preparedness and response to and surveillance of health threats and epidemics, reduction of the number of antimicrobial-resistant infections, improving vaccination rates, demographic change, mental health and digital empowerment in health literacy. In particular, the topics under this destination will support activities aiming at: i) better understanding of diseases, their drivers and consequences, including pain and the causative links between health determinants and diseases, and better evidence-base for policy-making; ii) better methodologies and diagnostics that allow timely and accurate diagnosis, identification of personalised treatment options and assessment of health outcomes, including for patients with a rare disease; iii) development and validation of effective intervention for better surveillance, prevention, detection, treatment and crisis management of infectious disease threats; iv) innovative health technologies developed and tested in clinical practice, including personalised medicine approaches and use of digital tools to optimise clinical workflows; v) new and advanced therapies for non-communicable diseases, including rare diseases developed in particular for those without approved options, supported by strategies to make them affordable for the public payer; and vi) scientific evidence for improved/tailored policies and legal frameworks and to inform major policy initiatives at global level (e.g. WHO Framework Convention on Tobacco Control; UNEA Pollution Implementation Plan).

In view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic but also between other projects funded under another topic, cluster or pillar of Horizon Europe (but also with ongoing projects funded under Horizon 2020). In particular, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health and EIT-KIC Health (under pillar III of Horizon Europe), or in areas cutting across the health and other clusters (under pillar II of Horizon Europe). For instance, with cluster 3 "*Civil security for society*" such as on health security/emergencies (preparedness and response, medical counter measures, epidemic outbreaks/pandemics, natural disasters and technological incidents, bioterrorism); with cluster 4 "*Digital, Industry and Space*" such as on decision-support systems or on geo-observation and monitoring (e.g. of disease vectors, epidemics); or with cluster 6 "*Food, bioeconomy, natural resources, agriculture and environment*" such as on health security and AMR (one-health: human/animal/plant/soil/water health).

Some research and innovation actions under Destination 3 should deliver relevant complementary inputs to the announced "Europe's Beating Cancer Plan"⁷⁶, contributing to

⁷⁶ <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan>

actions covering the entire cancer care pathway, including prevention, early detection, diagnosis, treatment, cancer data monitoring, as well as quality of life of cancer patients and survivors. Furthermore, synergies and complementarities will be sought between Destination 3 and the implementation of the EU4Health Programme (2021-2027)⁷⁷. These synergies and complementarities could be achieved, notably through mechanisms based on feedback loops, enabling on the one hand to identify policy needs that should be prioritised in research and innovation actions and facilitating on the other hand the implementation of research results into policy actions and clinical practice, thereby providing an integrated response across sectors and policy fields.

Expected impacts:

Proposals for topics under this destination should set out a credible pathway to contributing to tackling diseases and reducing disease burden, and more specifically to several of the following impacts:

- Health burden of diseases in the EU and worldwide is reduced through effective disease management, including through the development and integration of innovative diagnostic and therapeutic approaches, personalised medicine approaches, digital and other people-centred solutions for health care. In particular, patients are diagnosed early and accurately and receive effective, cost-efficient and affordable treatment, including patients with a rare disease, due to effective translation of research results into new diagnostic tools and therapies.
- Premature mortality from non-communicable diseases is reduced by one third (by 2030), mental health and well-being is promoted, and the voluntary targets of the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 are attained (by 2025), with an immediate impact on the related disease burden (DALYs)^{78,79,80}.
- Health care systems benefit from strengthened research and innovation expertise, human capacities and know-how for combatting communicable and non-communicable diseases, including through international cooperation. In particular, they are better prepared to respond rapidly and effectively to health emergencies and are able to prevent and manage communicable diseases transmissions epidemics, including within healthcare settings.
- Citizens benefit from reduced (cross-border) health threat of epidemics and AMR pathogens, in the EU and worldwide^{81, 82}. In particular, the epidemics of AIDS,

⁷⁷ https://ec.europa.eu/health/funding/eu4health_en

⁷⁸ WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 (resolution WHA66.10), https://www.who.int/nmh/events/ncd_action_plan/en.

⁷⁹ Including for instance the following voluntary targets (against the 2010 baseline): A 25% relative reduction in the overall mortality from cardiovascular diseases, cancer, diabetes, or chronic respiratory diseases; Halt the rise in diabetes and obesity; An 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major non-communicable diseases in both public and private facilities.

⁸⁰ Disability-adjusted life year (DALY) is a quantitative indicator of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death.

⁸¹ WHO global action plan on antimicrobial resistance, 2015.

⁸² EU One Health Action Plan against AMR, 2017.

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tuberculosis, malaria and neglected tropical diseases are contained and hepatitis, water-borne diseases and other communicable diseases are being combated⁸³.

- Patients and citizens are knowledgeable of disease threats, involved and empowered to make and shape decisions for their health, and better adhere to knowledge-based disease management strategies and policies (especially for controlling outbreaks and emergencies).

The EU benefits from high visibility, leadership and standing in international fora on global health and global health security, especially in partnership with Africa.

The following call(s) in this work programme contribute to this destination:

Call	Budgets (EUR million)		Deadline(s)
	2021	2022	
HORIZON-HLTH-2021-DISEASE-04	263.00		21 Sep 2021
HORIZON-HLTH-2022-DISEASE-06-two-stage		160.00	01 Feb 2022 (First Stage) 06 Sep 2022 (Second Stage)
HORIZON-HLTH-2022-DISEASE-07		37.00	21 Apr 2022
HORIZON-HLTH-2022-DISEASE-03		30.00	21 Apr 2022
Overall indicative budget	263.00	227.00	

⁸³ Target 3.3 of the UN's Sustainable Development Goals, 2015.

Call - Tackling diseases (2021)

HORIZON-HLTH-2021-DISEASE-04

Conditions for the Call

Indicative budget(s)⁸⁴

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ⁸⁵	Number of projects expected to be funded
		2021		
Opening: 22 Jun 2021 Deadline(s): 21 Sep 2021				
HORIZON-HLTH-2021-DISEASE-04-01	RIA	50.00 ⁸⁶	Around 6.00	8
HORIZON-HLTH-2021-DISEASE-04-02	RIA	50.00 ⁸⁷	Around 25.00	2
HORIZON-HLTH-2021-DISEASE-04-03	RIA	40.00 ⁸⁸	Around 8.00	5
HORIZON-HLTH-2021-DISEASE-04-04	RIA	60.00 ⁸⁹	Around 6.00	10
HORIZON-HLTH-2021-DISEASE-04-05	CSA	1.00	Around 1.00	1
HORIZON-HLTH-2021-DISEASE-04-06	CSA	2.00	Around 2.00	1
HORIZON-HLTH-2021-DISEASE-04-07	RIA	60.00 ⁹⁰	Around 7.00	9
Overall indicative budget		263.00		

General conditions relating to this call

⁸⁴ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

⁸⁵ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

⁸⁶ Of which EUR 30.00 million from the 'NGEU' Fund Source.

⁸⁷ Of which EUR 30.00 million from the 'NGEU' Fund Source.

⁸⁸ Of which EUR 24.00 million from the 'NGEU' Fund Source.

⁸⁹ Of which EUR 36.00 million from the 'NGEU' Fund Source.

⁹⁰ Of which EUR 36.00 million from the 'NGEU' Fund Source.

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<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2021-DISEASE-04-01: Improved supportive, palliative, survivorship and end-of-life care of cancer patients

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 50.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Reduced health-related suffering and improved well-being and quality of life for cancer patients in need of supportive, palliative, survivorship or end-of-life care as well as for their professional and family caregivers.

- Cancer patients (independently of their age) have early and better access to supportive, palliative, survivorship or end-of-life care services of higher quality and (cost)effectiveness.
- Reduced societal, healthcare and economic burden associated with increasing demands of supportive, palliative, survivorship or end-of-life care services that is beneficial for citizens and preserves the sustainability of the health care systems.
- Health care providers and health policy makers have access to and use improved clinical guidelines and policies with respect to pain management, psychological and/or spiritual support, and supportive, palliative, survivorship or end-of-life care for cancer patients.
- Cancer patients and their professional and family caregivers use the improved evidence-based and information-driven palliative care decision-making process.

Scope: The complexity of health conditions related to cancer and late or long-term side effects as consequences of its treatments affect the quality of life of cancer patients and their families and pose a significant societal and economic burden. Palliative⁹¹, supportive⁹², survivorship and end-of-life care approaches improve the quality of life for cancer patients and professional and family caregivers through the prevention and relief of suffering by means of early identification, assessment and treatment of pain and other problems such as physical, psychosocial and spiritual problems. Although a variety of interventions are in use, they are often insufficiently validated or adapted to the specific needs of cancer patients and cancer survivors, often affected by co- or multi-morbidities. Thus, there is a need to strengthen the evidence base for patient-centred, effective interventions improving the quality of life and outcomes of cancer patients and cancer survivors of all ages in the domains of supportive, palliative, survivorship and end-of-life care.

Proposals should address all of the following activities:

- Demonstrate the effectiveness and cost-effectiveness of newly proposed or specifically adapted pharmacological and/or non-pharmacological interventions to improve well-being and the quality of life of cancer patients. Serious late and long-term side effects of cancer treatments or symptoms that occur at the end of life of those patients as well as of cancer survivors should be considered. The legal and ethical aspects of the proposed interventions should be taken into consideration and be fully addressed.
- Prove the feasibility of integrating the proposed interventions in current pain management, palliative, supportive, survivorship and/or end-of-life care regimes and healthcare systems across Europe. The complex human, social, cultural and ethical aspects that are necessarily managed by those care regimes and healthcare systems should be reflected from the patients' perspectives as well as those of their professional and family caregivers. The views and values of patients and their caregivers (including

⁹¹ <https://www.who.int/cancer/palliative/definition/en/>

⁹² <https://www.mascc.org/about-mascc>

families, volunteers, nurses and others) should also be appropriately taken into account in patient-centred care decisions.

- Identify and analyse relationships between sex, gender, age, disabilities and socio-economic factors in health and any other relevant factors (e.g. ethical, familial, cultural considerations, including personal beliefs and religious perspectives, etc.) that could affect health equity⁹³ of the proposed interventions, including equitable access.
- Analyse the barriers and opportunities to re-invigorating and enhancing timely social inclusion and active engagement of cancer patients in need of supportive, palliative, survivorship and end-of-life care and their caregivers.
- Provide guidelines for patient-centred communication as well as standards for evidence-based communication trainings for caregivers, considering the potential of social innovation approaches or tools.
- When relevant, provide policy recommendations for pain management, psychological and/or spiritual support, and supportive, palliative, survivorship or end-of-life care of cancer patients afflicted by late and long-term side effects of cancer treatments.

Randomised clinical trials and observational studies, targeting children or adults or elderly, should be considered for this topic. Proposals should give a sound feasibility assessment, provide details of the methodology, including an appropriate patient selection and realistic recruitment plans, justified by available publications and/or preliminary results.

This topic requires effective contributions from the social sciences and humanities (SSH) through the involvement of SSH experts and institutions as well as the inclusion of relevant SSH expertise, in order to produce meaningful and significant effects enhancing the societal impact of the related research activities. Proposals should consider a patient-centred approach that empowers patients, promotes a culture of dialogue and openness between health professionals, patients and their families, and unleashes the potential for social innovation.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

⁹³ https://www.who.int/topics/health_equity/en/

HORIZON-HLTH-2021-DISEASE-04-02: Building a European innovation platform for the repurposing of medicinal products

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 25.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 50.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Researchers continue to use the platform as an effective and sustained approach to coordinate and manage their efforts on the repurposing of medicines, making the best use of scientific knowledge and resources.
- Patients have new and effective therapeutic options addressing unmet medical needs, both for communicable and non-communicable diseases.
- Health care systems and payers have available more cost-effective treatments that reduce the financial burden in the medium- to long-term.
- The public sector and the pharmaceutical industry engage in new models of sustainable collaboration, at European level and beyond.
- Policy-makers adjust the EU’s regulatory landscape for pharmaceuticals towards further harmonisation and increased fitness for purpose.

Scope: Development of therapeutics is a lengthy process that requires a large amount of efforts, time and financial resources. It is often burdened by delays and barriers that account for an average of almost 15 years until a promising candidate molecule becomes an approved medicine. It is therefore of paramount importance to define strategies that facilitate the reduction of timeframes, decrease costs and improve the success rate of this complex and lengthy process. One efficient strategy towards this direction is the repurposing of already approved medicinal products⁹⁴ and repositioning of investigational products⁹⁵ beyond their

⁹⁴ Medicinal products with a market authorisation in the EU.

⁹⁵ Investigational products without a market authorisation in the EU.

original indication. This approach has already proved successful⁹⁶ in several instances but its potential is far from having been fully exploited.

Proposals should address all of the following:

- Set up a platform⁹⁷ supporting an innovative repurposing model with a harmonized and sustainable dimension in the EU, attracting investments and taking a position of leadership at global level. This model should integrate the scientific, methodological, financial, legal, regulatory, and intellectual property aspects of the repurposing approach.
- Provide robust and transparent selection mechanisms for prioritising already approved medicinal products or investigational products for repurposing, based on recognized unmet medical needs and sound preliminary data, and identify research priorities for the better understanding of mechanisms of action.
- Leverage, pool and share existing high quality data assets in the European repurposing landscape, also by using pharmacogenomics, in silico, and artificial intelligence (AI) approaches, innovative preclinical human in vitro cellular/multi-organ validation methods, and deliver new computational tools.
- Resolve the fragmentation and lack of ownership of the repurposing approach that greatly impedes the efficient exploitation of its potential, networking existing projects⁹⁸ and initiatives in the field. Particular attention should be given in supporting and strengthening academic driven research.
- Devise and test a European innovation platform to enhance the collaboration among relevant European stakeholders, including academia, non-profit organisations, patients, health-care professionals, regulators, health technology assessment bodies, payers, industry, and European Research Infrastructures.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

⁹⁶ Notable examples are thalidomide and sildenafil.

⁹⁷ Platform built around innovative concepts and comprising the components and expertise necessary to create a solid foundation on which to build a sustainable EU infrastructure to overcome the bottlenecks and fragmentation in the field of medicine repurposing.

⁹⁸ Particular attention should be given to already EC funded repurposing projects and regulators initiatives in the field.

In order to achieve the expected outcomes, international cooperation is encouraged.

HORIZON-HLTH-2021-DISEASE-04-03: Innovative approaches to enhance poverty-related diseases research in sub-Saharan Africa

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 40.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>Due to the scope of this topic, legal entities established in all member states of the African Union are exceptionally eligible for Union funding.</p> <p>The following additional eligibility criteria apply:</p> <p>In order to achieve the expected objectives, namely that more clinicians and researchers in sub-Saharan Africa have the capacity to develop and design large-scale studies, the consortium must include at least one legal entity established in a sub-Saharan African country.*</p> <p>*Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo (Democratic People’s Republic), Congo (Republic), Côte d’Ivoire, Djibouti, Eritrea, Ethiopia, Equatorial Guinea, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, São Tomé and Príncipe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe.</p>

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Health care providers and professionals in sub-Saharan Africa have a better understanding of poverty-related infectious diseases affecting these countries and use

new evidences and advanced innovative health technologies or concepts to prevent, treat or diagnose poverty-related infectious diseases in sub-Saharan Africa.

- Health authorities and health care systems have access to health data and evidences to better develop and implement informed health policies and improved clinical guidelines for health care in sub-Saharan Africa.
- Health care systems, clinicians and researchers have access to improved clinical research capacities and strengthened infrastructures for clinical research, development and implementation in sub-Saharan Africa, enabling in particular an accelerated development of new, low-cost, easy-to-implement solutions for improved delivery of medical interventions for vulnerable populations in low-resource settings.
- More researchers at the early stages of their career (e.g. Master's, PhD or post-doctoral level) are able to develop their own scientific career in sub-Saharan Africa and/or establish themselves as scientific leaders in sub-Saharan Africa.
- More clinicians and researchers in sub-Saharan Africa have the capacity to develop and design large-scale studies.

Scope: The European and Developing Countries Clinical Trials Partnership (EDCTP) has established itself as the focal point of cooperation in clinical research on infectious disease between the EU and sub-Saharan Africa. To continue these investments after the last calls of the EDCTP2 programme, there is a need to further support research on the major infectious disease threats facing sub-Saharan Africa. Despite large-scale investments in product development for poverty-related infectious diseases (PRDs), progress in achieving public health gain is slow, while sub-Saharan Africa bears the highest burden of these diseases. There is a need to support product development and to encourage the use of new, innovative approaches and emerging technologies in sub-Saharan Africa to achieve rapid progress and impact. The COVID-19 pandemic is generating novel knowledge that could also advance prevention, treatment or diagnosis of PRDs in this part of the world.

Proposals should address all of the following:

- Any PRD disease or group of PRDs affecting sub-Saharan Africa (within the scope of EDCTP2⁹⁹ or the proposed EDCTP3 and its draft strategic research and innovation agenda¹⁰⁰).
- Combine health technologies with other scientific areas such as mobile technologies and digital technologies (mHealth and eHealth), big data processing, and other emerging technologies.

⁹⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0556&from=GA>

¹⁰⁰

https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/edctp3_draft_proposal_14_august_2020.pdf

- Implement one or more medium-scale clinical trials and/or clinical research studies that can deliver the proof-of-concept or validate smart, highly innovative health technologies or concepts to prevent, treat or diagnose PRDs in sub-Saharan Africa, drawing lessons from the COVID-19 experience.
- Increase collaboration with investors in development cooperation and international partnerships to create solutions for improved development or delivery of medical interventions for vulnerable populations in low-resource settings.
- Proposals involving pharmaceutical companies and small- or medium-sized enterprises (SMEs) are encouraged.
- Develop solutions that are easily integrated or linked to existing electronic or digital systems that are used in the implementation of clinical research and health systems' patient management.
- Include activities that promote collaboration with ongoing and future EDCTP projects. In this context the granting authority may share project-relevant information with the EDCTP Association and the future EDCTP3 Joint Undertaking.
- Promote the integration of research work and health care service delivery.

HORIZON-HLTH-2021-DISEASE-04-04: Clinical validation of artificial intelligence (AI) solutions for treatment and care

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Health care professionals employ safer and evidence-based clinical decision support systems for affordable treatment, including home-based care.
- Health care professionals better predict patients' (long-term) response, including adverse side effects of a specific personalised treatment.

- Patients and carers have access to disease-specific communication packages informing about a disease and the proposed treatment.
- Clinical guidelines are enhanced thanks to novel, clinically validated and (cost-) effective AI solutions.

Scope: Applying trustworthy-AI¹⁰¹ in healthcare contexts generate a multitude of benefits, including more effective disease management by optimised personalised treatments and assessment of health outcomes.

Based on existing (pre)clinical evidence, proposals should focus on implementing clinical studies to validate AI-based solutions comparing their benefits versus standard-of-care treatments in non-communicable diseases. Proposals should pay special attention to the usability, performance and safety of the AI-based solutions developed, and above all to their clinical evaluation and (cost-)effectiveness in view of their inclusion into current clinical guidelines for personalised treatments following current EU regulatory framework.

Proposals should address all of the following:

- Supporting the clinical development, testing and validation of AI-assisted treatment and care options, hereby assisting in clinical decision-making;
- Timely end-user inclusion (e.g. patient, caregiver and health care professional) along the clinical development of the AI-based solutions and the clinical validation process, considering the potential of social innovation approaches to support inclusion and dialogue between patients, carers and health care professionals;
- Enhancing accurate prognosis for and response to a specific personalised treatment, hereby providing a solid risk assessment (e.g. potential adverse events, side effects, expected treatment compliance and adherence over the time compared to standard care);
- Inclusion of sex and gender aspects, age, socio-economic, lifestyle and behavioural factors and other social determinants of health, as soon as possible considering also early stages/phases of development;
- Assessing potential manual or automated biases for large uptake;
- Integration of an extensive information and communication package about AI-assisted treatment options, highlighting their relevance for the patients and carers;
- Measuring the (cost-)effectiveness of AI-assisted development of therapeutic strategies and its implementation in clinical practice.

Proposals should describe a pathway for establishing standard operating procedures for the integration of AI in health care (e.g. for supporting clinical decision-making in treatment and

¹⁰¹ High Level Group on Artificial Intelligence, set up by the European Commission, Ethics Guidelines for Trustworthy AI, document made public on 8 April 2019.

care). Proposals are encouraged to consider multidisciplinary approaches and allow for intersectoral representation. Proposals have to ensure that resulting data comply with the FAIR¹⁰² principles and data generated by the AI-based solutions are in line with established international standards.

Integration of ethics and health humanities perspectives are essential to ensure an ethical approach to the development of robust, fair and trustworthy AI solutions in health care, taking into account underrepresented patient populations. In relation to the use and interpretation of data, special attention should be paid to systematic discrimination or bias (e.g. due to gender or ethnicity) when developing and using AI solutions. Proposals should also focus on traceability, transparency, and auditability of AI algorithms in health. The international perspective should be taken into account, preferably through international collaboration, to ensure the comprehensiveness, interoperability and transferability of the developed solutions.

Where relevant, applicants are highly encouraged to deliver a plan for the regulatory acceptability of their technologies and to interact at an early stage with the relevant regulatory bodies. SME(s) participation is encouraged.

HORIZON-HLTH-2021-DISEASE-04-07: Personalised medicine and infectious diseases: understanding the individual host response to viruses (e.g. SARS-CoV-2)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 7.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- All stakeholders along the health care value chain dispose of enhanced knowledge of risk factors, symptoms expression, disease progression and clinical outcomes in relation

¹⁰² FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

to host and viral characteristics, and host-pathogen interaction (i.e., the mechanistic understanding of the interplay between host and virus).

- Clinicians, regulators and other stakeholders along the health care value chain have access to decision support based on characterized diversity of host response at the level of genetic patterns, molecular pathways and physiological mechanisms, in relation to a large number of variables that inform disease predisposition, disease progression, symptoms expression and clinical outcomes.
- Clinicians and researchers use information on the deep characterization of the dynamics of the immune responses to the chosen virus(es), identifying factors critical for viral control and immune protection. This will provide a robust and common evidence base for the development of personalised therapeutic interventions and vaccines in the future.
- Clinicians use biomarkers¹⁰³ in the broad sense for personalised patient management.
- Clinicians and other stakeholders along the healthcare value chain have access to and use guidance on preventive measures and for the early identification of patients at risk of developing severe symptoms.

Scope: Proposals are expected to characterize the host response and host-pathogen interaction to a virus (or viruses) at the level of genetic patterns, physiological mechanisms and molecular pathways involving different organs and systems to identify factors that predispose to different clinical symptoms, different progression of the viral disease and different clinical outcomes. The study should include patient follow-up to identify conditions (including long-term ones) that may appear after the patient has recovered from the viral disease.

In all cases, actions should cover deep immunological phenotyping of the host response, including the use of animal models or in-vitro models if relevant. The latter should cover the dynamics of the innate and adaptive immune responses to the chosen virus(es) (comprising immunity duration, the effect of potential subsequent infections, etc.) including, if relevant, the association of HLA assets of patients with protective or harmful immune responses. Ultimately, this research should inform disease progression and the development of personalised prophylactic and therapeutic strategies.

The analysis should address the effect of differences in age, sex, gender, ethnicity, chronic conditions, co-morbidities, treatments offered and other relevant characteristics. The sample should be geographically representative for Europe. Where relevant, the sample could also include the data of subjects from outside Europe.

The data used should be standardized following the best available international practices and standards. Equally, sample collection and processing should be done following recognised

¹⁰³ A biomarker has been defined as a characteristic that is objectively measured and evaluated as indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to therapeutic interventions (NIH working group (Clin. Pharmacol. Ther. Vol. 38 n°3 (2001))

standard operating procedures. All data should be treated in accordance with GDPR and ethical principles.

Proposals that focus on COVID-19 are strongly encouraged to build links with the EU-funded project ORCHESTRA¹⁰⁴. Proposals should pay special attention and link to the newly established European COVID-19 data sharing platform¹⁰⁵ and collaborate with the existing network of COVID-19 projects¹⁰⁶ funded under Horizon 2020.

Proposals could consider the involvement of the European Commission's Joint Research Centre (JRC) on modelling the pathogenesis of COVID-19 using Adverse Outcome Pathways.

Collaboration with other relevant initiatives, such as the International Consortium for Personalised Medicine (ICPerMed)¹⁰⁷, the 1+ Million Genomes initiative¹⁰⁸ and the EBrains¹⁰⁹ research infrastructure is encouraged, where relevant. Whenever the proposed data sources or fields of application include genomics, the proposals should consider the data standards, and legal, ethical and technical interoperability requirements and guidelines agreed within the 1+ Million Genomes initiative where relevant.

HORIZON-HLTH-2021-DISEASE-04-05: A roadmap towards the creation of the European partnership on One Health antimicrobial resistance (OH AMR)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 1.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 1.00 million.
<i>Type of Action</i>	Coordination and Support Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Research funders, policy makers, relevant agencies and authorities, and the research community have a Strategic Research and Innovation Agenda (SRIA) to be implemented

¹⁰⁴ <https://cordis.europa.eu/project/id/101016167>

¹⁰⁵ <https://www.covid19dataportal.org/>

¹⁰⁶ https://cordis.europa.eu/programme/id/H2020_SC1-PHE-CORONAVIRUS-2020

¹⁰⁷ <https://www.icpermed.eu/>

¹⁰⁸ <https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes>

¹⁰⁹ <https://ebrains.eu>

by the expected future European partnership on *One Health* antimicrobial resistance (OH AMR).

- Research funders, policy makers, relevant agencies and authorities, and the research community profit from a strengthened coordination and collaboration among different fields of research and innovation with relevance to antimicrobial resistance (AMR) maintaining Europe's leading role in combating AMR.
- Academics, innovators, end-users, researchers, public health authorities and citizens form a strong ecosystem that improves the implementation of the European *One Health* AMR strategy and its contribution to the Sustainable Development Goals.
- Research funders, policy makers, relevant agencies and authorities, and the research community are in a position to close the current gaps and break existing silos on AMR in accordance with the European *One Health* Action Plan against AMR¹¹⁰.

Scope: The increasing levels of AMR present a major threat to human health with serious consequences also to animal and environmental health. Tackling AMR in bacteria, fungi, viruses and parasites requires a strong and coordinated response to protect citizens in Europe and beyond, as indicated in the European *One Health* Action Plan against AMR. This action plan provides the framework within which actions should be taken against this threat. It is recognised that combatting AMR requires a *One Health* approach, recognizing that human and animal health and the environment are interconnected. Many diseases affected by AMR are transmitted from animals to humans and vice versa, encompassing the environment as a link between humans and animals and as a reservoir of resistant microorganisms. Tackling AMR has also become a key priority as part of the Green Deal, including through the Farm to Fork Strategy¹¹¹. Of importance are also the socio-economic drivers that affect the use of antimicrobials in human and animal healthcare veterinary medicine. However, the challenge in the current situation is that the AMR research and innovation landscape is still too fragmented addressing human health, animal health, feed, food safety and environment in silos, and it is also fragmented across Member States. Therefore, there is the need to move towards the integration of the various disciplines to overcome this fragmentation, thus tackling the problem of AMR with a comprehensive *One Health* approach bringing the diverse actors together.

Importantly, better co-ordination is essential to foster and accelerate the development and adoption of solutions to reverse the rising levels of AMR. This should allow generating the capacity and the ecosystem to improve the prevention, diagnosis and treatment of drug-resistant infections in humans.

Accordingly, proposals should cover all of the following activities:

¹¹⁰ https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf

¹¹¹ https://ec.europa.eu/food/farm2fork_en

- Development of a Strategic Research and Innovation Agenda (SRIA) for a comprehensive approach to inform the expected future European partnership on *One Health* antimicrobial resistance (OH AMR).
- Integration of key actors for AMR encompassing the field of human, veterinary and environmental disciplines and the broad spectrum of pathogens, including fungi and viruses.
- Robust communication and effective information exchange between diverse scientific disciplines and among multiple sectors of the society that are implicated such as patients, clinicians, veterinarians, pharmacists, food producers, pharmaceutical industry, policy makers and researchers (including those working in the social sciences and humanities).

In order to achieve the expected outcomes, international cooperation, including with low- and middle-income countries where AMR is highly prevalent and prone to spread to Europe, is strongly encouraged. Proposals should build on, be complementary to and go beyond existing initiatives such as the JPIAMR¹¹²[1], the One Health EJP¹¹³ [2] and ICARS¹¹⁴[3]. It should also implement collaborative activities with International organisations such as the World Health Organization, the World Animal Health Organisation (OIE), the Food and Agriculture Organization (FAO), and the G7 and G20 fora, with the aim to avoid duplication of efforts.

As regards integration and coordination activities, the proposal should be ambitious in its inclusiveness, encompassing the broad spectrum of pathogens, and mobilise experts from diverse disciplines, including from the social sciences and humanities, to address understanding, prevention, monitoring, epidemiology (e.g. emergence, spread, persistence), treatments and detection of AMR. It should also be a pan-European consortium with a large geographical coverage of European countries.

Proposals are expected to explore links with the following expected future European partnership of Horizon Europe: Pandemic preparedness; Innovative Health Initiative; EU-Africa Global Health; Personalised Medicine; Animals and Health; Safe and Sustainable Food Systems for People; Planet and Climate; Biodiversity, Towards more Sustainable Farming; Agro-ecology Living Labs and Research Infrastructures; Water4All – Water Security for the Planet.

The project selected for funding is expected to inform the expected future European partnership on OH AMR. To that end, the proposal selected for funding is also expected to interact with other relevant projects funded under other topics and other clusters to ensure synergies on cross-cutting challenges of common interest such as those from the health cluster's destination 2 "*Living and working in a health-promoting environment*".

¹¹² <https://www.jpiamr.eu/>

¹¹³ <https://onehealth.jp.eu/>

¹¹⁴ <https://www.icars-global.org/>

HORIZON-HLTH-2021-DISEASE-04-06: Building a European partnership for pandemic preparedness

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 2.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 2.00 million.
<i>Type of Action</i>	Coordination and Support Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Research funders, policy-makers and the research community have established a consolidated research and innovation framework that provides the foundation of the expected future European partnership for pandemic preparedness, including the Partnership’s scope, objectives, governance and ways of working/operationalisation;
- Research funders, policy-makers and the research community are aligned towards common objectives and have a common understanding of the long-term Strategic Research and Innovation Agenda for the Partnership, developed in consultation with future partners and relevant stakeholders;
- Healthcare providers, European and international stakeholders engage with the appropriate partners through the research and innovation framework for the partnership

Scope: The COVID-19 pandemic illustrated how unilateral research initiatives may lead to a fragmented research landscape, with substantial room for efficiency gains in the development of the highly needed evidence to guide policy actions when facing an emergency. The expected future European partnership for pandemic preparedness should aim to improve the EU’s preparedness to predict and respond to emerging infectious health threats by better coordinating funding for research and innovation at EU, national (and regional) level towards common objectives and an agreed Strategic Research and Innovation Agenda.

Such a partnership should contribute to building a coherent European Research Area (ERA), enabling Member States, Associated Countries and the European Commission to rapidly and jointly support research and innovation in pandemic preparedness. Aligned around a multi-annual Strategic Research and Innovation Agenda with common objectives for research and innovation in pandemic preparedness, the prospective partners – in close collaboration with ECDC, EMA and other relevant actors – will define research needs in the medium- to long-term. The Partnership is expected to build on existing pandemic preparedness networks, and

work in synergy with the future Health Emergency Response Authority (HERA)¹¹⁵. Collaboration with the private sector is anticipated.

The specifics of the European partnership for pandemic preparedness are being discussed with Member States and Associated Countries, and will be shared as they become available. It is anticipated that in its initial phase, the Partnership will primarily focus on epidemics/pandemics preparedness, although its scope may be revised to include further health threats that would be in scope of the activities of the future HERA. As relevant, the Partnership will apply a cross-cutting, interdisciplinary *One Health* approach.

Proposals should foresee the establishment of a secretariat to coordinate the creation the expected future European partnership for pandemic preparedness, with a strong involvement of public authorities (policy makers, research funders).

Proposals should include all of the following activities:

- Perform the preparatory groundwork to inform an innovative and visionary Strategic Research and Innovation Agenda for pandemic preparedness;
- Actively engage with all prospective partners of the expected future Partnership to support alignment on its scope, common objectives, governance and ways of working/operationalisation;
- Actively engage with relevant stakeholders and initiatives in the area of pandemic preparedness, ensuring collaboration and coordination, and avoiding duplication; e.g. GloPID-R, WHO R&D blueprint, ACT-Accelerator, etc.
- Implement strong communication and dissemination activities on the purpose, foreseen activities and outputs of the expected future European partnership for pandemic preparedness, both outside and during epidemic/pandemic episodes.
- Establish coordination and collaboration with relevant initiatives related to pandemic preparedness such as the future HERA to ensure complementarity and avoid overlaps.
- As relevant, apply a cross-cutting, interdisciplinary *One Health* approach.
- Communication activities at EU level and in Member States and Associated Countries to raise and maintain awareness of the importance of increased pandemic preparedness.

The proposal selected for funding is expected to engage with other relevant research and innovation initiatives, such as the expected future European partnerships on *Transforming Health and Care Systems*, *One Health antimicrobial resistance*, *ERA for Health research* and *Animal Health and Welfare*, or other relevant projects funded under Horizon 2020 or Horizon Europe.

¹¹⁵ COM(2020) 724 - A dedicated European authority that will strengthen the EU's preparedness and response capability for new and emerging cross-border threats to human health.

Call - Tackling diseases (Two Stage - 2022)

HORIZON-HLTH-2022-DISEASE-06-two-stage

Conditions for the Call

Indicative budget(s)¹¹⁶

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹¹⁷	Number of projects expected to be funded
		2022		
Opening: 06 Oct 2021				
Deadline(s): 01 Feb 2022 (First Stage), 06 Sep 2022 (Second Stage)				
HORIZON-HLTH-2022-DISEASE-06-02-two-stage	RIA	60.00 ¹¹⁸	Around 6.00	10
HORIZON-HLTH-2022-DISEASE-06-03-two-stage	RIA	40.00 ¹¹⁹	Around 8.00	5
HORIZON-HLTH-2022-DISEASE-06-04-two-stage	RIA	60.00 ¹²⁰	Around 8.00	8
Overall indicative budget		160.00		

General conditions relating to this call

<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and</i>	The criteria are described in General Annex

¹¹⁶ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹¹⁷ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹¹⁸ Of which EUR 36.00 million from the 'NGEU' Fund Source.

¹¹⁹ Of which EUR 24.00 million from the 'NGEU' Fund Source.

¹²⁰ Of which EUR 36.00 million from the 'NGEU' Fund Source.

<i>exclusion</i>	C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-DISEASE-06-02-two-stage: Pre-clinical development of the next generation of immunotherapies for diseases or disorders with unmet medical needs

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- The scientific and clinical communities make effective use of the pre-clinical validation of new immunotherapies for high burden diseases or disorders with unmet medical needs.
- The scientific and clinical communities have access to new knowledge allowing for a better understanding of the mode of action of the next generation of immunotherapies and/or combinatorial treatments, which enables further development and optimisation of treatments.
- The scientific and clinical communities have access to and use new personalized models (*in vitro* and *in vivo*) for high burden diseases or disorders as well as protocols for the next generation of immunotherapies.

- Health care professionals have access to and use new evidence-based safety and efficacy guidelines for immunotherapies. Proof-of-clinical concept, when applicable, as single or combinatorial treatment, should be compared to existing approaches.

Scope: Immunotherapy is defined as a treatment able to stimulate or restore the ability of the immune (defence) system to fight infection, disease or disorder. It has proved to be a valuable medical treatment notably when preventive interventions are not available. Passive and active immunotherapies (such as antibody-based, RNA-based and cell-based therapies, respectively) are covered by this topic, which is aiming at the pre-clinical to first-in human development of next generation immunotherapies for unmet needs.

Proposals should build on existing knowledge in the field, when available, in order to save time and to avoid spilling resources, and could build on the knowledge of the interaction between the immune system (innate and adaptive arms) and the microbiota, or take advantage of key enabling technologies such as biotechnology and nanotechnology, advanced manufacturing, imaging, 5G, internet of things, artificial intelligence and existing databases.

The next generation of immunotherapies are needed in order to improve and diversify the capabilities of health care for several communicable and non-communicable diseases¹²¹ that cannot be effectively tackled with the currently available treatments.

Proposals are expected to address some of the following research gaps for the development of the next generation of effective and safe immunotherapies:

- Preclinical development and study of new immunotherapeutic agents *in vitro* and in relevant animal model(s) of the disease(s). This includes understanding of the therapy's agent(s) mode of action, its toxicity, the development of related potency assay(s), and its/their validation *in vitro* and *in vivo*. A robust regulatory and Health Technology Assessment (HTA) strategy should be in place at the start of the proposal.
- Off-the-shelf therapies, including the cell-based therapies, will be considered as assets during the evaluation.
- Proposals could include proof-of-concept (PoC)/first-in-human studies for testing the new therapies, with a clear regulatory and clinical pathway¹²² and should address as appropriate the therapy-related potential for adverse side effects. PoC and clinical studies in humans should take sex, gender, age and socio-economic factors into account, where relevant. Phase II studies or later phase trials will not be supported.
- Development of a standardised framework for assays and data usage to enable a robust assessment of the safety and efficacy.

¹²¹ **Excluded** from the scope are the **preventive vaccines**, the immunotherapies for **rare diseases** and the **repurposing of drugs** as they are covered by other topics in the HE research programme 2021-2022. Research on **cancer** immunotherapies is **excluded** as it will be covered by the Mission on Cancer.

¹²² In case proposals are involving clinical studies, please use the document on essential information for clinical studies provided on the portal.

- In case treatments are already available for the proposed targeted disease(s), a justification of the need for development of a new immunotherapy treatment is requested.
- The proposed action should include a pathway of the necessary steps to ensure sustainable therapeutic agent production (considering intellectual property management if relevant) and uptake by health systems and rapid access to patients.

Projects may consider the use of the nanobiotechnology infrastructure platform of the European Commission’s Joint Research Centre, in particular for the accurate physicochemical characterization of therapeutic proteins and antibodies.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

Projects could consider the use of the Nanobiotechnology infrastructure platform of the European Commission’s Joint Research Centre, in particular for the accurate physicochemical characterization of therapeutic proteins and antibodies.

HORIZON-HLTH-2022-DISEASE-06-03-two-stage: Vaccines 2.0 - developing the next generation of vaccines

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 40.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The scientific and clinical communities use the increased knowledge on pathogens and better understanding of the immune system's role in infectious diseases to develop vaccines with improved efficacy.
- Vaccine manufacturers use more innovative and sustainable manufacturing technologies and improved GMP manufacturing know-how for producing the next generation of vaccines.
- A diversified portfolio of vaccine candidates ready for testing in clinical trials help policy makers and funders to make informed decisions about support to vaccine development.
- New innovative and improved design of preclinical/clinical studies that match the features of the next generation of vaccines is available for clinical community and regulators, and will shorten vaccine development time.

Scope: Infectious diseases, including antimicrobial resistant (AMR) infections, remain a major threat to health and health security in the EU and globally. The availability of more effective, accessible and affordable vaccines would provide the most cost-effective preventive measure against the health threat of epidemics and AMR pathogens. Vaccines against diseases, such as AIDS, tuberculosis (TB), malaria, neglected tropical diseases, hepatitis C and water-borne diseases are essential to achieve the WHO targets to control the spread of infectious diseases. The first generation of vaccines against some of the pathogens have proven to be suboptimal and not effective enough to protect the population. Many viruses of pandemic potential are variable in their surface antigen composition, and novel technologies are required to develop efficient vaccines against each new variant efficiently and in a short timeframe. To ensure that more effective, accessible and affordable vaccines against all major infectious diseases become a reality, it is essential to sustain a diverse and modernised vaccine development pipeline.

Proposals should aim to diversify and accelerate the global vaccine research and development pipeline, and to strengthen the current leading role of the EU in vaccine research and development. Proposals should cover those pathogens, which still lack vaccines of sufficient efficacy, but where earlier efforts have already produced promising vaccine candidates.

The proposals should address several of the following areas:

- Innovation and integration of expertise and capabilities, including alignment of preclinical and clinical models, biomarker studies and new vaccine approaches from discovery to late stage development, from bench-based research to clinical development of promising preventive candidates.
- Application of iterative processes (including cross-learning, back-translation steps, integrative analysis of data) to allow exploitation and integration of novel findings between clinical, preclinical and discovery research and development.

- Deciphering mechanisms of protection of candidates, new approaches to antigen discovery and immunogen engineering, reverse vaccinology, evaluation of vaccines in novel platforms and technologies, novel adjuvants, innovative vaccine manufacturing approaches, relevant animal models, evaluation of alternative vaccine delivery routes.
- Effective, evidence-based decision-making for progression of vaccine candidates in the pipeline based on transparent and objective portfolio management. Regulatory requirements be considered. Sex, gender, age and socio-economic factors should be taken into account.

HORIZON-HLTH-2022-DISEASE-06-04-two-stage: Development of new effective therapies for rare diseases

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Researchers and developers make the best use of the state-of-the-art knowledge and resources for a fast and effective development of new therapies for rare diseases.
- Researchers and developers increase the development success rate of therapies for rare diseases by employing robust preclinical models, methods, technologies, validated biomarkers, reliable patient reported outcomes and/or innovative clinical trials designs.
- Developers and regulators move faster towards market approval of new therapies for rare diseases (with currently no approved treatment option) due to an increased number of interventions successfully tested in late stages of clinical development.
- Healthcare professionals and people living with a rare disease get access to new therapeutic interventions and/or orphan medicinal products.

Scope: Despite the considerable amount of knowledge that has been accumulated and the new orphan medicines developed in recent years, the number of available therapies for rare diseases remains low, as fewer than 6% of rare diseases have an approved treatment option.

The joint evaluation¹²³ of the regulations on orphan medicinal products and paediatric medicines concluded that those regulations have boosted the development for new therapies for rare diseases but have not yet adequately managed to direct research and innovation in areas of greatest unmet medical need. Actually, there is an urgent unmet medical need for the development of therapies for rare diseases, where there is still no approved therapeutic option available.

Therefore, proposals should aim to develop therapies for rare diseases with no approved therapeutic option. Proposals should focus on group(s) of rare diseases with commonalities, such as shared biological features, possibly within the same and/or across different medical areas within the rare diseases landscape¹²⁴. Thus, proposals should not address a single disease only (for example with an Orphacode representing a single disease).

The therapies to be developed may include a broad family of therapeutic interventions such as small molecule(s), advanced therapy medicinal products, repurposing of existing medicinal products, including non-pharmacological interventions and/or their combinations, as relevant. Sex and gender aspects should be considered, where relevant. To ensure that the needs of people living with a rare disease are adequately addressed, the involvement of patient representatives in all phases of the research and development process is strongly encouraged. Rare infectious diseases and rare cancers are excluded from this topic and will not be considered.

The topic will support proposals covering several different stages in the continuum of the innovation pathway (i.e. translational, preclinical, clinical research, validation in the clinical and/or real-world setting etc.), as relevant. SME(s) participation is encouraged with the aim to strengthen the scientific and technological basis of SME(s) and valorise their innovations for the benefit of people living with a rare disease.

The proposals should address most of the following research activities:

- Establish multidisciplinary collaborations between all relevant stakeholders by integrating disciplines, technological developments and existing knowledge. Integrate harmonised data from multiple sources (i.e. natural history studies/clinical trials, multi-omics, medical imaging, registries etc.) by utilising data analytics and/or other suitable methods, with the aim to understand the pathophysiology/heterogeneity of the rare diseases concerned and to identify therapeutically actionable mechanisms.

¹²³ https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/orphan-regulation_eval_swd_2020-163_part-3.pdf

¹²⁴ Medical areas such as: neurology, immunology, dermatology, endocrinology-metabolism etc. - see EMA therapeutic areas: <https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines>

- Develop and utilise relevant preclinical models and/or innovative tools/technologies to: verify molecular/cellular pathways/genes that can be therapeutically targeted, increase the confidence in the targets selection and/or perform toxicity studies. When using disease models the applicants should describe how well the model replicates the pathology or the human condition.
- Develop and/or execute innovative clinical trials designs for small populations and novel approaches to assess and monitor the safety and efficacy of the proposed interventions. Such approaches may include but are not limited to: biomarkers defining robust surrogate and clinical endpoints; artificial intelligence tools/medical devices/biosensors/companion/ complementary diagnostics for defining reliable patient reported outcomes; modelling and simulation and in-silico trials methodologies.
- Carry out preclinical proof-of-concept (PoC) studies and/or multinational interventional clinical studies¹²⁵ to demonstrate the safety and efficacy of the therapeutic interventions under study. Preclinical PoC studies should include late-stage preclinical studies (i.e. toxicological properties, adverse effects etc.). Clinical studies may cover all necessary development stages. Applicants should propose a clear exploitation pathway through the different necessary steps (research, manufacturing, regulatory approvals and licensing, IP management etc.) in order to accelerate marketing authorisation and uptake by the health systems.

Proposals should involve group(s) of rare diseases (i.e. a rare disease being individually defined in the European Union as affecting not more than five in 10.000 persons). Proposals that plan to run clinical trials should demonstrate that they have already taken into account scientific advice¹²⁶ or protocol assistance from EMA. In particular, proposals planning the clinical development of orphan medicinal products should demonstrate that they have been granted approval for an orphan designation at the latest on the date of the call deadline.

Proposals should adhere to the FAIR¹²⁷ data principles and take stock, wherever relevant, of data standards, harmonisation guidelines and good practices for data sharing/access developed by existing European health research infrastructures (i.e. ESFRI infrastructures¹²⁸). Proposals should take stock, where relevant, of the FAIR guidance, of good practices for analytical methods and preclinical models and of good exploitation strategies for the translation of research results into high impact interventions, developed by the European Joint Programme on Rare Diseases¹²⁹ (EJP RD) and other relevant EU-funded projects. Whenever the proposed data sources or fields of application include genomics, the proposals should take into account,

¹²⁵ Template for providing essential information in proposals involving clinical studies https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_2018-2020_en.pdf

¹²⁶ <https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance>

¹²⁷ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

¹²⁸ 2018 Roadmap of the European Strategy Forum on Research Infrastructures (ESFRI) with list of ESFRI research infrastructures (pp 15-17), https://ec.europa.eu/info/sites/info/files/research_and_innovation/esfri-roadmap-2018.pdf.

¹²⁹ <https://www.ejprarediseases.org/>

where relevant, the data standards, and legal, ethical and technical interoperability requirements and guidelines agreed within the 1+ Million Genomes initiative¹³⁰. Data-intensive proposals, particularly those using data from patient registries, could consider the involvement of the European Commission's Joint Research Centre (JRC) and take stock of the tools and services provided by the European Platform on Rare Disease Registration (EU RD Platform), including the adoption, where relevant, of the European standards such as the "set of common data elements"¹³¹. In addition, synergies should be sought with the European Reference Networks¹³², where relevant.

Projects funded under this topic will contribute towards the goals of the International Rare Diseases Research Consortium (IRDiRC) that supports the development of 1000 new therapies for rare diseases by 2027 and may take stock of the IRDiRC Orphan Drug Development Guidebook¹³³, where relevant.

Call - Tackling diseases (Single Stage - 2022)

HORIZON-HLTH-2022-DISEASE-07

Conditions for the Call

Indicative budget(s)¹³⁴

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹³⁵	Number of projects expected to be funded
		2022		
Opening: 12 Jan 2022 Deadline(s): 21 Apr 2022				
HORIZON-HLTH-2022-DISEASE-07-01	CSA	2.00	Around 2.00	1
HORIZON-HLTH-2022-DISEASE-07-02	RIA	10.00	Around 3.00	3

¹³⁰ <https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes>

¹³¹ https://eu-rd-platform.jrc.ec.europa.eu/set-of-common-data-elements_en

¹³² https://ec.europa.eu/health/ern_en

¹³³ <https://irdirc.org/orphan-drug-development-guidebook-materials/>

¹³⁴ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹³⁵ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Horizon Europe - Work Programme 2021-2022
Health

HORIZON-HLTH-2022-DISEASE-07-03	RIA	25.00 ¹³⁶	Around 3.00	8
Overall indicative budget		37.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-DISEASE-07-02: Pandemic preparedness

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 3.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 10.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

¹³⁶ Of which EUR 15.00 million from the 'NGEU' Fund Source.

- The scientific community has better understanding of the biology of the pathogens (virus, bacteria etc.), its transmission, its interaction with humans, animals and plants, in particular in view of emerging threats to human health, such as infectious diseases and anti-microbial resistance.
- Health care providers and practitioners have access to and use appropriate medical countermeasures, e.g. vaccines, diagnostics, therapeutics and digital solutions.
- Health authorities have the evidence-base and tools for better public health measures.

Scope: The COVID-19 pandemic has revealed weaknesses in the ability of the Union and its Member States to respond quickly and effectively to such an unprecedented health emergency. Therefore, the Commission is stepping up its efforts in supporting the Union's ability to respond to serious cross-border threats.

Member States agreed to step up their coordination in the area of pandemic preparedness research and aim to establish a European partnership on pandemic preparedness. A dedicated coordination support action¹³⁷ will help develop a common long-term Strategic Research and Innovation Agenda for such a partnership.

A key component for the European Health Union will be the establishment of the Health Emergency Preparedness and Response Authority (HERA) for which the Commission will put forward a legislative proposal by the end of 2021. It should build on experiences dealing with COVID-19, SARS and influenza, and consider emerging biological threats to human health, e.g. in the context of climate change, deforestation and biodiversity loss.

This topic aims to contribute and complement both of these initiatives, notably by addressing priority research and innovation gaps also identified by Member States and that would contribute and support the establishment and work of a potential future Health Emergency Preparedness and Response Authority (HERA).

Research focussing on 'pathogen X' from threat assessment, horizon scanning for the identification of potential medical countermeasures and innovative technologies, including the development of standardised research protocols would be in the scope of this topic.

HORIZON-HLTH-2022-DISEASE-07-03: Non-communicable diseases risk reduction in adolescence and youth (Global Alliance for Chronic Diseases - GACD)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 3.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹³⁷ HORIZON-HLTH-2021-DISEASE-04-06: Building a European partnership for pandemic preparedness

<i>Indicative budget</i>	The total indicative budget for the topic is EUR 25.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Health care practitioners and providers in low- and middle-income countries (LMICs) and those in high-income countries (HICs) serving vulnerable populations have access to and use specific guidelines to implement prevention interventions able to support adolescents and young people to decrease future risks of developing NCDs.
- Public health managers and authorities have access to improved insights and evidences on the NCDs related to behaviours and conditions in youth and adolescence. They establish improved health policies to diminish these risks, including to facilitate the deployment of effective public health interventions.
- Researchers, clinicians and authorities have an improved understanding of the factors that influence the implementation of preventive actions that address risk behaviours in youth and adolescence.
- Communities and local stakeholders and authorities are fully engaged in implementing and taking up health interventions and thus contribute to deliver better health.

Scope: The European Commission is a member of the Global Alliance for Chronic Diseases (GACD), an alliance of international funding agencies representing over 80% of the world’s public health research funding and the first collaboration of its kind to specifically address non-communicable diseases (NCDs). The GACD supports implementation science to improve health outcomes. This topic is launched in concertation with the other GACD members funding agencies and aligned with the GACD call 2021.

The topic is focused on implementation research about common risk prevention interventions targeting adolescents and youth to reduce the impact of non-communicable diseases (NCDs) in low- and middle-income countries (LMICs) and vulnerable populations in high-income countries (HICs). Proposals should focus on implementation science around evidence-based interventions that promote healthy behaviours, and that have the potential to profoundly reduce the risk of chronic diseases and multimorbidity.

The GACD Alliance is particularly interested in funding projects that focus on interventions that reduce health risk and/or enhance a healthy lifestyle in young people, which the WHO defines as the period from ages 10-24 and includes adolescence (ages 10-19) and youth (15-24). Adolescence and youth mark a period of emerging independence and an important time for laying the foundations of good health. Adolescence and youth is a period in life where patterns of behaviour are established around diet, physical activity, substance use and sexual

activity, which can affect their health in the present; in their future adult lives; and even in the next generation. In the transition from childhood to adulthood, young people become increasingly exposed to harmful products such as tobacco, alcohol and drugs, and can experience devastating mental health issues such as depression, anxiety, self-harm, substance abuse and addictions, as well as eating disorders and suicide. Over 150 million young people smoke; 81% adolescents do not meet physical activity guidelines; 11.7% of adolescents partake in heavy episodic drinking; and suicide has emerged as a leading cause of death in young people globally.

All proposals must make the case for why their selected life stage is a critical period for the reduction of NCD risk in the communities where the research will be undertaken. There are a range of evidence-based interventions, including the WHO Best Buys, which aim to reduce the health risks associated with common NCD risk factors. Implementation research is necessary to understand the uptake, accessibility, acceptability, adaption, sustainability and costs of known interventions for use in young adults and adolescents. Applicants are invited to consider interventions at the individual, family, community (e.g., work or school) or population level. Multi-sectoral approaches and a combination of different types of interventions, including biomedical, digital (such as artificial intelligence and big data), socio-behavioural, and/or structural¹³⁸ are encouraged. Projects will be expected to build on evidence-based interventions that focus on prevention interventions and strategies that reduce common risk factors for chronic non-communicable diseases, or that promote healthy behaviours. Such interventions/strategies might include, but are not limited to, those in the following three areas: nutrition, physical activity, and/or sleep; tobacco, substance abuse and/or alcohol use; social wellbeing and loneliness. Proposals should be gender-responsive and consider socioeconomic, racial or other factors that relate to equitable impacts of the intervention or barriers to equitable implementation.

Proposals should include implementation research outcomes (e.g. feasibility, fidelity and/or adaptation, spread and/or penetration, acceptability, sustainability, uptake, and cost effectiveness) and where relevant, include service outcomes (e.g. efficiency, safety, effectiveness, patient-centeredness, timeliness). The aim is to harmonise the research common goals and the outcomes assessment of GACD-funded projects in order to maximise the potential for learning across the network and the impact of the initiative as a whole. To this end, all funded teams are expected to use explicit indicators and measures of project context, reach, outcomes evaluation and scale-up potential in their plans and protocols. In this topic, the use of the following measures is encouraged: evidence of uptake of promoted healthy behaviours; evidence of reduction in harmful behaviours; and proxy mental and/or physical health outcomes, if appropriate (pre- and post- intervention PHQ-9 scores, blood pressure, HbA1C, etc.).

¹³⁸ Structural interventions are defined as interventions that attempt to change the social, physical, economic, or political environments in order to improve health behaviours and outcomes, altering the larger social context by which health disparities emerge and persist. They can include policy-driven fiscal or legislative changes focused on social and/or commercial determinants of health.

Proposals should include a strategy to include policy makers and local authorities, as well as other relevant stakeholders such as community groups. Such engagement should inform the conception and development of the project and should continue throughout the duration of project and afterwards during the knowledge translation phase. Participants that are local stakeholders can be powerful assets to the projects indeed. Their contributions should be nurtured through meaningful engagement throughout all phases of the project, not only as participants in the research undertaken.

HORIZON-HLTH-2022-DISEASE-07-01: Support for the functioning of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 2.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 2.00 million.
<i>Type of Action</i>	Coordination and Support Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- International research funders are supported by a dynamic and efficient secretariat in their coordination efforts for a rapid research response when a pandemic or a severe epidemic strikes.
- International research funders can rely on a tested framework underpinning a rapid and effective research response, and as such ensure stronger research preparedness and response for public health emergencies, including in cross-cutting areas such as data sharing, social science, clinical trial networks and others.
- Research funders, policy makers and the research community are well informed of the activities of GloPID-R members, both as a group and individually.

Scope: The COVID-19 pandemic has been a confronting reality-check of the potential extent of threats posed by new or emerging infectious diseases. The pandemic overwhelmingly confirmed that to fight such international challenges, global collaboration and coordination is crucial. The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)¹³⁹ was established in 2013 for this reason, in response to a request for coordination by the Heads of International Research Organisations. Years on, GloPID-R now provides a widely

¹³⁹ <https://www.glopid-r.org/>

recognised platform for infectious disease research funders to work together to better tackle severe epidemics such as Ebola or Zika, as well as global pandemics such as COVID-19.

The COVID-19 pandemic response illustrated the value added by GloPID-R, by enabling coordination between funders and with relevant global actors such as the World Health Organization (WHO) or the Coalition for Epidemic Preparedness Innovation (CEPI); or by promoting exchanges and synergies between funded researchers. Ongoing efforts with the network include reflections on improved data sharing during outbreaks, creating links between clinical trial networks, addressing specificities of research in low and middle-income countries, and the inclusion of social sciences into the research response to public health emergencies.

Proposals should foresee administrative and technical support through a secretariat to maintain, but above all to support GloPID-R's continuous evolution for an optimal value added.

Proposals are expected to cover all of the following activities:

- Provide administrative and organisational support to the Chair and Vice Chairs of GloPID-R, in close collaboration with the European Commission;
- Provide strong scientific support on topics requested by the GloPID-R Chairs, scientific advisors or (working) groups;
- Facilitate the work of the scientific advisors, ISG and GloPID-R working groups, using earlier experience in research preparedness and response to infectious disease outbreaks;
- Manage information dissemination and communication between the Chairs, Members, Scientific Advisors, Industry Stakeholder Group (ISG), working groups, enquiries, and outside stakeholders;
- Reinforce GloPID-R's external communications activities, such as the website and newsletter, as requested by the Chairs;
- Submit an annual work plan to the Commission each year following the annual meeting of GloPID-R, taking into account the conclusions of the annual meeting.
- Ensure a high level of adaptability to respond to rapidly evolving situations, following the guidance of the Chairs of GloPID-R.

Call - Partnerships in Health (2022)

HORIZON-HLTH-2022-DISEASE-03

Conditions for the Call

Indicative budget(s)¹⁴⁰

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁴¹	Number of projects expected to be funded
		2022		
Opening: 12 Jan 2022 Deadline(s): 21 Apr 2022				
HORIZON-HLTH-2022-DISEASE-03-01	COFUND	30.00 ¹⁴²	Around 30.00	1
Overall indicative budget		30.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant</i>	The rules are described in General Annex G.

¹⁴⁰ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹⁴¹ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹⁴² Of which EUR 18.00 million from the 'NGEU' Fund Source.

<i>Agreements</i>	
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Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-DISEASE-03-01: European partnership fostering a European Research Area (ERA) for health research

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 30.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 30.00 million.
<i>Type of Action</i>	Programme Co-fund Action

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Research funders, policy-makers and the research community work together in an effective joint approach, including for identifying and prioritising topics of common interest and European benefit, thanks to a trusted governance and effective working modalities.
- Research funders and policy-makers generate knowledge for cardiovascular diseases, diet related diseases and Nano medical technologies, and have access to and use evidences of the benefit and drawback of health interventions, in particular for optimising clinical management, repurposing, comparative effectiveness, treatment combination or optimisation studies, personalised medicine and avoiding overtreatment.
- Research funders and policy-makers have removed the main barriers to test health interventions at European level, and thus the research community conducts large-scale investigator-initiated clinical studies (IISs) of various health interventions addressing important public health needs in a seamless way.

Scope: Since 2003, several initiatives have developed a healthy eco-system of Public-Public Partnerships bringing together research funders across the EU and beyond. These networking ERA-NETs and joint programming activities are focused on specific priority areas with coordinated co-funding strategies to align and leverage national funding and depend on EU investments, to support coordination and joint implementation of activities and to achieve a critical level of investments.

The continuously growing arsenal of health interventions, whether it is a new pharmaceutical product, a medical device, a surgical intervention, or other measures utilised during health and care provision, all reflecting the increasing demand for better quality of care by citizens, force decision makers of public health systems to optimally allocate limited resources in a well-informed manner. **Investigator-initiated clinical studies (IICSs)** generate data on safety and effectiveness of a health intervention in real-world settings and thus provide evidence to answer questions that clinicians face in their day-to-day practice in order to optimise the clinical management of patients. Such studies deal with potential diagnostic and therapeutic innovations that traditionally does not attract the private sector but are crucial for optimised clinical management and for the sustainability of healthcare systems.

This new European Partnership will integrate these networks and eco-systems, building on their long-standing experience also expanding towards investigator-initiated clinical studies. It will identify bottlenecks, which hinder multinational clinical studies and propose ways to overcome them.

Phase 1 of the Partnership will serve as a transition from diverse scientific research agenda towards a shared scientific agenda which will include the support of investigator-initiated clinical studies. This phase will focus on governing, expanding and improving coordinated research funding actions, thereby taking into account the experiences made in the three quality Horizon 2020 ERA-NET addressing Cardiovascular Diseases (ERA-CVD), Nano Medical Technologies (EuroNanoMed) and Diet related diseases/Healthy Diets (related to the JPI "A Healthy Diet for a Healthy Life").

Phase 1 will integrate previous European initiatives¹⁴³ and implements joint calls in those areas. In parallel, it will pilot the possibility to carry out joint calls on IICSs. It will last 2 years. At the end of this period, the Health Programme Committee will decide or not to extend and intensify the focus on IICSs, based on pre-agreed criteria. This decision will only affect the focus area of the partnership, not its existence over the 7 years. During Phase 2, multinational calls for IICSs and joint calls for other priority areas will be launched in accordance with the decision of the Health Programme Committee taken at the end of Phase 1 on the appropriately shared focus of the Partnership between IICSs and other areas. Such a partnership should contribute to building a coherent European Research Area (ERA), enabling Member States, Associated Countries and the European Commission to rapidly and jointly support research and innovation to assess the relevance of health intervention.

The total indicative budget for the partnership matching Member State's commitment should be up to EUR 110 million. The additional budget of up to EUR 80 million will be foreseen in the 2025-2027 budgets to cover for Phase 2.

¹⁴³ ERANET CVD, TRANSCAN, Nano Medical Technologies; JPI 'A Healthy Diet for a Healthy Life'

Destination 4. Ensuring access to innovative, sustainable and high-quality health care

Calls for proposals under this destination are directed towards the Key Strategic Orientation KSO-D *'Creating a more resilient, inclusive and democratic European society'* of Horizon Europe's Strategic Plan 2021-2024. Research and innovation supported under this destination should contribute to the impact areas *'Good health and high-quality accessible health care'* and *'A resilient EU prepared for emerging threats'*, and in particular to the following expected impact, set out in the Strategic Plan for the health cluster: *'Health care systems provide equal access to innovative, sustainable and high-quality health care thanks to the development and uptake of safe, cost-effective and people-centred solutions, with a focus on population health, health systems resilience, as well as improved evidence-based health policies'*. In addition, research and innovation supported under this destination could also contribute to the following impact areas: *'Climate change mitigation and adaptation'*, *'High quality digital services for all'* and *'A Competitive and secure data economy'*.

Health systems are affected by limitations in sustainability and resilience, challenges which have been reinforced by the COVID-19 crisis that has also revealed inequalities in access to high-quality health care services. Our health systems need to become more effective, efficient, accessible, fiscally and environmentally sustainable, and resilient in order to cope with public health emergencies, to adapt to environmental challenges like climate change and to contribute to social justice and cohesion. Therefore, the transformation and modernisation of our health systems will be one of the biggest challenges in the economic recovery-bound future, but it will also be a time of opportunity for generating evidence, taking advantage of digital and data-driven innovation and developing more flexible and equitable health systems.

Under this destination, research and innovation aims at supporting health care systems in their transformation to ensure fair access to sustainable health care services of high quality for all citizens. Funded activities should support the development of innovative, feasible, implementable, financially sound and scalable solutions in the various dimensions of health care systems (e.g. governance, financing, human and physical resources, health service provision, and patient empowerment). Ultimately, these activities should provide decision-makers with new evidence, methods, tools and technologies for uptake into their health care systems and, consequently, allow improving governance of the European health care systems, supporting health care professionals and providers and allocating resources according to citizens' health needs and preferences, while ensuring fiscal and environmental sustainability to assure those needs can be met on the long-term. Funded activities should adopt a patient-centred approach that empowers patients, promotes a culture of dialogue and openness between citizens, patients, caregivers, health care providers and other relevant stakeholders, and unleashes the potential for social innovation.

In this work programme, destination 4 will focus on the following issues:

- Modernising health care systems in the EU, especially through a European public-public partnership on transforming health and care systems;
- Improving the quality of health care along the entire health care continuum and being people-centred;
- Supporting evidence-based health care decisions both for health care providers and policy-makers, fostering improved foresight and enabling sound planning of health care resources;
- Enhancing development and uptake of innovative health care services and solutions, including environmentally sustainable ones that contribute to the European Green Deal.

In view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic but also between other projects funded under another topic, cluster or pillar of Horizon Europe (but also with ongoing projects funded under Horizon 2020). In particular, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health and EIT-KIC Health (under pillar III of Horizon Europe), or in areas cutting across the health and other clusters (under pillar II of Horizon Europe). For instance, with cluster 2 “*Culture, Creativity and Inclusive Society*” such as on health economics and economic models, on cost-effectiveness, fiscal sustainability and accessibility of health care, or on adaptation of public health systems to societal challenges (climate change, environmental degradation, migration, demographic change, emerging epidemics and One Health AMR) thereby contributing to building resilience; with cluster 3 “*Civil Security for Society*” such as on security of health care infrastructures, incl. digital health infrastructures, health systems preparedness and response to disasters and other emergencies, and quality and safety of medicine (counterfeit and substandard medicine, illicit drugs, One Health AMR); with cluster 4 “*Digital, Industry and Space*” such as on cybersecurity of (public) health systems, products and infrastructures of digitalised health and care, or on health impact assessment (e.g. related to consumer products, working place innovation).

Expected impacts:

Proposals for topics under this destination should set out a credible pathway to contributing to ensuring access to innovative, sustainable and high-quality health care, and more specifically to one or several of the following impacts:

- Health and social care services and systems have improved governance mechanisms and are more effective, efficient, accessible, resilient, trusted and sustainable, both fiscally and environmentally. Health promotion and disease prevention will be at their heart, by shifting from hospital-centred to community-based, people-centred and integrated health

care structures and successfully embedding technological innovations that meet public health needs, while patient safety and quality of services is increased.

- Health care providers are trained and equipped with the skills and competences suited for the future needs of health care systems that are modernised, digitally transformed and equipped with innovative tools, technologies and digital solutions for health care. They save time and resources by integrating and applying innovative technologies, which better involve patients in their own care, by reorganising workflows and redistributing tasks and responsibilities throughout the health care system, and by monitoring and analysing corresponding health care activities.
- Citizens are supported to play a key role in managing their own health care, informal carers (including unpaid carers) are fully supported (e.g. by preventing overburdening and economic stress) and specific needs of more vulnerable groups are recognised and addressed. They benefit from improved access to health care services, including financial risk protection, timely access to quality essential health care services, including safe, effective, and affordable essential medicines and vaccines.
- Health policy and systems adopt a holistic approach (individuals, communities, organisations, society) for the evaluation of health outcomes and value of public health interventions, the organisation of health care, and decision-making.
- The actions resulting from the calls under this destination will also create strong opportunities for synergies with the EU4Health programme and in particular to contribute to the goals under general objectives 1a “protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with those threats” and 3 “strengthening health systems by improving their resilience and resource efficiency, in particular through: i) supporting integrated and coordinated work between Member States; ii) promoting the implementation of best practices on data sharing; iii) reinforcing the healthcare workforce; iv) tackling the implications of demographic challenges; and v) advancing digital transformation”.

The following call(s) in this work programme contribute to this destination:

Call	Budgets (EUR million)		Deadline(s)
	2021	2022	
HORIZON-HLTH-2021-CARE-05	70.00		21 Sep 2021
HORIZON-HLTH-2022-CARE-08		70.00	21 Apr 2022
HORIZON-HLTH-2022-CARE-10		100.00	21 Apr 2022

Horizon Europe - Work Programme 2021-2022
Health

Overall indicative budget	70.00	170.00	
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Call - Ensuring access to innovative, sustainable and high-quality health care (2021)

HORIZON-HLTH-2021-CARE-05

Conditions for the Call

Indicative budget(s)¹⁴⁴

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁴⁵	Number of projects expected to be funded
		2021		
Opening: 22 Jun 2021 Deadline(s): 21 Sep 2021				
HORIZON-HLTH-2021-CARE-05-01	RIA	25.00 ¹⁴⁶	Around 5.00	5
HORIZON-HLTH-2021-CARE-05-02	RIA	40.00 ¹⁴⁷	Around 10.00	4
HORIZON-HLTH-2021-CARE-05-04	CSA	5.00	Around 5.00	1
Overall indicative budget		70.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.

¹⁴⁴ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹⁴⁵ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹⁴⁶ Of which EUR 15.00 million from the 'NGEU' Fund Source.

¹⁴⁷ Of which EUR 24.00 million from the 'NGEU' Fund Source.

<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2021-CARE-05-01: Enhancing quality of care and patient safety

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 25.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 “*Ensuring access to innovative, sustainable and high-quality health care*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Health policymakers use context specific knowledge and evidence to develop inclusive, effective and affordable interventions ensuring patient safety;
- Health care professionals know how to prevent, identify, evaluate and address risks for patient safety, and use harmonised or standardised patient-centred procedures and practice guidelines for improving patient safety developed in partnership with empowered patients;
- Health care providers integrate harmonised and standardised practices with personalised treatment schemes;
- Health care providers use quality assured processes to bridge inter-sectorial gaps in the clinical pathways of patients to improve patient safety;

- An increased number of health care professionals and patients/citizens adhere to recommendations for improved patient safety.

Scope: Patient safety remains an issue of increasing concern for EU health systems. The Commission estimates that between 8% and 12% of patients admitted to hospitals in the EU suffer from adverse effects of health care¹⁴⁸.

Overall, the most common types of in-hospital adverse effects are operative/surgical related, medication or drug related, and health care associated infections, half of them being preventable¹⁴⁹. According to the Organisation for Economic Co-operation and Development (OECD), more than 7 million admissions in the OECD countries result from safety lapses in primary and ambulatory care¹⁵⁰. Diagnostic errors persist throughout all settings of care and contribute to increased risks and harms from the treatment¹⁵¹. Therefore, it is necessary to develop and implement coherent quality improvement and patient safety strategies in Europe. Harmonisation and standardisation of health care processes (Guidelines and Standard Operating Procedures) along the continuum of care contribute to improve quality and safety of health services, minimise the risk of errors and at the same time ensure the quality and comparability of health data. It is also a mean to address inequities in health care delivery.

The proposals should take into consideration the already existing EU-funded initiatives in this area and must address in a coherent manner at least three of the following items, but may also contain other research and innovations activities for improving patient safety:

- Fill knowledge and practice gaps in quality of care and patient safety, including through harmonisation and standardisation of health care delivery, optimizing inter-sectoral clinical pathways and decision-making processes and tools across regions and countries.
- Development and piloting of harmonised evidence-based interventions in a uniform and structured way in health care institutions of different EU regions and countries. This should be addressed in case studies at hospital, primary and outpatient care levels, and it should also take into consideration the diverse health care landscape across European Union and Associated Countries.
- Research on translation of international standards and clinical guidelines into national practice for improved quality of care and patient safety.
- Provide context-specific evidence on facilitators and barriers for transferring identified good practices across regions and countries.
- Comprehensive comparison of practices related to clinical guidelines in European Union and Associated Countries, including the regulatory basis underpinning guidelines in each

¹⁴⁸ Communication from the Commission to the European Parliament and the Council on patient safety, including the prevention and control of healthcare-associated infections (COM (2008) 836).

¹⁴⁹ Schwendimann et al., The occurrence, types, consequences and preventability of in-hospital adverse events – a scoping review (BMC Health Services Research (2018) 18:521).

¹⁵⁰ The Economics of Patient Safety in Primary and Ambulatory Care: Flying blind (OECD, 2018).

¹⁵¹ Erin P. Balogh et al., Improving Diagnosis in Health Care (The National Academy of Sciences, 2015).

health system, the guideline development process, mechanisms of quality control, implementation modalities, and evaluation of produced recommendations.

- Development of innovative approaches for the integration of harmonised and standardised practices with personalised treatment plans.

Proposals should consider a patient-centred approach that empowers patients/citizens, promotes a culture of dialogue and openness between health professionals and citizens/patients, and unleashes the potential for social innovation.

The proposals should contribute to improved patient safety along the continuum of care in European Union and Associated Countries. The proposal should present a clear strategy for empowering and involving patients and caregivers in addressing the selected item(s), giving attention to both PROMs (Patient-Reported Outcome Measures) and PREMs (Patient-Reported Experience Measures). The research design, including the expected results, should carefully analyse and tackle the sex and gender dimension. The proposed evidence-based interventions, including clinical guidelines and standards, should meet health care providers' needs and goals to increase patient safety and health care quality.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-HLTH-2021-CARE-05-02: Data-driven decision-support tools for better health care delivery and policy-making with a focus on cancer

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 40.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 “*Ensuring access to innovative,*

sustainable and high-quality health care". To that end, proposals under this topic should aim for delivering results that are directed at, tailored towards and contributing to some of the following expected outcomes:

- Health care organisations and policymakers adopt robust and transparent modelling (including data collection, storage and analysis), planning algorithms and artificial intelligence (AI) solutions in support of health care decision-making processes;
- Health care providers, caregivers (formal and informal), citizens, and other relevant stakeholders take better informed decisions about their health or the health of persons they are responsible for and/or about the organisation of the health care service or system they are involved in or in charge of;
- Health system owners are provided with evidence-based participative decision-making processes that take into consideration all relevant values, needs and perspectives, enabling to deliver health care services to patients in the most suitable and efficient manner;
- Policymakers access evidence-based, interoperable decision support tools for public health policy-making and health care delivery.

Scope: This call topic will contribute to Europe's Beating Cancer Plan activities¹⁵² and other relevant initiatives such as the European Cancer Information System¹⁵³. For this reason, proposals must focus on one or more phases of the cycle of the disease, starting from prevention and early diagnosis to treatment and quality of life of patients and survivors.

An ever-increasing amount of data is at the disposal of decision- and policy-makers, which, if analysed, pooled and used, could lead to novel data-driven approaches in health care delivery and policy-making, thus improving quality of life, health equity and producing better health outcomes. The collection, access, processing, and (primary and secondary) use of data is still very fragmented across national health systems. The availability and use of structured and unstructured health data represents an opportunity for the implementation of data-driven innovation and it provides new opportunities for developing, monitoring and evaluating decisions, and providing feedback into decision-making processes and policy strategies.

In this topic, research and innovation actions should aim at optimising and/or transforming health care delivery decision-making processes, supporting policy-making, and/or empowering citizens and cancer patients. The development of innovations, including tools, processes and services, should be done together with end-users (i.e. citizens, health professionals and policymakers), and represent both a support-base and scientific evidence for data-driven innovation. Design thinking and other relevant design methodologies should be considered.

¹⁵² <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan>

¹⁵³ European Cancer Information System <https://ecis.jrc.ec.europa.eu/>

The proposals should adhere to the FAIR data¹⁵⁴ principles and adopt data quality standards, data integration operating procedures and GDPR-compliant data sharing/access best practices developed by the European research infrastructures, if relevant. In addition, the proposals are encouraged to adopt best practices of international standards used in the development of computational models.

Data-driven algorithms should be explainable, unbiased and inclusive. Caution needs to be paid to systematically control for gender and racial bias and/or discrimination bias, when developing and using data and algorithms. The actions should ensure that the novel ideas are accompanied by frameworks/guidelines for new forms of collaboration and incentivising mechanisms/tools in order to support implementation of the innovations in the public sector. The tools should aim to improve health outcomes and quality of life, not only to lower health care costs.

Actions should pursue a multi-disciplinary and multi-stakeholder approach to integrate health care research, health services research, innovation, health economics, implementation science, operations management/research, data science and other relevant disciplines (i.e. sociology and anthropology) to ensure more equitable, innovative and sustainable health care systems.

Applicants should propose activities underpinned by health care data in one or more of the following areas:

- The development of data-driven, interactive policy and visualisation tools (i.e. through creation of digital twins/virtual models) bringing novel insights on populations, systems and services as a whole, to help policymakers make data-driven decisions. These can be foreseen to be used solely for health care decisions or constitute health-relevant inputs for other sectorial approaches, and promote multi-disciplinary knowledge exchange;
- The development of data-driven solutions (i.e. scenario-building tools and models) helping health care organisations take evidence-informed decisions on cancer care delivery processes such as logistics planning and management, capacity, utilisation of health services and allocation of resources and infrastructures (i.e. human resources, health goods, etc.), and availability of and access to health care technologies (i.e. pharmaceuticals, vaccines, medical devices, etc.) and interventions;
- The development of data-driven solutions empowering citizens' and cancer patients' interaction with the health care systems, including feedback mechanisms, guidance on health care pathways and on managing health care data, supporting patients in making health care decisions and treatment adherence;
- The development of digital toolkits and indicators to improve the reporting and assessment of outputs from end-user involvements, including those of patient-reported outcomes measures (PROMs) and patient-reported experience measures (PREMs), and help gauge the actual impact in health care (including interaction between patients and health care providers).

¹⁵⁴ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

Applicants are encouraged to establish dynamic relations and synergies with the following areas, where applicable:

- Decision-making processes and tools, including social innovation;
- Monitoring and evaluating the budgetary impact of health care interventions (i.e. innovative solutions, digital services and health care models);
- Health technology assessment and cost-effectiveness analysis;
- Artificial intelligence/deep learning tools in social medicine to determine causal factors of disease/conditions and develop interventions;
- Data sharing between different institutions;
- European Health Data Space (EHDS);
- Open source and/or common building blocks used in Connecting Europe Facility (CEF) (e.g. eDelivery, eID);
- Standards and mechanisms to allow for interoperability between primary and secondary use of data;
- Privacy-preserving protocols for secondary use of data for public health policy-making and research;
- Federated/distributed access or data processing protocols for data-driven decision-support tools for better health care delivery and policy-making.

Proposals should adopt a patient-centred approach that empowers patients, promotes a culture of dialogue and openness between citizens/patients, caregivers, health care providers and other relevant stakeholders, and unleashes the potential for social innovation.

Whenever the data sources proposed to be used by the applicants include genomics data, the proposals should consider the data standards and legal, ethical and technical interoperability requirements and guidelines agreed under the 1+ Million Genomes Initiative¹⁵⁵ where relevant.

If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).

HORIZON-HLTH-2021-CARE-05-04: Health care innovation procurement network

Specific conditions	
<i>Expected EU</i>	The Commission estimates that an EU contribution of around EUR

¹⁵⁵ <https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes>

<i>contribution per project</i>	5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 5.00 million.
<i>Type of Action</i>	Coordination and Support Actions
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G. The following exceptions apply: Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. The maximum amount to be granted to each third party is EUR 60 000.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 “*Ensuring access to innovative, sustainable and high-quality health care*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Stakeholders involved in the demand side of health and social care innovations (such as procurement agencies, health care providers, payers/health insurers, public authorities, health care professionals, citizens) reach a common understanding that reflects their key clinical, procurement/supply, organisational and coordination priorities.
- Public/private procurers and decision makers at a local, regional, national and EU level collectively develop and adopt optimal, cost-efficient and flexible innovation procurement strategies, taking into account the ongoing changes in the organisational procedures of health care structures caused by the COVID-19 pandemic.
- Procurers and decision makers in procurement organisations mainstream health care-related Innovation Procurement best practices in their respective policy and investment strategies.
- Health care procurers from participating Member States and associated countries scale up cross-border collaborations in research and deployment of innovative solutions, thereby minimising investment risks.

Scope: This call aims to support the creation of a network of public¹⁵⁶ and private procurers that are responsible for deploying health care innovations across the EU, in order to identify potential areas of interest for innovation procurement.

¹⁵⁶ Public procurers are organisations that are contracting authorities or contracting entities according to the definition of those terms in the EU public procurement directives 2014/24/EU, 2004/25/EU, 2009/81/EC.

Health care stakeholders on the demand side can address their clinical or organisational challenges through networking and the coordinated use of innovation procurement tools and policies. A network's scale, internal transfer of knowledge and engagement with external stakeholders in health, research and industry would facilitate the development of a holistic approach in innovation procurement and an increased collective capacity to procure solutions, which improve health outcomes for patients in inclusive, flexible and fiscally sustainable ways.

This network should assemble a critical mass of European procurers with a strong track record, processes and resources for deploying innovative solutions in health and social care, as well as less experienced ones (due, for example, to budget constraints, lack of expertise or language barriers) who are interested to venture into this area. Through collaboration, experience sharing and in particular through twinning activities, the network should offer the opportunity to less experienced procurers in health innovation to build up capacity on innovation procurement. To this aim, beneficiaries may provide financial support to third parties. This support can only be given in the form of grants and the maximum amount to be granted to each third party is EUR 60 000. The respective options of the Model Grant Agreement will apply. Beneficiaries should refer to General Annex B of the Work Programme for further information and guidance.

These goals are particularly relevant in light of the COVID-19 pandemic, which highlighted issues such as the timing, financing and coordination of cross-border/emergency procurement in the EU, supply chain diversity and security, as well as the benefits of digital solutions for patients, health professionals and citizens. The ongoing pandemic has demonstrated that new critical challenges for health care systems may arise in the future, which will need to be addressed properly and swiftly, sometimes with innovative tools and flexible approaches.

The proposals should present a credible plan for a network, which will:

- Create a sustainable mechanism for decision-makers in the health and social care sector to enable and facilitate the use of Innovation Procurement as a tool to tackle current and future challenges faced by the procurers involved;
- Develop a holistic innovation procurement action plan for key health care challenges ahead, that is adaptable to the procurement strategies of most public organizations in the health care sector in Europe and covering all stages of Innovation Procurement implementation (from the identification of a need and pre-tender market consultation, until evaluation of the procurement's impact);
- Set the ground for mainstreaming (cross-border) Innovation Procurement implementation in Europe's health sector (EU-funded or not), by engaging, in an appropriate way, other key stakeholders, such as patients, industry (including SMEs/start-ups), policymakers (local, regional and/or national authorities) or investors (e.g. private investors, National Promotional Banks and Economic Development Agencies etc.).

Applicant consortia should be composed primarily of public and/or private procurers, dealing with or interested in the purchase of health care innovations. Consortia may also include health authorities or innovation procurement competence centres, which support these health care procurers in implementing innovation procurement¹⁵⁷. The composition of the applicant consortia should ensure a broad and balanced geographical representation of Member States and Associated Countries.

Proposals should not promote a silo mentality but should interconnect different types of procurers with their counterparts in other countries across Europe and with the wider healthcare/eHealth ecosystem and an enlarged group of stakeholders critical to the success of Innovation Procurement activities. Applicants should demonstrate that they have the mandate and capacity to procure and can engage key decision-makers from their organisation (e.g. procurement departments, clinical, academic and research departments) who would provide the backbone for such an innovation procurement policy and coordination mechanism to operate effectively (e.g. leverage funds and external expertise, recruit stakeholders, develop/adapt strategies, provide policy recommendations, facilitate emergency procurement procedures).

Proposals should include all of the following aspects:

- Hold an open market consultation with the industry across Europe on the current state of the art for the shared unmet needs for innovative solutions identified by the procurers, including on technical and service readiness;
- Develop capacity and cooperation models for implementing Innovation Procurement (in the form of Innovation Partnerships, PCP/PPI or other relevant instruments), which overcome potential differences among the legal public procurement frameworks of the participating procurers in health and social care;
- Conduct a user analysis of Innovation Procurement, identify barriers and propose solutions to overcome these barriers (e.g.: standardisation, certification, regulatory requirements, intellectual property rights, contracting models, payment/reimbursement models) and facilitate uptake of such solutions;
- Plan for procurement(s) based on identified common needs;
- Take measures ensuring the sustainability of outcomes beyond the lifespan of the proposed project and their integration into the procurement strategies of participating organisations, taking into account acceptance with users and professionals as well as health economics considerations.

¹⁵⁷ Innovation procurement competence centres are organisations/organisational structures that have been assigned the task by their government and have a mandate according to national law to encourage wider use of pre-commercial procurement (PCP) and public procurement of innovation (PPI) that includes among others providing practical and/or financial assistance to public procurers in the preparation and/or implementation of PCP and PPI procurements.

Call - Ensuring access to innovative, sustainable and high-quality health care (Single Stage - 2022)

HORIZON-HLTH-2022-CARE-08

Conditions for the Call

Indicative budget(s)¹⁵⁸

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁵⁹	Number of projects expected to be funded
		2022		
Opening: 06 Oct 2021 Deadline(s): 21 Apr 2022				
HORIZON-HLTH-2022-CARE-08-02	PCP	25.00	Around 5.00	5
HORIZON-HLTH-2022-CARE-08-03	PPI	15.00	Around 5.00	3
HORIZON-HLTH-2022-CARE-08-04	RIA	30.00	Around 5.00	6
Overall indicative budget		70.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.

¹⁵⁸ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹⁵⁹ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-CARE-08-02: Pre-commercial research and innovation procurement (PCP) for building the resilience of health care systems in the context of recovery

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 25.00 million.
<i>Type of Action</i>	Pre-commercial Procurement
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: The following additional eligibility criteria apply: Specific conditions for actions implementing pre-commercial procurement or procurement of innovative solutions (see General Annex H).

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 “*Ensuring access to innovative, sustainable and high-quality health care*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Public and private procurers in the area of health care procure the competitive development of market-ready, sustainable, innovative solutions (materials, equipment, technologies and systems/practices) which are made in Europe and can improve the preparedness and resilience of health care systems in the context of the recovery;
- European health and technology industry actors (including start-ups/SMEs) bring to the market secure, interoperable digital health care solutions (complying with relevant ethical and privacy protection standards) which are proven to improve health outcomes and access to care for patients;

- Procurers facilitate the commercialisation of innovative solutions at a large scale (EU/international) by their successful suppliers through providing them with first customer references for the validation and first pilot deployment in multiple countries and health care settings;
- Policymakers, health care providers and professionals, patients and their carers – each in their respective areas – exchange and adopt good practices and the best solutions the market can deliver to improve the resilience of health care systems.

Scope: Pre-commercial procurement (PCP) can boost innovation in health care systems, while building the capacity of providers and increasing resilience and preparedness in the context of cross-border public health emergencies. Through the competitive development of a range of breakthrough innovations for a concrete health care challenge, PCP can strengthen the security of the supply chain in the health care sector. At the same time, these instruments can support the economic recovery of the EU by providing incentives to the EU health and technology industry (especially spin-offs, start-ups and SMEs) to innovate and commercialise their products or services at a larger scale than they normally would. Fostering the development of such innovative solutions in Europe can reinforce EU strategic autonomy in strategic health technologies and lead to the creation of new markets for the EU industry, thereby contributing to EU growth, employment and competitiveness. At the same time, joint/collaborative demand-side initiatives can help create economies of scale and early adoption of innovations by the health sector. Advances in this area can help EU health care systems build resilience and respond to public health threats better than if they would act individually.

Pre-commercial procurement actions in the area of health care gather relevant public and private procurers to address a common, unmet need through the cross-border public and private procurement of research and development for demand-driven innovative solutions. Specific guidance on PCP actions and minimum eligibility requirements can be found in General Annex H¹⁶⁰ of the Horizon Europe work programme.

Proposals should therefore be based on clearly identified user needs and well-structured work plans, explaining how the procured research and development will contribute to the expected outcomes. In addition, proposals should clearly state the expected health benefits of the solutions that will be developed during the course of the action. In this context, applicants should also consider aspects of accessibility and affordability of the solution, efficiency of the technology when implemented in the relevant contexts and how it contributes to health systems resilience.

This topic prioritises areas of health care such as health promotion, preparedness, prevention, surveillance and rapid response to cross-border health threats. Promoting coordination, cooperation and common standards in the procurement of innovation in health care (including emergency procurement) should be at the heart of any proposal submitted as well as facilitating the digital and green transition of EU health systems.

¹⁶⁰ Link not yet available.

A wide variety of settings are potentially relevant for the implementation of such innovative solutions, such as: primary health care settings, ambulatory care, hospitals, specialised centres, and long-term health care facilities. The involvement of end-users and the use of cross-sectorial approaches are essential in the area of health. They can lead to more impactful proposals, especially if combined with cost-effectiveness/cost-benefit analyses in comparison with the status quo.

Within this topic, it is possible to provide for the transfer and adaptation of solutions and/or interventions from other sectors to health care. It is open both to proposals requiring: i) improvements mainly based on one specific solution/technology field; and ii) end-to-end solutions that need combinations of different types of innovation.

Proposals should demonstrate the potential and any future plans for the sustainability of good practices developed or implemented during the action, beyond its life. Such good practices could include cooperation with policy makers to reinforce relevant national policy frameworks, relevant actions to improve the skills of health professionals, patients or carers in the use of the solutions and collaboration with stakeholders for standardisation purposes or in order to leverage additional national funds or private investment for procuring solutions.

Synergies with the Technical Support Instrument ¹⁶¹ and the European Structural and Investment Fund are encouraged.

HORIZON-HLTH-2022-CARE-08-03: Public procurement of innovative solutions (PPI) for building the resilience of health care systems in the context of recovery

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 15.00 million.
<i>Type of Action</i>	Public Procurement of Innovative Solutions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: The following additional eligibility criteria apply: Specific conditions for actions implementing pre-commercial procurement or procurement of innovative solutions (see General Annex H).

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 “*Ensuring access to innovative,*

¹⁶¹ Proposal for a Regulation of the European Parliament and of the Council of 28 May 2020 on the establishment of the Technical Support Instrument, COM(2020) 409 final.

sustainable and high-quality health care". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes specified below:

- Public and private procurers in the area of health care deploy at a critical scale, innovative, market-ready solutions (materials, technologies and systems/practices), that are relevant to the preparedness and resilience of health care systems;
- European health and technology industry actors (including start-ups/SMEs) bring to the market secure, interoperable digital health care solutions (complying with relevant ethical and privacy protection standards) which are proven to improve health outcomes and access to care for patients;
- Procurers facilitate the commercialisation of innovative solutions at a large scale (EU/international) by their successful suppliers through providing them with customer references for the validation and first pilot deployment in multiple countries and health care settings;
- Policymakers, health care providers and professionals, patients and their carers – each in their respective areas – exchange and adopt good practices and the best solutions the market can deliver to improve the resilience of health care systems.

Scope: Public procurement of innovative solutions (PPI) can boost the wider market uptake of high impact innovations in health care systems, while building the capacity of providers and increasing resilience and preparedness in the context of cross-border public health emergencies. This can support the economic recovery of the EU by providing incentives to the EU health and technology industry (especially spin-offs, start-ups and SMEs) to innovate and by providing business opportunities to commercialise innovative products or services at a larger scale than they would normally have. By acting as early adopters of such innovative solutions, procurers can open up new growth markets for the EU industry, thereby contributing to EU growth, employment and competitiveness. At the same time, joint/collaborative demand-side initiatives can help create economies of scale and scale up the wider adoption of innovations by the health sector. Advances in this area can help EU health care systems build resilience and respond to public health threats better than if they would act individually.

The actions supported will target critical-scale deployment of relevant health care solutions across different regions in Europe by engaging public and/or private procurers from each participating country (at national, regional or local level) that have deployment responsibilities and budget control in the relevant area of care or supply of services. Procurers will specify, purchase and deploy solutions addressing their relevant, shared unmet needs, while engaging together in a supply and demand side dialogue, in order for the deployed solutions to deliver sustainable, new or improved health care services and outcomes, always taking into account patient feedback. Specific guidance on PPI actions and minimum eligibility requirements can be found in General Annex Hof the Horizon Europe work programme.

Proposals should therefore be based on clearly identified user needs and well-structured work plans, explaining how the procurement of the innovative solutions will contribute to the expected outcomes. In addition, proposals should clearly state the benefits of the solutions that will be developed during the course of the project. In this context, applicants should consider aspects of accessibility and affordability of the solution, efficiency of the technology when implemented in the relevant contexts and how it contributes to health systems resilience.

This topic prioritises areas of health care such as health promotion, preparedness, prevention, surveillance and rapid response to cross-border health threats. Promoting coordination, cooperation and common standards in the procurement of innovation in health care (including emergency procurement) should be at the heart of any proposal submitted as well as facilitating the digital and green transition of EU health systems.

Activities covered should include cooperation with policymakers to reinforce the national policy frameworks and mobilise substantial additional national budgets for the PPI, searching support and collaborating with respective coordination and networking projects. 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.

A wide variety of settings are potentially relevant for the implementation of such innovative solutions, for example primary health care settings, hospitals, specialised centres, and long-term health care facilities. The involvement of end-users and the use of cross-sectorial approaches are necessary in the area of health. They can lead to more impactful proposals, especially if combined with cost-effectiveness analyses in comparison with the status quo.

Within this topic, it is possible to foresee the transfer and adaptation of solutions and/or interventions from other sectors to health care. 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 types of innovation.

Synergies with the Technical Support Instrument¹⁶² and the European Structural and Investment Fund are encouraged.

HORIZON-HLTH-2022-CARE-08-04: Better financing models for health systems

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹⁶² Proposal for a Regulation of the European Parliament and of the Council of 28 May 2020 on the establishment of the Technical Support Instrument, COM(2020) 409 final.

<i>Indicative budget</i>	The total indicative budget for the topic is EUR 30.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 “*Ensuring access to innovative, sustainable and high-quality health care*”. More specifically, this topic aims at supporting activities that are contributing to some of the following expected impacts:

- Health and social care services and systems have improved governance mechanisms and are more effective, efficient, accessible, resilient, trusted and sustainable, both fiscally and environmentally. Health promotion and disease prevention will be at their heart, by shifting from hospital-centred to community-based, people-centred and integrated health care structures and successfully embedding technological innovations that meet public health needs, while patient safety and quality of services is increased.
- Health policy and systems adopt a holistic approach (individuals, communities, organisations, society) for the evaluation of health outcomes and value of public health interventions, the organisation of health care, and decision-making.

To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Decision and policymakers in the field of health care avail of new approaches to financial planning and financing mechanisms that provide flexibility to stretched health budgets, including alternative procurement and contractual methods;
- Decision and policymakers in the field of health care apply cost-effective spending strategies based on the optimisation of the use of resources, while maintaining or improving health outcomes in an equitable way;
- Decision and policymakers in the field of health care access tools that enable them to better remunerate, contract and incentivise health care professionals and providers;
- Decision and policymakers in the field of health care take evidence-based and socially equitable health care financial decisions.

Scope: In 2017, spending on health care in the EU stood at 9.6% of gross domestic product, ranging from over 11% in France and Germany to less than 6% in Romania. In most countries, in-patient care services made up the bulk of health spending, while spending on pharmaceuticals also accounted for a large share of health expenditure in some countries.¹⁶³

Due to demographic changes in the EU with a population projected to continue ageing and higher expectations regarding provision of health care services, public health threats with relevant repercussions for society and the introduction of innovative and digital solutions to

¹⁶³ Health at a Glance: Europe 2018.

improve health care systems' functioning, the demand for health care services as well as the budgetary pressures on health care systems are and will keep increasing.

Future models of care delivery will have to take into account both the systemic and multi-dimensional performance perspective and to look at relevant outcome and quality indicators, structure of care delivery, and knowledge base regarding optimal care delivery systems,

Therefore, research and innovation should tackle the challenges of financing health care services in the EU by addressing one or more of the following:

- Financing of health care – development of new cost-effective models for financing and reimbursement, including incentive mechanisms and outcome-based financing in order to promote good performance of the health care systems.
- Financing of preventive health care – novel models and appropriate structure of financial incentives for effective health promotion and disease prevention, financial incentives for stronger co-operation between primary care and public health services, long-term sustainable financing mechanism for local- and municipality-run promotion programmes and the assessment of personal health risk behaviour and its potential impact on health costs.
- Innovative purchasing and contract methods – new strategies for contracting provision of health care services (public sector hired services) as well as solutions to better assess provision capacity and quality, to assess markets, and cost-effectiveness as well as equal access of contracting-out services. This can help align the incentives of providers with those of patients and the public good.
- New and improved tools for better design of incentives for health care professionals – incentives that minimise differentiation between services and “cream-skimming” by patients, fostering better health care planning, optimized use of health care services and avoidance of resources' overconsumption and -waste.

Value-based pricing- and payment models for health technologies are not in the scope of this topic; such models are covered by topic “New pricing and payment models for cost-effective and affordable health innovation” (HORIZON-HLTH-2022-IND-13-03) under destination 6.

Research and innovation in these areas should take into account the potential impact of public health emergencies and threats on the sustainability, financing, as well as the effective and efficient functioning of EU health care systems.

To ensure wide uptake by user communities and scalability of the models and methods across health systems, actions should promote the highest standards of transparency and openness, going well beyond documentation and extending to aspects such as assumptions, architecture, code and any underlying data.

Applicants are highly encouraged to actively involve public authorities (i.e. ministries of finances and health, procurement agencies/procurers and agencies responsible for the

management of health services contracts, public health and health-policy institutes, health administrations, among other) in the proposals.

Projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate, and in particular they are expected to liaise with successful applicants under topic “New pricing and payment models for cost-effective and affordable health innovation” (HORIZON-HLTH-2022-IND-13-03) and the consortium to be created under the planned “European Partnership on Transforming Health and Care Systems” (HORIZON-HLTH-CARE-2022-IND-10-01). These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activity without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

Call - Partnerships in Health (2022)

HORIZON-HLTH-2022-CARE-10

Conditions for the Call

Indicative budget(s)¹⁶⁴

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁶⁵	Number of projects expected to be funded
		2022		
Opening: 06 Oct 2021 Deadline(s): 21 Apr 2022				

¹⁶⁴ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹⁶⁵ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

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HORIZON-HLTH-2022-CARE-10-01	COFUND	100.00 166	Around 100.00	1
Overall indicative budget		100.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-CARE-10-01: European partnership on transforming health and care systems

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 100.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 100.00 million.
<i>Type of Action</i>	Programme Co-fund Action
<i>Procedure</i>	The procedure is described in General Annex F. The following exceptions apply:

¹⁶⁶ Of which EUR 60.00 million from the 'NGEU' Fund Source.

	The granting authority can fund a maximum of one project.
<i>Legal and financial set-up of the Grant Agreements</i>	<p>The rules are described in General Annex G. The following exceptions apply:</p> <p>Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. Financial support provided by the participants to third parties is one of the primary activities of the action in order to be able to achieve its objectives. The EUR 60 000 threshold provided for in Article 204(a) of the Financial Regulation No 2018/1046¹⁶⁷ does not apply.</p> <p>The funding rate is 30 % of the eligible costs.</p>

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4, notably “*Ensuring access to innovative, sustainable and high-quality health care*”, “A resilient EU prepared for emerging threats” and “High-quality digital services for all”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Researchers across European countries and regions are engaged in enhanced collaborative research on transforming health and care systems;
- Health and care authorities, policymakers and other stakeholders use the research results to develop evidence-based strategies and policies on transforming health care systems and learn from good practices of European countries and regions;
- Health and care providers and professionals implement innovative ways of delivering care and maintaining population health;
- Health and care authorities, policymakers and other stakeholders plan and carry out efficient investments in health and care systems at national/regional level to use innovative solutions and care models;
- An increased number of innovators and stronger local/regional ecosystems of stakeholders are in place and facilitate uptake of successful innovations for health and care;
- Citizens and health and care professionals have increased digital and health literacy;

¹⁶⁷ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1046>

- Countries cooperate better and use context-specific knowledge and evidence to make their health and care systems more resilient with respect to upcoming needs and crises.

Scope: For many reasons (demographic changes, technological progress, fiscal constraints, public health emergencies etc.) the European health and care systems are expected to be subject to severe stress. In particular, the COVID-19 pandemic has highlighted existing structural weaknesses in health and care systems, and emphasised areas where not enough effort, planning and resources had been directed to. In addition, rapid technological and societal evolutions call for urgent responses to increasing demands and expectations from citizens. There is a need to accelerate the transition towards more efficient, sustainable, resilient, innovative and accessible health and care systems in Europe. To this end, the creation of a research and innovation (R&I) partnership with a focus on health and care systems' transformation represents a unique strategic opportunity to bring together stakeholders, create synergies, coordinate R&I actions, facilitate the digitization of health and care services and support the transformation of health and care systems with innovative solutions driven by knowledge and evidence. The partnership should build on knowledge gained from initiatives taken under Horizon 2020 (TO-REACH, Active and Assisted Living programme (AAL), Joint Programming Initiative More Years, Better, Lives (JPI MYBL), European Innovation partnership (EIP-AHA), ICPeMed, etc.). In order to increase the likelihood of successful system transformation, the partnership will facilitate exchange of information and good practices among countries, provide robust guidance and tools, network institutional stakeholders and involve regional ecosystems. It will stimulate service, policy and organisational innovations, as well as the integration of biomedical and technological innovations for the benefit of the European citizens and the European industry. Development of new products is beyond the scope of this Partnership. By laying the ground for the transformation of the health and care systems, the partnership will contribute to the transition of Europe to a more sustainable development and address emerging threats raised by environmental changes and globalisation.

The partnership should bring together a broad range of actors with a common vision of future health and care systems. Through the objectives of Horizon Europe, the partnership should contribute to achieving the following European Commission priorities:

- Promoting our European way of life
- An economy that works for people
- A Europe fit for the digital age
- A European green deal

The partnership will contribute to priorities of the “*Communication on effective, accessible and resilient health systems*” (COM(2014) 215 final), the “*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) and support the objectives of the Commission proposal for the new EU4Health Programme (COM(2020) 405 final).

Thanks to its capacity to bring together different stakeholders (e.g. research funders, health authorities, health and care institutions, innovators, policy makers), to create a critical mass of resources and to implement a long-term Strategic Research and Innovation Agenda (SRIA), the partnership will address the following objectives:

- Supporting multidisciplinary R&I to fill knowledge gaps, produce evidence and develop guidance and tools in priority areas for the transformation of health and care systems,
- Supporting the interdisciplinary development of service, policy and organisational innovations for health and care systems,
- Strengthening the R&I community in the field of health and care systems,
- Improving the capability of health and care actors to take up innovative solutions,
- Gathering stakeholders to develop the ecosystems needed for a swift uptake of innovations by health and care systems.

The European Partnership on transforming health and care systems¹⁶⁸ should be implemented through a joint programme of activities ranging from research to coordination and networking activities, including training, demonstration, piloting and dissemination activities, to be structured along the following main building blocks:

- Joint implementation of the SRIA;
- Joint annual calls for R&I activities, applied R&I, pilots, twinning projects;
- Joint annual calls for experimental development and innovation funding, co-creation, involvement of end-users, new concepts of care and innovative solutions for supporting health according to WHO definition; development of ecosystems, business models;
- Capacity building activities;
- Activities to increase health and digital literacy among citizens and health care practitioners;
- Flanking measures.

The Partnership is open to all EU Member States, as well as to countries associated to Horizon Europe and will remain open to those countries wanting to join. It should include the following actors:

- Ministries in charge of R&I policy, as well as national and regional R&I and technology funding agencies and foundations;

¹⁶⁸ More information on the planned European Partnerships is available on the Horizon Europe Webpage: https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme/european-partnerships-horizon-europe_en#partnership-candidates-and-contact-details.

- Ministries in charge of health and care policy, as well as national and regional health and care authorities, organisations and providers.

The Partnership may also encourage engagement with other relevant Ministries and will involve other key actors from civil society and end-users, research and innovation community, innovation owners, health and care systems owners/organisers and health and care agencies.

The Partnership's governance structure should enable an upfront strategic steering, effective management and coordination, daily implementation of activities and ensure the use and uptake of the results. The governance should leave sufficient space for involving the key stakeholders, including but not limited to R&I community, patients and citizens, health and care professionals, formal and informal care organisations, and innovation owners.

Financial commitments and in-kind contributions are expected to be provided for the governance structure, the joint calls and other dedicated implementation actions and efforts for national coordination.

To encourage national coordination and avoid an excess of grant signatories it is recommended to limit their number to two per country. However, in duly justified cases this number could differ, including for countries with decentralised administration to allow for participation of regional authorities in charge of R&I policy and health and care policy.

To ensure coherence and complementarity of activities and leverage knowledge and investment possibilities, the Partnership is expected to establish relevant collaborations with other Horizon Europe partnerships (institutionalized and co-funded) and missions as set out in the working document on 'Coherence and Synergies of candidate European partnerships under Horizon Europe'¹⁶⁹ as well as to explore collaborations with other relevant activities at EU and international level. On top of this, the proposal should consider synergies with EU programmes, including but not limited to EU4Health, DEP, ESF+, ERDF, InvestEU, RRF and TSI.

The Partnership should align with EU-wide initiatives on open access and FAIR data¹⁷⁰.

Although this Partnership will focus on the transformation of European health and care systems, cooperation with international organisations, and non-European institutions and experts may be considered. Applicants should describe in their proposal the methodology for their collaboration and the aims they want to achieve with this kind of collaboration.

Proposals should pool the necessary financial resources from the participating national (or regional) research programmes with a view to implementing joint calls for transnational proposals resulting in grants to third parties. Financial support provided by the participants to third parties is one of the primary activities of this action in order to be able to achieve its

¹⁶⁹ https://ec.europa.eu/info/horizon-europe/european-partnerships-horizon-europe_en#synergies

¹⁷⁰ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

objectives. The EUR 60 000 threshold provided for in Article 204(a) of the Financial Regulation No 2018/1046¹⁷¹ does not apply.

The expected duration of the partnership is seven years.

Horizon Europe contribution will be limited to a maximum of 30% of the total eligible costs of the action with a maximum of EUR 100 million of EU contribution

¹⁷¹ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1046>

Destination 5. Unlocking the full potential of new tools, technologies and digital solutions for a healthy society

Calls for proposals under this destination are directed towards the Key Strategic Orientation KSO-A *'Promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains'* of Horizon Europe's Strategic Plan 2021-2024. Research and innovation supported under this destination should contribute to the impact area *'High quality digital services for all'* and in particular to the following expected impact, set out in the Strategic Plan for the health cluster: *'Health technologies, new tools and digital solutions are applied effectively thanks to their inclusive, secure and ethical development, delivery, integration and deployment in health policies and health and care systems'*. In addition, research and innovation supported under this destination could also contribute to the following impact areas: *'A competitive and secure data-economy'*, *'Industrial leadership in key and emerging technologies that work for people'*, and *'Good health and high-quality accessible health care'*.

Technology is a key driver for innovation in the health care sector. It can provide better and more cost-efficient solutions with high societal impact, tailored to the specific health care needs of the individual. However, novel tools, therapies, technologies and digital approaches face specific barriers and hurdles in piloting, implementing and scaling-up before reaching the patient, encountering additional challenges such as public acceptance and trust. Emerging and disruptive technologies offer big opportunities for transforming health care, thereby promoting the health and well-being of citizens. Unlocking this potential and harnessing the opportunities depends on the capacity to collect, integrate and interpret large amounts of data, as well as ensure compatibility with appropriate regulatory frameworks and infrastructures that will both safeguard the rights of the individual and of society and stimulate innovation to develop impactful solutions. In addition to existing European Research Infrastructures, the European Health Data Space will promote health-data exchange and facilitate cross-border research activities. This destination aims to promote the development of tools, technologies and digital solutions for treatments, medicines, medical devices and improved health outcomes, taking into consideration safety, effectiveness, appropriateness, accessibility, comparative value-added and fiscal sustainability as well as issues of ethical, legal and regulatory nature.

In view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic but also between other projects funded under another topic, cluster or pillar of Horizon Europe (but also with ongoing projects funded under Horizon 2020). In particular, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health and EIT-KIC Health (under pillar III of Horizon Europe) or in areas

cutting across the health and other clusters (under pillar II of Horizon Europe). For instance, with cluster 4 “*Digital, Industry and Space*” such as on digitalisation of the health sector, incl. health technologies, medical devices and key enabling technologies; assisted, autonomous, independent and empowered living; smart homes; decision support systems; health impact assessment (e.g. related to consumer products, working place innovation).

Expected Impacts

Proposals for topics under this destination should set out a credible pathway towards unlocking the full potential of new tools, technologies and digital solutions for a healthy society, and more specifically to several of the following expected impacts:

- Europe’s scientific and technological expertise and know-how, its capabilities for innovation in new tools, technologies and digital solutions, and its ability to take-up, scale-up and integrate innovation in health care is world-class.
- Citizens benefit from targeted and faster research resulting in safer, more efficient, cost-effective and affordable tools, technologies and digital solutions for improved (personalised) disease prevention, diagnosis, treatment and monitoring for better patient outcome and well-being, in particular through increasingly shared health resources (interoperable data, infrastructure, expertise, citizen/patient driven co-creation).¹⁷²
- The EU gains high visibility and leadership in terms of health technology development, including through international cooperation.
- The burden of diseases in the EU and worldwide is reduced through the development and integration of innovative diagnostic and therapeutic approaches, personalised medicine approaches, digital and other people-centred solutions for health care.
- Both the productivity of health research and innovation, and the quality and outcome of health care is improved thanks to the use of health data and innovative analytical tools, such as artificial intelligence (AI) supported decision-making, in a secure and ethical manner, respecting individual integrity and underpinned with public acceptance and trust.

Citizens trust and support the opportunities offered by innovative technologies for health care, based on expected health outcomes and potential risks involved.

The following call(s) in this work programme contribute to this destination:

Call	Budgets (EUR million)		Deadline(s)
	2021	2022	
HORIZON-HLTH-2021-TOOL-06	115.00		21 Sep 2021

¹⁷² Commission Communication on the digital transformation of health and care; COM(2018) 233 final.

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HORIZON-HLTH-2022-TOOL-11		95.00	21 Apr 2022
HORIZON-HLTH-2022-TOOL-12-two-stage		60.00	01 Feb 2022 (First Stage) 06 Sep 2022 (Second Stage)
Overall indicative budget	115.00	155.00	

Call - Tools and technologies for a healthy society (2021)

HORIZON-HLTH-2021-TOOL-06

Conditions for the Call

Indicative budget(s)¹⁷³

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁷⁴	Number of projects expected to be funded
		2021		
Opening: 22 Jun 2021 Deadline(s): 21 Sep 2021				
HORIZON-HLTH-2021-TOOL-06-01	IA	25.00 ¹⁷⁵	Around 6.00	4
HORIZON-HLTH-2021-TOOL-06-02	RIA	60.00 ¹⁷⁶	Around 6.00	10
HORIZON-HLTH-2021-TOOL-06-03	RIA	30.00 ¹⁷⁷	Around 8.00	4
Overall indicative budget		115.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.

¹⁷³ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹⁷⁴ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹⁷⁵ Of which EUR 15.00 million from the 'NGEU' Fund Source.

¹⁷⁶ Of which EUR 36.00 million from the 'NGEU' Fund Source.

¹⁷⁷ Of which EUR 18.00 million from the 'NGEU' Fund Source.

<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2021-TOOL-06-01: Smart medical devices and their surgical implantation for use in resource-constrained settings

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 25.00 million.
<i>Type of Action</i>	Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 “*Unlocking the full potential of new tools, technologies and digital solutions for a healthy society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes.

- Medical device developers provide sustainable and affordable smart active implants validated in the operational environment.
- Medical professionals in resource-constrained clinical settings use sustainable and affordable surgical procedures for smart active implants.
- Patients have access to sustainable and affordable smart medical devices suitable for minimally invasive surgical implantation through further clinical studies.

Scope: “Smart” technologies, i.e. micro-electronic sensor/actuator systems provide novel functionalities to surgically-implanted active medical devices. “Smart” active implants involve microelectronic components and are placed inside the body of the patient to achieve the desired physiological response. They open up therapeutic avenues for a wide range of medical handicaps, complex chronic conditions and lesions, thanks to their integrated

diagnostic capabilities, and may help addressing hitherto unmet medical needs. Challenges involved in the development of these devices include but are not limited to miniaturization, sensor robustness, wireless power supply, etc. Such devices require specific surgical implantation procedures, dependant on the type of device and on the intended use, with the successful surgical implantation and activation of such smart medical implants, being crucial steps for their functioning. The device targeted and its intended use is open for applicants to choose (e.g. orthopaedic, neural, cardiovascular, metabolic, etc.), but should at the start of the proposed work be at a TRL of minimum four and will necessitate appropriate tailored surgical procedures and interventions. Surgical conditions account for approximately 30% of the global burden of disease and have a huge social and economic impact. However, of the 300 million surgical interventions undertaken globally every year only around 6% occur in low-income countries, where a third of the world’s population lives. There is therefore a strong need for high-quality, affordable surgical interventions for implanting “smart” active medical devices suitable for resource-limited or -constrained clinical settings. Resource-constrained settings are clinical environments that are affected by limitations such as lack of medical staff, scarcity of medical equipment or medicines supply, etc. To address this gap, the sustainability of both the medical device and the applied surgical intervention, including the necessary equipment and operating skills, are essential elements. Implantation procedures should be fully compatible with resource-constrained environments and minimally invasive approaches should be favoured. Hence, research and innovation activities should comprise medical device design, regulatory work, clinical stages and developmental iterations, reaching a TRL of at least seven, and involve key medical specialists (e.g. surgeons) and/or other health care professionals, developers, patients and relevant regulatory bodies as appropriate. The work proposed should take into account the new EU legal framework on medical devices with the targeted implants meeting all the essential requirements as defined therein.

HORIZON-HLTH-2021-TOOL-06-02: Next generation advanced therapies to treat highly prevalent and high burden diseases with unmet medical needs

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 “*Unlocking the full potential of new tools, technologies and digital solutions for a healthy society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored and contributing to all of the following expected outcomes:

- Competent authorities, researchers and developers use assays for the valorisation and/or assessment of efficiency, delivery, safety, potency or mode of action of novel advanced therapeutic interventions based on either pluripotent stem cells, genome editing or RNA, that are aligned with regulatory standards.
- Clinicians, researchers and developers test several new advanced therapies based on pluripotent stem cells, gene editing or RNA ready through clinical trials meeting the regulatory requirements.

Scope: The recent development of advanced therapies has been hampered by the lack of robust research on certain key parameters e.g. safety, upscaling, immunity, potency assays, cost-effectiveness, and early on in development. This topic aims to ensure that the next wave of advanced therapies, based on either pluripotent stem cells, gene editing or RNA, are established in a timely fashion and in accordance with the appropriate regulatory standards for further clinical testing. It will support preclinical research platforms for disorders with high prevalence and burden¹⁷⁸ that tackle the bottlenecks currently encountered in the field, ensuring that promising advanced therapies can reach the market within the next decade. Applicants should justify the disease or disorder to be targeted with its prevalence level, the related burden and unmet needs. Applicants could propose activities in one or several of the following areas, and should take into consideration the Oviedo Convention, eligible actions and ethical principles as defined by the Horizon Europe Framework Programme¹⁷⁹:

- Method development for the production and differentiation of pluripotent stem cells¹⁸⁰ (defined as cells that can give rise to cells from all three embryonic germ layers), to include defining appropriate potency assays. Complementary activities to assess mode of action, safety, *in vivo* validation or upscaling procedures could be considered.
- Development and validation of biological assays and methods that can demonstrate efficacy, delivery, specificity, and safety (including off-target effects) of genome editing products in targeted cells and tissues (e.g. base editing, prime editing, transcription activator-like effector nucleases, zinc-finger nucleases, clustered regularly interspaced short palindromic repeats). Complementary activities to assess *in vivo* validation or upscaling procedures could be considered.
- Development and validation of novel RNA-based therapeutics targeting non-communicable diseases. Complementary activities to assess mode of action, delivery, safety, *in vivo* validation and/or upscaling procedures could be considered.
- Study, analysis and tackling of different immune responses, taking into account factors like sex and age, generated by any of the above-mentioned advanced therapies *in vivo*, facilitating regulatory approval for next phase of research and development.

¹⁷⁸ As defined by www.who.int/medicines/areas/priority_medicines/en/

¹⁷⁹ <https://data.consilium.europa.eu/doc/document/ST-6692-2021-ADD-3/en/pdf>

¹⁸⁰ Definition: Embryonic stem cells and induced pluripotent stem cells are pluripotent stem cells. www.nature.com/subjects/pluripotent-stem-cells.

HORIZON-HLTH-2021-TOOL-06-03: Innovative tools for use and re-use of health data (in particular of electronic health records and/or patient registries)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 30.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 “*Unlocking the full potential of new tools, technologies and digital solutions for a healthy society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored and contributing to all of the following expected outcomes:

- Novel solutions improve quality, ensure interoperability and enable re-use of health data, data analytics and metadata from different repositories across countries by health professionals, researchers and health authorities, in compliance with FAIR data¹⁸¹ management principles as well as national and EU legal and ethical requirements (in particular with regard to personal data protection).
- Health professionals, researchers and health authorities make effective use of tools enabling them to exploit unstructured and heterogeneous data from different sources to improve the delivery of care and advance health research.
- Increased use and valorisation of health data by patients, researchers and clinicians thanks to better data portability due to the standardization of meta knowledge (meta data, ontologies and reference repositories) and clinical data, especially health data coming from different clinical services and sites, and/or from multiple countries.
- Health care professionals use more efficient and cost-effective health care procedures and workflows that contribute to improved disease prevention, early detection/diagnosis and more effective treatment.

Scope: Health data exists in many forms and multiple fragmented repositories; there is still significant room for improvement in the way both structured and unstructured health data is stored, analysed and interpreted. Sharing and analysing data from multiple countries in a safe and legally compliant manner (in particular with regard to personal data protection) remains a challenge. Powerful analytic tools are already helping providers to use structured data in increasingly impactful ways. On the other hand, the heterogeneity, diversity of sources,

¹⁸¹ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

quality of data and various representations of unstructured data in health care increase the number of challenges as compared to structured data.

Advances in AI and machine learning, however, have the potential to transform the way clinicians, providers and researchers use unstructured data. Furthermore, developing data interoperability standards, trust and harmonization of GDPR's interpretation across the EU for the sharing and processing of personal health data will support establishing a sound health data culture in view of the European Health Data Space.

Proposals should address all of the following aspects:

- Developing robust novel solutions compliant with legal requirements (in particular concerning personal data protection) that will improve the quality, interoperability, machine-readability and re-use of health data and metadata in compliance with FAIR data management principles, making these data more accessible to clinicians, researchers and citizens. The focus should be on data in electronic health records (EHRs) and/or patient registries, taking into account the Commission Recommendation on a European Electronic Health Record exchange format¹⁸².
- Developing innovative natural language processing tools, including computational semantics, ontologies, text mining, associated machine learning and deep learning, to improve accessibility, interoperability, translation, transcription, and analysis of health data (e.g. to predict risks). Tools should extract health information from unstructured data in different clinical and medical sources, and bring that data into EHRs/patient registries in a structured form. The innovative solutions should also address missing data in EHRs and/or patient registries and their related metadata, to reduce bias and improve the quality of conclusions.
- Developing and piloting AI-powered virtual assistants that will utilise the tools and solutions developed (as mentioned above) in order to demonstrate improved usability of health data for end-users.

Proposals are expected to build on and contribute to existing European and international data standards, specifications and schemas for health data. The use of open standards should be considered and interactions with relevant ongoing research infrastructure efforts are encouraged. Applicants should focus on health data coming from a number of EU Member States and EEA countries, constituting as much as possible a representative sample of the European healthcare landscape, so as to contribute to the work on the creation of the European Health Data Space.

To guarantee their adoption, the developed solutions should be quick and easy to use by researchers and clinicians. Therefore active involvement of end-users from the onset is encouraged. In particular, patient advocacy groups and citizens should be involved to ensure adequate consideration of diverse patient needs, with respect to their gender, ethnicity, age,

¹⁸² <https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format>

ability, and socio-economic background, to underpin acceptance by patients and other data subjects. SMEs participation is also encouraged.

The proposals should duly take into account requirements stipulated in the relevant European regulations (Data protection, *in vitro* diagnostics and medical devices) and must meet appropriate ethical standards.

Call - Tools and technologies for a healthy society (Single Stage - 2022)

HORIZON-HLTH-2022-TOOL-11

Conditions for the Call

Indicative budget(s)¹⁸³

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁸⁴	Number of projects expected to be funded
		2022		
Opening: 06 Oct 2021 Deadline(s): 21 Apr 2022				
HORIZON-HLTH-2022-TOOL-11-01	RIA	60.00 ¹⁸⁵	Around 10.00	6
HORIZON-HLTH-2022-TOOL-11-02	RIA	35.00 ¹⁸⁶	Around 7.00	5
Overall indicative budget		95.00		

General conditions relating to this call

<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.

¹⁸³ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹⁸⁴ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹⁸⁵ Of which EUR 36.00 million from the 'NGEU' Fund Source.

¹⁸⁶ Of which EUR 21.00 million from the 'NGEU' Fund Source.

<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-TOOL-11-01: Optimising effectiveness in patients of existing prescription drugs for major diseases (except cancer) with the use of biomarkers

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 “*Unlocking the full potential of new tools, technologies and digital solutions for a healthy society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored and contributing to all of the following expected outcomes:

- Diagnostics industries move towards market approval for companion diagnostics.
- Regulatory authorities approve companion diagnostics and make recommendations for the prescription of existing drugs.
- Health care providers use biomarkers with existing pharmaceuticals to treat more efficiently and cost-effectively patients, with less adverse effects.

Scope: The applicants should perform the clinical validation of qualified biomarkers (not limited to molecular biomarkers) that will enable the identification of appropriate patients to ensure an effective and efficient use of existing pharmaceuticals in the treatment of major

diseases and conditions. The relevant biomarkers should allow providing the right medicinal product, at the right dose and the right time, according to the concept of personalised medicine, taking into account, among others, differences of sex, age, ethnicity and gender identity. This topic refers to medicines that are already on the market and not to the validation of biomarkers for the development of new medicinal products. It addresses broadly prescribed medicines for major diseases and conditions, including but not limited to cardiovascular diseases. A condition is that preliminary studies or publications have demonstrated that the pharmaceuticals considered are efficient in less than 50% of the population treated. This topic excludes cancer and rare disease treatments. The applicants should consider existing guidelines, standards and regulations, as appropriate. Synergies with relevant European Research Infrastructures are encouraged.

HORIZON-HLTH-2022-TOOL-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 7.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 35.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 “*Unlocking the full potential of new tools, technologies and digital solutions for a healthy society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Health regulatory bodies and/or *Health Technology Assessment (HTA)* bodies adopt optimised data-driven methodologies for the effective use of real-world data (including omics data)¹⁸⁷, and/or synthetic data derived from digital twins and advanced

¹⁸⁷ Real world data is an umbrella term for data regarding the effects of health interventions that are not collected in the context of highly-controlled RCTs. Instead, RWD can either be primary research data collected in a manner which reflects how interventions would be used in routine clinical practice or secondary research data derived from routinely collected data

computational methods (such as modelling and simulation or approaches based on machine learning/AI), for the assessment of medicinal products and/or digital health innovations.

- Health regulatory authorities and bodies (e.g. medicines agencies, HTA bodies, notified bodies for medical devices) use optimised guidelines for the development and assessment of medicinal products and/or medical devices including digital health innovations.
- Health regulatory authorities and bodies across Europe are trained in data-driven decision making using emerging data types.

Scope: With the emerging use of real-world data (RWD) and synthetic data by the pharmaceutical industry and medical devices industry, regulators and HTA bodies need to perform targeted validation of claims through independent analysis. The principal aim of this topic is to address the data needs of health regulatory bodies and HTA bodies across the EU, as outlined in the recently published “HMA-EMA Joint Big Data Taskforce Phase II report: ‘Evolving Data-Driven Regulation’”¹⁸⁸ and its associated DARWIN (Data Analysis and Real World Interrogation Network) project¹⁸⁹.

To harness the potential of RWD and synthetic data from digital twins and advanced analytical models, and make them actionable for health regulatory decision-making and for health technology assessment, targeted research is needed on the evidentiary value of these data for a number of relevant use cases. In addition, methods need to be developed to increase the usability of such data by different stakeholder groups. Doing so will contribute to the European Health Data Space and maximise the positive impact of DARWIN in driving up the quality of evidence and decisions on the development and use of medicines and digital health innovations.

Access to and analysis of RWD and synthetic data can inform regulatory decision-making throughout the product lifecycle, namely: 1) support product development (e.g. scientific advice, PRIME ¹⁹⁰); 2) support authorisation of new medicines and digital health innovations; and 3) monitor the performance of medicines and digital health innovations on the market (effectiveness and safety). Eventually, this will put in place methods and processes that will enable continuous learning from pre-authorisation procedures and authorisation applications on the use of RWD and/or synthetic data.

Proposals should address all of the following areas:

(https://www.ema.europa.eu/en/documents/presentation/presentation-session-1-use-real-world-data-pre-authorisation-what-can-it-answer-peter-mol_en.pdf)

¹⁸⁸ https://www.ema.europa.eu/en/documents/other/hma-ema-joint-big-data-taskforce-phase-ii-report-evolving-data-driven-regulation_en.pdf

¹⁸⁹ https://www.ema.europa.eu/en/documents/presentation/presentation-proposal-darwin-eu-data-analytics-real-world-interrogation-network-parlett-ema_en.pdf

¹⁹⁰ <https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines>

- Develop a set of evidentiary standards to be pre-specified and used in the analysis of real-world evidence and/or synthetic data applied to different types of regulatory advice and/or health technology assessment and decisions on the safety and efficacy/effectiveness of medicines and digital health innovations (e.g. in complement to clinical trial data in an authorisation application, or for extension of indications, post marketing surveillance, amendment of product information or regulatory actions on the marketing authorisation due to safety concerns). This includes validating the use of advanced analytical methods for regulatory decision-making and/or health technology assessment.
- Address aspects that would enable moving towards a standard data quality framework reproducible across different types of RWD and/or synthetic data sources for regulatory decision-making and/or health technology assessment, with a characterisation of the data collection, management and reporting and an empirical data quality validation. In this regard, it will be important that successful proposals liaise with and closely monitor the work carried out in the context of the European Health Data Space.
- Enhance the performance and efficiency of large randomised clinical trials and new models of clinical trials by developing standardised processes and methods to access RWD and/or synthetic data (e.g., facilitating the detection of various types of health outcomes during the treatment period of a double-blinded trial by linkage to appropriate electronic health care record databases, etc.), for regulatory decision-making and/or health technology assessment.
- Define methodological standards for the regulatory acceptability of RWD, and/or synthetic data in the context of clinical trials augmented with RWD, and/or synthetic data, for regulatory decision making and/or health technology assessment.
- Test the ability of machine learning methods to help identify relevant RWD, and/or synthetic data to match with and to interpret clinical trials, for regulatory decision-making and/or health technology assessment.
- Assess and validate how machine learning methods can be systematically harnessed to screen a large amount of data, including unstructured data, in many electronic databases to identify factors affecting efficacy and safety of treatments and/or digital health innovations, for regulatory decision-making and/or health technology assessment. The cross-border interoperability dimension should be taken into account.

Proposals should involve researchers who are specialised in the use of real-world data and/or synthetic data to evaluate medicinal products and/or health care digital innovation products and services. Proposals should involve national competent authorities (national health care product regulatory bodies and/or medical device notified bodies) and could involve citizens and patients' representatives where relevant. Proposals should include capacity-building efforts to address inequalities of health regulatory processes across Europe. This should comprise education and training activities and sharing of best practices.

In addition to national competent authorities, proposals could consider the involvement of the European Medicines Agency (EMA) for an added value in order to provide an effective interface between the research activities and regulatory aspects and/or to translate the research results into validated test methods and strategies that would be fit for regulatory purpose.

Proposals could also consider the involvement of the European Commission's Joint Research Centre (JRC) to provide added-value regarding health registry data, interoperability, harmonisation and quality and linking with other data.

Call - Tools and technologies for a healthy society (two-stages - 2022)

HORIZON-HLTH-2022-TOOL-12-two-stage

Conditions for the Call

Indicative budget(s)¹⁹¹

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁹²	Number of projects expected to be funded
		2022		
Opening: 06 Oct 2021 Deadline(s): 01 Feb 2022 (First Stage), 06 Sep 2022 (Second Stage)				
HORIZON-HLTH-2022-TOOL-12-01-two-stage	RIA	60.00 ¹⁹³	Around 6.00	10
Overall indicative budget		60.00		

General conditions relating to this call

<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.

¹⁹¹ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹⁹² Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹⁹³ Of which EUR 26.88 million from the 'NGEU' Fund Source.

<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-TOOL-12-01-two-stage: Computational models for new patient stratification strategies

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 “*Unlocking the full potential of new tools, technologies and digital solutions for a healthy society*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored and contributing to some of the following expected outcomes:

- Clinical researchers use effective health data integration solutions for the classification of the clinical phenotypes.
- Researchers and/or health care professionals use robust and validated data-driven computational tools to successfully stratify patients.
- Regulatory bodies approve computer-aided patient stratification strategies to enable personalised diagnosis and/or personalised therapy strategies.
- Health care professionals adopt evidence-based guidelines for stratification-based patient management superior to the standard-of-care.

Scope: In the era of big and complex data, the challenge remains to make sense of the huge amount of health care research data. Computational approaches hold great potential to enable superior patient stratification strategies to the established clinical practice, which in turn are a prerequisite for the development of effective personalised medicine approaches.

The proposals may include a broad range of solutions, such as computational disease models, computational systems medicine approaches, machine-learning algorithms, Virtual Physiological Human, digital twin technologies and/or their combinations, as relevant. The topic covers different stages in the continuum of the innovation path (i.e. translational, pre-clinical, clinical research, validation in the clinical and real-world setting, etc.), as relevant to the objectives of the proposals.

The topic will support the development of the computational models driven by the end users' needs.

Proposals should address several of the following areas:

- Establish interdisciplinary research by bridging disciplines and technologies (disease biology, clinical research, data science, -omics tools, computational and mathematical modelling of diseases, advanced statistical and/or AI/machine learning methods, Virtual Physiological Human and/or digital twin technologies).
- Develop new computational models for the integration of complex health data from multiples sources, including structured and unstructured data.
- Develop and optimise robust, transparent and accurate computational models to guide patient stratification strategies for improving clinical outcomes.
- Demonstrate, test and clinically validate such models with respect to their utility to realistically stratify patients with the aim of improving the standard-of-care.
- The development of new patient stratification strategies guided by computational models and the validation of the new concepts of stratification in pre-clinical and/or clinical studies.

The proposals should adhere to the FAIR data¹⁹⁴ principles, adopt data quality standards, data integration operating procedures and GDPR-compliant data sharing/access good practices developed by the European research infrastructures, wherever relevant. In addition, proposals are encouraged to adopt good practices of international standards used in the development of computational models, and make available the tools and solutions developed early. Proposals aiming to develop computational models of high technology readiness level are encouraged to deliver a plan for the regulatory acceptability of their technologies. Early interaction with the relevant regulatory bodies is recommended (i.e. the EMA qualification advice for new technologies, etc.) for the proposals contributing to the development of new medicinal products, improvement of the effectiveness of marketed products and the development of

¹⁹⁴ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

medical devices. The proposals aiming to validate their models as high-risk medical devices in the relevant clinical environment are encouraged to deliver a certification implementation plan.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate. In addition, the proposals will be encouraged to exchange with other successful proposals developing AI algorithms and *in silico* models under other relevant topics.

Destination 6. Maintaining an innovative, sustainable and globally competitive health industry

Calls for proposals under this destination are directed towards the Key Strategic Orientation KSO-A *'Promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains'* of Horizon Europe's Strategic Plan 2021-2024. Research and innovation supported under this destination should contribute to the impact area *'A competitive and secure data-economy'* and in particular to the following expected impact, set out in the Strategic Plan for the health cluster: *'EU health industry is innovative, sustainable and globally competitive thanks to improved up-take of breakthrough technologies and innovations, which makes the EU with its Member States more resilient and less dependent from imports with regard to the access to and supply of critical health technologies'*. In addition, research and innovation supported under this destination could also contribute to the following impact areas: *'Industrial leadership in key and emerging technologies that work for people'*, *'High quality digital services for all'*, and *'Good health and high-quality accessible health care'*.

The health industry is a key driver for growth and has the capacity to provide health technologies to the benefit of patients and providers of health care services. The relevant value chains involve a broad variety of key players from supply, demand and regulatory sides. In addition, the path of innovation in health is long and complex. The development of novel health technologies is generally associated with uncertainties and market barriers due to expensive and risky development (e.g. attrition rate in pharmaceutical development), high quality and security requirements (e.g. clinical performance, safety, data privacy and cybersecurity) and market specificities (e.g. strong regulation, pricing and reimbursement issues). In addition, the growing concern about environmental issues is putting more pressure on this industry. Therefore, there is a need for research and innovation integrating various stakeholders to facilitate market access of innovative health technologies (medical technologies, pharmaceuticals, biotechnologies, digital health technologies).

In order to address these challenges, in particular green and digital transitions and proper supply of health technologies and products, destination 6 will focus on research and innovation activities that aim at:

- Production of pharmaceuticals in compliance with the objectives of the European Green Deal.
- Methodologies, guidelines and standards, assessment studies, and structuring activities adapted to digital solutions and interventions for GDPR compliant translation into health care practice, including inter-operability, cyber-security and data confidentiality.
- Public authorities supported with better methodologies and interdisciplinary approaches to assess and value new health technologies and interventions.

- Development of pharmaceutical products meeting unmet medical needs in the context of market failures.

In view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic but also between other projects funded under another topic, cluster or pillar of Horizon Europe (but also with ongoing projects funded under Horizon 2020). In particular, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health and EIT-KIC Health (under pillar III of Horizon Europe), or in areas cutting across the health and other clusters (under pillar II of Horizon Europe). For instance, with cluster 4 “Digital, Industry and Space” such as on industrial research and innovation infrastructures (pilot plants, testing and simulation facilities, open innovation hubs); additive manufacturing (3D/4D printing) and other production technologies (incl. bio manufacturing); safe, smart and sustainable materials.

Expected Impacts:

Proposals for topics under this destination should set out a credible pathway to contributing to maintaining an innovative, sustainable and globally competitive health industry, and more specifically to one or several of the following expected impacts:

- Health industry in the EU is more competitive and sustainable, assuring European leadership in breakthrough health technologies and strategic autonomy in essential medical supplies and digital technologies, contributing to job creation and economic growth, in particular with small- and medium-sized enterprises (SMEs).
- Health industry is working more efficiently along the value chain from the identification of needs to the scale-up and take-up of solutions at national, regional or local level, including through early engagement with patients, health care providers, health authorities and regulators ensuring suitability and acceptance of solutions.
- European standards, including for operations involving health data, ensure patient safety and quality of healthcare services as well as effectiveness and interoperability of health innovation and productivity of innovators.
- Citizens, health care providers and health systems benefit from a swift uptake of innovative health technologies and services offering significant improvements in health outcomes, while health industry in the EU benefits from decreased time-to-market.
- Health security in the EU benefits from reliable access to key manufacturing capacity, including timely provision of essential medical supplies of particularly complex or critical supply and distribution chains, such as regards vaccines or medical radioisotopes.

Horizon Europe - Work Programme 2021-2022
Health

The following call(s) in this work programme contribute to this destination:

Call	Budgets (EUR million)		Deadline(s)
	2021	2022	
HORIZON-HLTH-2021-IND-07	44.00		21 Sep 2021
HORIZON-HLTH-2022-IND-13		69.00	21 Apr 2022
Overall indicative budget	44.00	69.00	

Call - A competitive health-related industry (2021)

HORIZON-HLTH-2021-IND-07

Conditions for the Call

Indicative budget(s)¹⁹⁵

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁹⁶	Number of projects expected to be funded
		2021		
Opening: 22 Jun 2021 Deadline(s): 21 Sep 2021				
HORIZON-HLTH-2021-IND-07-01	RIA	40.00 ¹⁹⁷	Around 8.00	5
HORIZON-HLTH-2021-IND-07-02	CSA	2.00	Around 2.00	1
HORIZON-HLTH-2021-IND-07-03	CSA	2.00	Around 2.00	1
Overall indicative budget		44.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex

¹⁹⁵ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

¹⁹⁶ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹⁹⁷ Of which EUR 13.08 million from the 'NGEU' Fund Source.

	D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2021-IND-07-01: Green pharmaceuticals

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 40.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “*Maintaining an innovative, sustainable and globally competitive health industry*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Researchers and regulators understand the environmental impact of pharmaceuticals.
- Public authorities inform pharmaceutical strategies and policies based on scientific evidences.
- Researchers, innovators and pharmaceutical industries develop and produce greener pharmaceuticals that are either greener by design, intrinsically less harmful for the environment, and/or use greener and economically more sustainable manufacturing processes for the production of pharmaceuticals.

Scope: The EU needs to address the increasing problem of environmental pollution due to pharmaceuticals throughout their life cycle. This encompasses both, the industry need to tackle the pollution due to their manufacturing as well as pollution resulting from the use and disposal of their pharmaceuticals. This topic is part of an EU strategic approach to pharmaceuticals in the environment¹⁹⁸ and the Pharmaceutical strategy for Europe¹⁹⁹ called for diversifying and secure supply chains and environmentally sustainable pharmaceuticals²⁰⁰. The purpose of this topic is twofold.

One of the purposes is to encourage taking into account the environmental aspects of pharmaceuticals as regards their use and disposal. The action intends to promote the development of pharmaceuticals intrinsically less harmful to environment. As regards the pharmaceuticals already in use, more understanding is needed concerning their environmental concentration and resulting levels of risk. In particular, the solid knowledge of the impact of molecules on the environment through the eco-toxicity studies will contribute to management of environmental risk and may be taken into account for designing of new molecules.

The second purpose is to promote the green innovation in the pharmaceutical manufacturing of marketed medicinal products, in particular manufacturing of their active pharmaceutical ingredients (APIs). It will contribute to ensuring supplies of medicinal products and prevent shortages as well as crisis preparedness. The difficulties in ensuring compliance with the high environmental standards in the EU and high costs of such compliance are considered one of the main reasons for pharmaceutical manufacturing leaving the EU. This in turn results in vulnerabilities of the supply chains (reduced number of suppliers of critical inputs, lack of geographical diversification of the suppliers, lack of critical manufacturing capacity in the EU). The new, greener and sustainable manufacturing methods, which would for the reason of lowering the environmental impact rely on recycled solvents, would need at the same time to address the risk of impurities.

Applicants should propose activities linked to several of the following elements:

- Research and innovation to support the development of “greener” pharmaceuticals that degrade more readily to harmless substances in waste water treatment plants and the environment;
- Research on the eco-toxicity and environmental fate of pharmaceuticals, in particular those that are not yet subject to environmental risk assessment;
- Propose innovative manufacturing technology that are greener, low in energy consumption and emissions, using less solvent or recycling solvents;
- Propose methods for eliminating carcinogenic impurities in pharmaceuticals (e.g. nitrosamines) process and medicinal products, in particular as complementary technologies to the manufacturing methods relying on recycled solvents;

¹⁹⁸ COM(2019) 128 final; Section 5.2

¹⁹⁹ COM(2020) 761

²⁰⁰ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0761&from=EN>

- Explore innovative uses of digital transformation or robotic for competitive and scalable methods of production.

The projects should favour a multi-stakeholders approach. They should address the industry needs, taking account of SMEs' specificities, and offer deployable technical solutions and/or relevant data. They should also integrate at the same time the academic and public health perspective.

Proposals could consider the involvement of the European Commission's Joint Research Centre (JRC) in the field of new approach methodologies for ecotoxicity assessment.

HORIZON-HLTH-2021-IND-07-02: Development, procurement and responsible management of new antimicrobials

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 2.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 2.00 million.
<i>Type of Action</i>	Coordination and Support Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “*Maintaining an innovative, sustainable and globally competitive health industry*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Health authorities and healthcare providers have identified the needs and potential procurers;
- Potential procurers are ready to establishing an innovation partnership for the development and the procurement of new antimicrobials;
- Potential procurers are able to engage and commit financially in view of the establishment of an innovation partnership.

Scope: The aim of this topic is to prepare for the establishment of a pull incentive for new antimicrobials where there is an unmet public health need and a market failure. In line with the Pharmaceutical Strategy for Europe that was published in November 2020²⁰¹ innovative approaches at EU level should be developed for supporting research, development and public procurement of antimicrobials to address the issue of antimicrobial resistance. These approaches could make use of European legislation, such as the possibility of an innovation

²⁰¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN>

partnership²⁰² that would allow for the combination of development of new antimicrobials and procurement elements and should be tailored to public health needs.

To that end, a preparatory phase is necessary. Proposers are expected to create the conditions for the establishment of a future innovation partnership. They should take advantage of the latest developments such as experiences gained within Europe on the advance purchase agreements for COVID-19 vaccines. With the help of experts, potential procurers of new antimicrobials in the Member States have to set out the requirements and conditions for the final product(s) to be developed and purchased. This will need to be guided by public health needs and should be based on priority pathogens such as those identified by WHO²⁰³. These requirements and conditions needed to guide development will have to be developed with input of scientific experts and in close collaboration with Commission services, and need to be agreed upon with a view of EU Member States' and Associated States commitments to purchase the new antimicrobials. Proposers should also develop a broad communication strategy towards stakeholders and other potential procurers.

Proposals are expected to address all of the following:

- Emerging health threats, particularly those resulting from antimicrobial resistance (AMR), and identification of relevant public health needs in the development of new antibiotics.
- Design of a feasible option for a pull incentive that combines EU support for late stage development of antimicrobials with procurement by Member States and Associated Countries (implementation of the pull incentive will be beyond the scope of this CSA).
- Readiness and interest of potential developers/suppliers of antimicrobials
- Market failures and the challenges of availability and accessibility of therapeutics.
- Conditions for development and purchase of new antimicrobials.
- Requirements for financing.
- Conditions for prudent use of new antimicrobials.

HORIZON-HLTH-2021-IND-07-03: Promoting a trusted mHealth label in Europe: uptake of technical specifications for quality and reliability of health and wellness apps

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 2.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

²⁰² https://ec.europa.eu/growth/content/8699-innovation-partnerships-keep-public-services-date_en
²⁰³ https://www.who.int/medicines/areas/rational_use/prioritization-of-pathogens/en/

<i>Indicative budget</i>	The total indicative budget for the topic is EUR 2.00 million.
<i>Type of Action</i>	Coordination and Support Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “*Maintaining an innovative, sustainable and globally competitive health industry*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- European suppliers of health technology and services benefit from enhanced single market conditions for mHealth that facilitate economies of scale.
- Health care systems and authorities are able to integrate mHealth solutions more rapidly thanks to a European ‘mHealth label’.
- Citizens, patients and health care professionals make more use of trusted mHealth solutions for promoting their health and self-managing their health care needs.
- European mHealth stakeholders build upon a digital ecosystem around a trusted mHealth label, an EU-wide promotion and uptake of technical specifications for health and wellness apps.
- Health systems and citizens benefit from the supply and use of health innovations facilitated by the promotion of common pan-European principles for validation and certification.

Scope: Europe is experiencing a fast growing market for health and wellness apps. At the same time, concerns about the quality and reliability of apps have risen (for example, many health and wellness apps are being published on app stores without clinical evidence supporting the claimed benefits that they will deliver)²⁰⁴. CEN²⁰⁵, together with CEN/TC 251, ISO and IEC, developed a new technical specification for ‘Quality and Reliability of Health and Wellness Apps’ together with a CEN/ISO 82304-2 health app quality label (capturing medical safety, usability, safety of personal data and technical quality of health apps).

The objective of the technical specification is to define quality and reliability criteria, which support app developers to design and users of apps to select better apps.

The specification is intended for use by manufacturers of health apps as well as by app checkers in order to communicate the quality and reliability of a health app.

Applicants should propose activities that bring together app developers, health care system representatives, a diverse range of users (citizens/patients, health care providers), and certification bodies in order to promote and stimulate the use and up-take of the health app

²⁰⁴ <https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth>

²⁰⁵ <http://www.ehealth-standards.eu/quality-reliability-for-health-and-wellness-apps/> due to be completed in 2020

quality label, building a digital ecosystem around a trusted mHealth label to support the integration and use of health and wellness apps in the health care system. Proposals should encourage a people-centred approach that empowers citizens and patients, promotes a culture of dialogue and openness between health professionals, citizens, patients and their families, and unleashes the potential of social innovation.

The proposals are expected to address all of the following:

- Set up a structured dialogue on the uptake of the technical specifications between app developers, health care system representatives, app stores, medical societies, patient organisations, users (including health care professionals) and certification bodies, building a digital ecosystem around a trustable mHealth label.
- Co-create, develop and implement an action plan on the promotion of the mHealth label in the health care system.
- Implement concrete actions on the integration and use of secure and qualitative health and wellness apps, using the new label, in specific health care settings, covering the entire EU.
- Ensure that the promoted health and wellness apps are bias-free and adequately address the needs of different social groups, considering gender, age, ability and ethnicity, where relevant.
- Support and set-up an inclusive dissemination strategy to promote the use of the mHealth app quality label (cfr. EU energy labels and EU Nutri-Score nutrition label) taking into account the different levels of digital health literacy among the actors involved.
- Interests of different age groups, sex and gender, as well as other categories like persons with disability, ethnicity and the LGBTI+ community should be considered, where relevant.

Call - A competitive health-related industry (2022)

HORIZON-HLTH-2022-IND-13

Conditions for the Call

Indicative budget(s)²⁰⁶

Topics	Type	Budgets	Expected EU	Number
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²⁰⁶ 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 are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Horizon Europe - Work Programme 2021-2022
Health

	of Action	(EUR million)	contribution per project (EUR million) ²⁰⁷	of projects expected to be funded
		2022		
Opening: 06 Oct 2021 Deadline(s): 21 Apr 2022				
HORIZON-HLTH-2022-IND-13-01	RIA	20.00 ²⁰⁸	Around 6.00	3
HORIZON-HLTH-2022-IND-13-02	RIA	30.00 ²⁰⁹	Around 7.00	4
HORIZON-HLTH-2022-IND-13-03	RIA	15.00 ²¹⁰	Around 5.00	3
HORIZON-HLTH-2022-IND-13-04	CSA	2.00	Around 2.00	1
HORIZON-HLTH-2022-IND-13-05	CSA	2.00	Around 2.00	1
Overall indicative budget		69.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.
<i>Eligibility conditions</i>	The conditions are described in General Annex B.
<i>Financial and operational capacity and exclusion</i>	The criteria are described in General Annex C.
<i>Award criteria</i>	The criteria are described in General Annex D.
<i>Documents</i>	The documents are described in General Annex E.
<i>Procedure</i>	The procedure is described in General Annex F.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G.

²⁰⁷ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

²⁰⁸ Of which EUR 12.00 million from the 'NGEU' Fund Source.

²⁰⁹ Of which EUR 18.00 million from the 'NGEU' Fund Source.

²¹⁰ Of which EUR 9.00 million from the 'NGEU' Fund Source.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-IND-13-01: Enhancing cybersecurity of connected medical devices

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 20.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “*Maintaining an innovative, sustainable and globally competitive health industry*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Stakeholders (e.g. manufacturers, suppliers, health care providers, integrators, operators) apply measures to identify and address cybersecurity risks and gaps in connected medical devices.
- Stakeholders adopt and use newly developed risk benefit analysis schemes and capabilities for cybersecurity of connected medical devices.
- Stakeholders adopt and use newly developed methodologies and toolboxes for ensuring cybersecurity of connected medical devices by design.
- Stakeholders adopt and use fit for purpose guidance covering challenges posed by connected medical devices, including software.

Scope: The proposals are expected to help strengthening cybersecurity maintaining the performance of medical devices while preserving or enhancing safety, security and data confidentiality, integrity and availability. The applicants should tackle the cybersecurity issue of connected medical devices and *in vitro* diagnostic medical devices, in particular those that are connected to the internet, allow remote access to data and exchange private or proprietary data. They should also consider the implications of Regulation (EU) 2017/745²¹¹ on medical devices and Regulation (EU) 2017/746²¹² on *in vitro* diagnostic medical devices regarding qualification and classification of software. In their proposals, applicants should consider to maximise synergies with relevant initiatives, activities and programmes.

²¹¹ OJ L 117, 5.5.2017, p. 1

²¹² OJ L 117, 5.5.2017, p. 176

Proposals are expected to address some or all of the following:

- Systematic review of current standards/guidelines/best practices applied to cybersecurity of connected medical devices, with the final objective to identify and specify gaps and requirements based on evidence.
- Propose risk benefit analysis schemes for cybersecurity of connected medical devices, taking into account several novel technological developments (e.g. 5G networks, big data, artificial intelligence, cloud computing, augmented reality, blockchain) and interconnection architectures.
- Explore, develop and validate novel methodologies and toolboxes for ensuring cybersecurity of connected medical devices by design.
- Identify representative case studies, evaluate the applicability of existing guidance MDCG 2019-16 (guidance on cybersecurity for medical devices²¹³) and make recommendations to (better) address specificities of the connected medical device, including software, of different risk classes.
- Assessment of the applicability (and revision) of current guidance, the MDCG 2019-16 (guidance on cybersecurity for medical devices), to connected medical device, including software.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

In this topic the integration of the gender dimension (sex and gender analysis) in research and innovation content is not a mandatory requirement.

HORIZON-HLTH-2022-IND-13-02: Scaling up multi-party computation, data anonymisation techniques, and synthetic data generation

Specific conditions	
<i>Expected EU contribution per</i>	The Commission estimates that an EU contribution of around EUR 7.00 million would allow these outcomes to be addressed appropriately.

²¹³ <https://ec.europa.eu/docsroom/documents/41863>

<i>project</i>	Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 30.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “*Maintaining an innovative, sustainable and globally competitive health industry*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The EU contributes strongly to global standards for health data through enhancement of common European standards for health data (including medical imaging data) by researchers and innovators. Researchers and innovators contribute to GDPR compliant guidelines and rules for data anonymisation.
- Innovators have access to advanced secure data processing tools to test and develop robust data-driven digital solutions and services in response to the needs of researchers, clinicians and health systems at large.
- Cross-border health data hubs further facilitate the innovation process by providing secure, trustable testing environments for innovators.
- Clinicians, patients and individuals use a larger variety of high quality data tools and services for wellbeing, prevention, diagnosis, treatment and follow-up of care.
- Researchers and innovators have more opportunities for testing and developing GDPR compliant data driven solutions based on actual needs of the health care environments.

Scope: It is essential to speed up and facilitate innovations in the field of data-driven tools and services for wellbeing, prevention, diagnosis, treatment and follow-up of care, among others. However, limited access by developers to health data and secure testing environments hinder the development of innovative data-driven digital health products and services.

Therefore, the proposals are expected to scale up multi-party computation, data anonymisation techniques and synthetic data generation. To ensure privacy, the data analytics should be conducted in a distributed way among processors that grant third parties access to analysis outcomes but not to the underlying data. The developers should have access to distributed testing data sources and cloud and computing resources at large scale, with a view to improving the speed and robustness of multi-party computation solutions for innovators. The aim is to allow secure GDPR-compliant data processing for research, and clinical purposes.

The proposals should consider the use of synthetic, i.e. artificially generated, data as they allow researchers and developers to test, verify and fine-tune algorithms in large-scale data experimentations without re-identifiable personal data.

In addition, the proposed anonymisation techniques will have to be sophisticated and robust enough to tackle the challenge of anonymised data sets that still make it possible to trace back to individuals.

The proposals are expected to foster the development of secure, interoperable, transparent - and therefore trustable - cross-border health data hubs that can facilitate the provision of the required testing environments for innovators. This will support the uptake of new data tools, technologies and digital solutions for health care.

To this end, integration of national/regional health data hubs/repositories/research infrastructures is appropriate to achieve the scope of the topic. The proposals are expected to address all of the following areas:

- Consolidate and scale up multi-party computation and data anonymisation techniques and synthetic data generation to support health technology providers, in particular SMEs.
- Support the development of innovative unbiased AI based and distributed tools, technologies and digital solutions for the benefit of researchers, patients and providers of health services, while maintaining a high level of data privacy.
- Advance the state-of-the-art of de-identification techniques, to tackle the challenge of anonymised datasets that can be traced back to individuals.
- Develop innovative anonymisation techniques demonstrating that effective data quality and usefulness can be preserved without compromising privacy.
- Explore and develop further the techniques of creating synthetic data, also dynamically on demand for specific use cases.
- Widen the basis for GDPR-compliant research and innovation on health data.
- Ensure wide uptake and scalability of the methodologies and tools developed, promote high standards of transparency and openness, going well beyond documentation and extending to aspects such as assumptions, architecture, code and any underlying data.

HORIZON-HLTH-2022-IND-13-03: New pricing and payment models for cost-effective and affordable health innovations

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a

	proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 15.00 million.
<i>Type of Action</i>	Research and Innovation Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “*Maintaining an innovative, sustainable and globally competitive health industry*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Health authorities and insurers adopt new payment models for health technologies, including pharmaceuticals.
- Health industries anticipate better the marketing conditions for innovative health technologies. Patients and health care providers have faster access to innovative health technologies.
- Health authorities, insurers and health care providers have affordable innovative health technologies both on short and longer terms.

Scope: Applicants are requested to propose new value-based pricing and reimbursement models that can help ensure equitable access to effective, efficient, affordable, and sustainable health technologies, including medicines, while supporting innovation and industrial competitiveness. The research should tackle the issue globally and be based on a multidisciplinary approach combining economic science, political science and sociology. The proposals should not be limited to the study of cost-effectiveness analyses and thresholds in decision-making. They should also address long term intended and unintended consequences of pricing and reimbursement decisions. Moreover, they should consider the potential limitation of no-coverage decision for products with high budgetary impact. Applicant consortia should include regulators and public entities that are in charge of attributing value tags to health technologies, negotiating with health technology manufacturers and/or reimbursing medical costs. Differences between public and private sectors could be considered, as appropriate. Proposals should also consider citizens engagement and dialogue, for seeking wider input and support, and could encourage other social innovation approaches.

Applicants should propose activities in all of the following areas:

- Affordability of health innovations.
- Variety of pricing/payment schemes in the EU.
- Cost-effectiveness and budget impact (including life-time indirect medical costs).

- Impact of payment schemes (e.g. pay-for-performance/multi-annual instalments) on long-term competition in health technology markets, in particular the pharmaceutical market.
- Potential influence of post-launch evidence-generation plans agreed with regulators and downstream decision makers (HTAs, payers) on the payment models.
- Transparent and comprehensive assessment of technology and medicine development costs, taking into account public investments and incremental character of some innovations (e.g. new indications).
- Development, integration and harmonisation of tools that allow for validation and revision of clinical evidence and cost-effectiveness, and long-term financial planning for effective and transparent decision-making.
- New methods for definition of cost-effectiveness thresholds, integration of greener production and environmental impact, rational applications in real world contexts, comparative analysis of influence in decision-making and influence in the formulation of prices of technologies.
- Potential equity issues derived by payment models and the measures for their mitigation.

HORIZON-HLTH-2022-IND-13-04: Setting up a European Smart Health Innovation Hub

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 2.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 2.00 million.
<i>Type of Action</i>	Coordination and Support Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “*Maintaining an innovative, sustainable and globally competitive health industry*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Empowered patients and citizens of all ages, gender, social and economic background adopt and use digital tools to monitor their health status independently.
- A strong European ecosystem is created by innovators in the health domain, including, but not limited to SMEs, Research and Technology Organisations (RTOs), accelerators,

incubators, (European) Digital Innovation Hubs (EDIH)²¹⁴, European Reference Sites of the EIP-AHA²¹⁵ and Knowledge Hubs, involving end-users.

- Public and private entities adopt the innovations of European digital health companies, especially SMEs and mid-caps, enhancing their sustainability and resilience.
- Citizens, patients, health practitioners and facilities, public and private actors access and make use of sustainable EU-wide reference repository of digitally-enabled innovative solutions addressing all health related sectors, areas and segments, with particular focus on self-management and prevention.

Scope: The EU has supported innovation of digital tools for better and more personalised treatments and self-monitoring of citizens and patients throughout Europe. However, adoption and deployment of digital health solutions in practice, both in the public health system and by private players remains low.

Building on the recommendations from the report of the Strategic Forum for Important Projects of Common European Interest²¹⁶, coordination and support is needed to: i) create a pan-European operational network as a mechanism (a European Smart Health Innovation Hub) that can assess and promote Smart Health initiatives; ii) stimulate the demand-side and the uptake of Smart Health products and services; and iii) support the development of Smart Health products and services.

Applicants should propose activities addressing the need to bring together different actors, working on innovative digital health solutions and to reinforce their collaboration, exchange and efforts on scaling-up digital health solutions across Europe. Proposals should encourage a people-centred approach that empowers citizens and patients, promotes a culture of dialogue and openness between citizens, patients, health practitioners and providers, and other public and private actors, and unleashes the potential of social innovation.

Applicants should link various existing repositories of digital health solutions, which are already deployable as part of different EU projects and initiatives. It is necessary to integrate them into a European Digital Health Smart Innovation Hub, which will serve as a European reference platform for scalable digital health solutions, both for public organisations and private actors, connecting supply and demand side.

Applicants should propose activities in several of the following areas:

- Promote transfer and exchange of knowledge and best practices (such as twinnings) between different actors, such as SMEs, mid-caps, accelerators, incubators, RTOs, EDIHs²¹⁷, Reference Sites of the EIP-AHA²¹⁸ and Knowledge Hubs, such as EIT KIC

²¹⁴ <https://ec.europa.eu/digital-single-market/en/digital-innovation-hubs>

²¹⁵ https://ec.europa.eu/eip/ageing/reference-sites_en

²¹⁶ <https://ec.europa.eu/docsroom/documents/37824>

²¹⁷ <https://ec.europa.eu/digital-single-market/en/digital-innovation-hubs>

²¹⁸ https://ec.europa.eu/eip/ageing/reference-sites_en

Health²¹⁹, eHealth Hub²²⁰ or mHealth Hub²²¹ – working on innovation of digital health solutions, including training to end-users, e.g. citizens, patients, health care providers, and deployment strategies.

- Promote scalability of digital innovation solutions by organising market places and pitching events to public health organisations and private entities and by involving industry and Member States representatives.
- Integrating existing repositories into a sustainable European repository, serving as a reference of ready to market solutions (supply side) and public and private organisations adopting them (demand side), as well as best practices.
- Reinforce the European Digital Health ecosystem by enhancing collaboration and networking between the different actors working on digital health innovation across Europe. Synergies with other relevant initiatives, like the Digital Transformation Accelerator that will manage the network of European Digital Innovation Hubs are encouraged, as well as with relevant initiatives in AI, Data and Robotics in Horizon 2020, Horizon Europe, Digital Europe and other programmes.
- The Digital Health solutions that would be part of the European Smart Health Innovation Hub should match the needs of all citizens and patients, regardless of their age, gender, social or economic background.

HORIZON-HLTH-2022-IND-13-05: Setting up a European Electronic Health Record Exchange Format (EEHRxF) Ecosystem

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 2.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 2.00 million.
<i>Type of Action</i>	Coordination and Support Actions

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “*Maintaining an innovative, sustainable and globally competitive health industry*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

²¹⁹ <https://eithealth.eu>
²²⁰ <https://www.ehealth-hub.eu/>
²²¹ <https://mhealth-hub.org/>

- Individuals, researchers, health services and the workforce across borders in the EU Digital Single Market use significantly improved and interoperable cross-border digital health solutions thanks to sophisticated ICT toolbox, representative use case applications, a Pan-European ecosystem of early adopters, and a framework for sustainability and exploitation. These will also contribute to the European Health Data Space.
- Individuals have an improved level of accessibility, control and portability of health data, including donation for research across Europe and jurisdictions.
- Policy makers and members of the eHealth Network²²² are better informed and advised regarding potential evolutions of the EEHRxF and its extension to other uses cases.
- Different target populations such as designers, developers, health care professionals, and individuals have access to exploitation and capacity building support, such as training material, dedicated tools, guidelines, mentorship and collaboration programs.

Scope: Interoperability of Electronic Health Record is key for the exchange and the portability of health data in view of better health outcomes and treatments. The EU has supported projects to ensure cross-border sharing of health data and, in 2019, adopted a Recommendation on EEHRxF²²³. There is a need to continue supporting the uptake of new use cases (i.e. laboratory results, medical imaging and reports, and hospital discharge reports) and take on board possible new requirements, and ultimately to bring together policy actors and stakeholders.

Applicants should propose activities in all of the following areas:

- Building on the outcomes of activities and projects²²⁴ related to the EEHRxF Recommendation, establishing and sustaining a scalable public infrastructure for digital health innovation based on the EEHRxF principles and the functional and technical specifications of its information domains (i.e. medical imaging, discharge letters, laboratory results, etc.). This infrastructure must provide a REST API²²⁵ to third-party developers, which should comprise a coherent set of functionality that significantly improve the development and deployment of interoperable cross-border digital health solutions. It should specifically allow individuals accessing and providing their own (electronic) health records across national borders. The infrastructure must ensure compliance with the General Data Protection Regulation²²⁶, the Network and Information Systems Directive²²⁷ and the operation in a European Digital Single Market.

²²² https://ec.europa.eu/health/ehealth/policy/network_en

²²³ <https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format>

²²⁴ E.g. from the H2020 topics PHC 34 – 2014, HCO-14-2016, HCO-15-2016, SC1-DTH-08-2018, SC1-HCC-07-2020.

²²⁵ <https://joinup.ec.europa.eu/collection/api4dt>

²²⁶ 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

- Demonstrating feasibility of real-life interoperable digital solutions for use by individuals, researchers, health services and the workforce across borders in the EU Digital Single Market by leveraging the above EEHRxF-based infrastructure. 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 and artificial intelligence should be strongly considered with special regard to analysis and corresponding further health-related data. Integration with population-based patient registries such as cardiovascular disease, congenital anomalies, diabetes, rare diseases, and cancer are highly recommended. Relevant activities of the eHealth Network²²⁸ 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. Local, regional, national and cross-border aspects (to cover e.g. differences in languages and terminologies) should be given adequate consideration.
- Establishing and sustaining a Pan-European ecosystem of digital health stakeholders by promoting and ensuring adoption of the EEHRxF-based infrastructure, involving both supply and demand sides, reinforcing collaboration and networking between the different actors working on digital health innovation across Europe around that infrastructure, and more particularly ensuring strong involvement and coordination at the governance level with the national authorities and Ministries represented in the eHealth Network and the eHealth agencies underneath it. The latter should include innovation initiatives related to a coherent selection of the following: clinical research, clinical trial integration, outcomes-based research, monitoring or decision aids for individuals, and business analytics, as well as application designers and developers, SMEs, innovation hubs, professionals networks e.g. rare disease network, health professionals and patient associations, and standardisation bodies.
- Creating and validating a framework for enabling further exploitation of the public infrastructure for digital health innovation, including its terms of reference, governance and operations rules and procedures, as well as support for capacity building such as training material, guidelines, mentorship and collaboration/twinning programs for designers, developers, health care professionals, policymakers, SMEs, etc.

In this topic the integration of the gender dimension (sex and gender analysis) in research and innovation content is not a mandatory requirement.

such data, and repealing Directive 95/46/EC (General Data Protection Regulation): <http://eur-lex.europa.eu/eli/reg/2016/679/oj>

²²⁷ 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>

²²⁸ https://ec.europa.eu/health/ehealth/policy/network_en

Other Actions not subject to calls for proposals

Grants to identified beneficiaries

1. Grant to the Global Alliance for Chronic Diseases (GACD)

The European Commission will make a contribution towards activities of the Global Alliance for Chronic Diseases (GACD)²²⁹.

Expected Impact. Proposals should set out a credible pathway to contributing to one or several expected impacts of destination “Tackling diseases and reducing disease burden”.

Expected Outcome. Project results are expected to contribute to the following expected outcome: This will enable the European Commission to take part in GACD, which brings together leading health research funding agencies of key countries (currently Argentina, Australia, Brazil, Canada, China, India, Japan, New Zealand, South Africa, Thailand, UK and USA) to coordinate research activities addressing on a global scale the prevention and treatment of chronic, non-communicable diseases such as cardiovascular diseases, diabetes, mental and neurological diseases, lung diseases and cancer.

Scope

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 in research and innovation.

This grant will be awarded without a call for proposals according to Article 195 (e) of the EU Financial Regulation and the relevant provisions of the Horizon Europe Regulation to the legal entity identified below as it manages the GACD (even if located in a third country, its participation is essential for the implementation of the action – Art. 19(2)b of Horizon Europe basic act).

Legal entities:

GACD Action, Gibbs Building, 215 Euston Road, London NW1 2BE, United Kingdom

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 195(e) - Coordination and support action

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes.

²²⁹ <https://www.gacd.org/>

Indicative timetable: 4th Quarter 2021

Indicative budget: EUR 0.70 million from the 2021 budget

2. European registry for human pluripotent stem cell lines

A contribution for 5 years will be made to ensure the continued registration of human Pluripotent Stem Cell (hPSC) lines in a European registry.

Expected Impact. Proposals should set out a credible pathway to contributing to one or several expected impacts of destination: “Unlocking the full potential of new tools, technologies and digital solutions for a healthy society”.

Expected Outcome. Project results are expected to contribute to the following expected outcome: Allow researchers to be informed on Stem Cell lines.

Scope

The aim is to gather and make available detailed information on the different hPSC lines derived in Europe and beyond, thereby also avoiding needless creation of new cell lines. This registry operates through an internet website that will continue to provide high quality data about the lines (e.g. cell characteristics), details regarding their source and contact information regarding their location.

This grant will be awarded without a call for proposals according to Article 195 (e) of the EU Financial Regulation and the relevant provisions of the Horizon Europe Regulation to the legal entity identified below as it manages the European registry

Legal entities:

Fraunhofer Gesellschaft zur Förderung der angewandten Forschung e.V., Hansastrasse 27C, 80686, Muenchen, Germany

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 195(e) - Coordination and support action

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes.

Indicative timetable: 4th Quarter 2021

Indicative budget: EUR 1.50 million from the 2021 budget

3. CEPI 3 - Contribution to the Coalition for Epidemics Preparedness Initiative

Expected Impact. Proposals should set out a credible pathway to contributing to one or several expected impacts of destination: “Tackling diseases and reducing disease burden”.

Expected Outcome. Project Results under this action are expected to contribute to all of the following expected outcomes:

- Health care providers have access to newly developed medical countermeasures against prioritised pathogens with epidemic potential.
- Citizens benefit from improvements in prevention and containment of epidemics.
- Research funders, policy makers and the research community will have better tools and solutions to achieve the Sustainable Development Goal 3.3²³⁰, “to combat communicable diseases” and to implement 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”

Scope:

This grant will be awarded without a call for proposals according to Article 195 (e) of the EU Financial Regulation and the relevant provisions of the Horizon Europe Regulation to the legal entities identified below as CEPI has been a key partner for implementing the common Union response to the COVID-19 epidemic. The funding rate will be 70%.

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 diseases that have epidemic potential, before these diseases become global health emergencies. The Horizon Europe 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 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.

Accordingly, the proposals should cover all of the following activities:

- Vaccine research and development for emerging pathogens to stop future epidemics.
- Research to advance adaptable vaccine technologies that can be used for rapid vaccine and immunoprophylactic development against previously unknown pathogens.

²³⁰ <https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals>

- Engagement with relevant stakeholders in the area of epidemic preparedness ensuring collaboration and coordination and avoiding duplication.

This action is expected to engage with other relevant initiatives, such as the new Partnership for Pandemic Preparedness.

Legal entities:

Coalition for Epidemic Preparedness Innovations, Marcus Thranes gate 2, 0473 Oslo, Norway

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 195(e) - Programme co-fund action

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes.

Indicative timetable: 2021 and 2022

Indicative budget: EUR 35.00 million from the 2021 budget and EUR 35.00 million from the 2022 budget

Other Instruments

1. Mobilisation of Research funds in case of Public Health Emergencies: COVID-19, second quarter of 2021

As part of the EU response to the Covid-19 pandemic, and because of the raising spread of SARS-CoV-2 variants, grants will be awarded without a call for proposals in accordance with Article 195(b) of the Financial Regulation²³¹ to address this exceptional emergency.

An invitation to apply for funding will be published on the Funding & Tenders Portal that will open a dedicated section where proposals can be submitted. This will be communicated to the National Contact Points. The invitation to apply for funding will be open to all eligible entities or limited to targeted entities, taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances (“extreme urgency” due to the COVID-19 pandemic).

Expected Impact: Proposals should set out a credible pathway to contributing to one or several of the following expected impacts: Health care providers are able to better tackle and manage diseases (infectious diseases, including poverty-related and neglected diseases, non-communicable and rare diseases) and reduce the disease burden on patients effectively thanks

²³¹ 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".

to better understanding and treatment of diseases, more effective and innovative health technologies, better ability and preparedness to manage epidemic outbreaks and improved patient safety.

Expected Outcome: Project results are expected to contribute to the following expected outcome: Allow the Union to respond to public health emergencies.

Scope:

On 30 January 2020, WHO declared the COVID 19 outbreak a public health emergency of international concern. One year later, the pandemic is still not under control.

While vaccines are now becoming available and being used, COVID 19 variants are increasingly of concern – because of their potential to affect transmissibility, severity of disease and vaccine effectiveness.

An additional concerted EU effort is needed to further speed up the process of understanding the occurrence and spread of variants and their effect on disease severity and vaccine effectiveness.

For this reason, in 2021, this Cluster will include two different specific actions:

- Support for the development of large scale, COVID19-related cohorts and networks beyond Europe’s borders, forging links with European initiatives as a global response to the pandemic;
- Conduct of vaccine & therapeutic trials to boost prevention and further inform public health policy and clinical management

It is expected that quality-controlled data are shared in accordance with the FAIR²³² principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

The standard eligibility and admissibility criteria, evaluation criteria, thresholds, weighting for award criteria, maximum funding rate and conditions for providing financial support to third parties, are provided in the General Annexes.

This action seeks to address the challenges linked to the COVID-19 variants. As such, the granting authority hereby requests activation of the public emergency provisions, meaning that the beneficiaries must comply with the public emergency related provisions listed in the General Annexes concerning the project implementation under - Intellectual Property Rights (IPR), background and results, access rights and rights of use (article 16 and Annex 5) for the duration of the pandemic; and under Communication, dissemination, open science and visibility (article 17 and Annex 5) during the entire duration of the action and for four years after the end of the action.

²³² FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability. <https://www.openaire.eu/how-to-make-your-data-fair>

The following derogations to the evaluation procedure described in General Annexes D and F apply to open invitations to submit applications:

In order to ensure a balanced portfolio covering responses to different aspects of the public health emergency under the specific actions above, and within each specific action, grants will be awarded to applications not only in order of ranking, but also to those projects that enhance the quality of the project portfolio through synergies between projects and avoidance of overlaps, provided that the applications attain all thresholds.

Seeing the need to cooperate across borders beyond the Union to better tackle the pandemic, the following topic specific conditions to the eligibility conditions contained in the General Annexes apply.

Due to the urgency of this action and geographical relevance of this action and considering the Union's interest to retain, in principle, relations with the countries associated to Horizon 2020, and other third countries in the process of association to Horizon Europe, legal entities established in Albania, Armenia, Bosnia and Herzegovina, Faroe Islands, Georgia, Iceland, Israel, Kosovo²³³, Moldova, Montenegro, Morocco, North Macedonia, Norway, Serbia, Switzerland, Tunisia, Turkey, Ukraine and United Kingdom are eligible for funding from the Union; even if the Horizon Europe association agreement with the third country concerned does not apply at the time of signature of the grant agreement.

The consortium must include at least one independent legal entity established in a Member State and at least two other independent legal entities each established in different Member States or countries listed above.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Research and Innovation Actions - Grant awarded without call for proposals in accordance with Article 195 (b) of the Financial Regulation

Indicative timetable: Second Quarter 2021

Indicative budget: EUR 90.00 million from the 2021 budget

2. Studies, conferences, events and outreach activities

A number of specific contracts will be signed under existing framework contracts in order to: (i) support the dissemination and exploitation of project results; (ii) contribute to the definition of future challenge priorities; (iii) undertake citizen surveys such as Eurobarometers, (iv) carry out specific evaluations of programme parts; and (v) 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.

²³³ This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

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

Form of Funding: Procurement

Type of Action: Public procurement

Indicative budget: EUR 3.00 million from the 2021 budget (Some 10 contracts expected for 2021 (indicative)) and EUR 3.00 million from the 2022 budget (Some 10 contracts expected for 2022 (indicative))

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

Expected Impact. Proposals should set out a credible pathway to contributing to one or several expected impacts of destination: “Tackling diseases and reducing disease burden”.

Expected Outcome. Project results are expected to contribute to the following expected outcome: Allow the Union to respond to Public Health Emergencies

Scope:

In case of a public health emergency²³⁴ (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), funding will be mobilised for :

1. The award of grants without a call for proposals according to Article 195 (b) of the EU Financial Regulation²³⁵ in exceptional and duly substantiated emergencies. At that time, the Funding & Tenders Portal will open a dedicated section where proposals can be submitted. This will be communicated to the National Contact Points. The invitation to apply for funding will be open to all eligible entities or be limited to targeted entities, taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances; and/or
2. The award of additional funding for ongoing grant agreements to cover additional activities specifically linked to the public health emergency, in exceptional and duly substantiated emergencies. Providing such additional funding to ongoing grants that can support pertinent short- and mid-term research efforts to confront the public health emergency will save valuable time and allow addressing the situation with the appropriate urgency. Restricted calls for expression of interest or proposals will develop such additional activities or add additional partners to existing actions.

²³⁴ Should there be no Public Health Emergency in 2021 or 2022, the indicative budget may be reallocated.
²³⁵ 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;"

It is expected that quality-controlled data are shared in accordance with the FAIR²³⁶ principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

The standard eligibility and admissibility criteria, evaluation criteria, thresholds, weighting for award criteria, maximum funding rate and conditions for providing financial support to third parties, are provided in the General Annexes.

The beneficiaries must comply with the public emergency related provisions listed in the General Annexes concerning the project implementation under - Intellectual Property Rights (IPR), background and results, access rights and rights of use (article 16 and Annex 5) for the duration of the Public Health Emergency; and under Communication, dissemination, open science and visibility (article 17 and Annex 5) during the entire duration of the action and for four years after the end of the action.

The following derogations to the evaluation procedure described in General Annexes D and F apply to open invitations to submit applications:

In order to ensure a balanced portfolio covering responses to different aspects of the public health emergency, grants will be awarded to applications not only in order of ranking, but also to those projects that enhance the quality of the project portfolio through synergies between projects and avoidance of overlaps, provided that the applications attain all thresholds.

The action may also include justified derogations from the standard limits to financial support to third parties. Where applicable, the relevant grant agreement options will be applied.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant awarded without call for proposals according to Financial Regulation Article 195 (b)

Indicative timetable: Will depend on the Public Health Emergency

Indicative budget: EUR 1.00 million from the 2021 budget and EUR 30.00 million from the 2022 budget

4. Subscription to the Human Frontier Science Program Organization

An annual subscription to the international Human Frontier Science Program Organization (HFSP)²³⁷ will allow researchers from EU non-G7 Member States to fully benefit from the Human Frontier Science Program (HFSP) and contribute to the implementation of the Union's strategy for international cooperation in research and innovation.

Type of Action: Subscription action

²³⁶ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability. <https://www.openaire.eu/how-to-make-your-data-fair>

²³⁷ The European Commission is a member of the HFSP Organization (HFSP) and has funded HFSP under previous Framework Programmes

Indicative timetable: 2021 and 2022

Indicative budget: EUR 5.30 million from the 2021 budget and EUR 5.30 million from the 2022 budget

5. 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 large actions 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.

Form of Funding: Other budget implementation instruments

Type of Action: Expert contract action

Indicative timetable: 2021 and 2022

Indicative budget: EUR 2.00 million from the 2021 budget and EUR 2.00 million from the 2022 budget

6. Implement, expand and improve the Global Observatory on Health R&D

Effective research policymaking and financing of health research requires strong evidence-base. There are persistent inequities or ‘gaps’ in the health R&D landscape. These gaps exist because of a combination of underinvestment by the public sector and market failures (meaning that there is also underinvestment in R&D in these areas by the private sector because they are not profitable). Identifying those ‘gaps’ requires analysis of harmonised and validated data in the specific areas of action.

The aim of this Contribution Agreement is to support data collection, data interoperability, data analysis and the development of two reports and research papers, one describing the status of health R&D for Cancer and a second one describing the status of Health R&D for Infectious Diseases in the EU and worldwide. These reports and research papers will provide an evidence-based analysis of the actual situation and gaps in research and funding in the areas of Cancer and Infectious Diseases. It will contribute to the priorities of the new European Commission to “promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes” and on the “European plan to fight Cancer”.

The Contribution Agreement will support the work of the Global Observatory on Health R&D, an initiative welcomed by European Union Member States with support for European Commission action. This Contribution Agreement will help expand the focus of the Observatory to other diseases, specifically Cancer and Infectious Diseases globally, as well as all types of health research to strengthen health system and improve overall health systems performance and population health.

The Global Observatory on Health R&D is a unique global-level initiative that aims to contribute to the identification of gaps and opportunities for health R&D. The Observatory does so by collating and analysing various types of information on health R&D, with a view to contribute to the identification of gaps and opportunities for new investments in health R&D based on public health needs. Its objective is to provide a centralized and comprehensive source of data on what, where, by whom and how health R&D is being conducted globally, and it brings together information from a wide range of data sources to provide this overview.

Expected outputs:

- Expansion and improvement of the Observatory online portal, addition of data elements and sources; development of improved functions for automated data analysis; and development of cross-country and cross-disease analyses for research on Cancer and Infectious Diseases.
- Development of two independent reports and research papers describing the status of health R&D for Cancer and for Infectious Diseases in the EU and worldwide

Legal entities:

World Health Organisation, Avenue Appia, 20, CH-1211 Geneva, Switzerland

Form of Funding: Indirectly managed actions

Type of Action: Indirectly managed action

Indicative timetable: Last Quarter 2021

Indicative budget: EUR 0.50 million from the 2021 budget

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Budget²³⁸

	Budget line(s)	2021 Budget (EUR million)	2022 Budget (EUR million)
Calls			
HORIZON-HLTH-2021-STAYHLTH-01		69.00	
	<i>from 01.020210</i>	33.00	
	<i>from 01.020210 - NGEU</i>	36.00	
HORIZON-HLTH-2022-STAYHLTH-01-two-stage			170.00
	<i>from 01.020210</i>		68.00
	<i>from 01.020210 - NGEU</i>		102.00
HORIZON-HLTH-2022-STAYHLTH-02			50.00
	<i>from 01.020210</i>		50.00
HORIZON-HLTH-2021-ENVHLTH-02		130.00	
	<i>from 01.020210</i>	52.00	
	<i>from 01.020210 - NGEU</i>	78.00	
HORIZON-HLTH-2021-ENVHLTH-03		200.00	
	<i>from 01.020210</i>	160.00	

²³⁸ The budget figures given in this table are rounded to two decimal places. The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

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	<i>from 01.020210 - NGEU</i>	40.00	
HORIZON-HLTH-2022-ENVHLTH-04			20.00
	<i>from 01.020210</i>		8.00
	<i>from 01.020210 - NGEU</i>		12.00
HORIZON-HLTH-2021-DISEASE-04		263.00	
	<i>from 01.020210</i>	107.00	
	<i>from 01.020210 - NGEU</i>	156.00	
HORIZON-HLTH-2022-DISEASE-06- two-stage			160.00
	<i>from 01.020210</i>		64.00
	<i>from 01.020210 - NGEU</i>		96.00
HORIZON-HLTH-2022-DISEASE-07			37.00
	<i>from 01.020210</i>		22.00
	<i>from 01.020210 - NGEU</i>		15.00
HORIZON-HLTH-2022-DISEASE-03			30.00
	<i>from 01.020210</i>		12.00
	<i>from 01.020210 - NGEU</i>		18.00

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HORIZON-HLTH-2021-CARE-05		70.00	
	<i>from 01.020210</i>	31.00	
	<i>from 01.020210 - NGEU</i>	39.00	
HORIZON-HLTH-2022-CARE-08			70.00
	<i>from 01.020210</i>		70.00
HORIZON-HLTH-2022-CARE-10			100.00
	<i>from 01.020210</i>		40.00
	<i>from 01.020210 - NGEU</i>		60.00
HORIZON-HLTH-2021-TOOL-06		115.00	
	<i>from 01.020210</i>	46.00	
	<i>from 01.020210 - NGEU</i>	69.00	
HORIZON-HLTH-2022-TOOL-11			95.00
	<i>from 01.020210</i>		38.00
	<i>from 01.020210 - NGEU</i>		57.00
HORIZON-HLTH-2022-TOOL-12-two- stage			60.00
	<i>from 01.020210</i>		33.12
	<i>from 01.020210 - NGEU</i>		26.88

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HORIZON-HLTH-2021-IND-07		44.00	
	<i>from 01.020210</i>	30.92	
	<i>from 01.020210 - NGEU</i>	13.08	
HORIZON-HLTH-2022-IND-13			69.00
	<i>from 01.020210</i>		30.00
	<i>from 01.020210 - NGEU</i>		39.00
Contribution from this part to call HORIZON-MISS-2021-UNCAN-01 under Part 12 of the work programme		3.00	
	<i>from 01.020210</i>	3.00	
Contribution from this part to call HORIZON-MISS-2021-COOR-01 under Part 12 of the work programme		0.29	
	<i>from 01.020210</i>	0.29	
Contribution from this part to call HORIZON-MISS-2021-NEB-01 under Part 12 of the work programme		3.67	
	<i>from 01.020210</i>	3.67	
Other actions			
Grant to identified beneficiary according to Financial Regulation Article 195(e)		37.20	35.00
	<i>from 01.020210</i>	37.20	35.00
Grant awarded without a call for proposals according to Financial Regulation Article 195		91.00	30.00
	<i>from 01.020210</i>	91.00	30.00
Public procurement		3.00	3.00
	<i>from 01.020210</i>	3.00	3.00

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Subscription action		5.30	5.30
	<i>from</i> <i>01.020210</i>	5.30	5.30
Expert contract action		2.00	2.00
	<i>from</i> <i>01.020210</i>	2.00	2.00
Indirectly managed action		0.50	
	<i>from</i> <i>01.020210</i>	0.50	
Contribution from this part to Public procurement under Part 12 of the work programme		2.29	
	<i>from</i> <i>01.020210</i>	2.29	
Contribution from this part to Expert contract action under Part 12 of the work programme		0.22	
	<i>from</i> <i>01.020210</i>	0.22	
Contribution from this part to Indirectly managed action under Part 12 of the work programme		0.29	
	<i>from</i> <i>01.020210</i>	0.29	
Contribution from this part to Grant to identified beneficiary according to Financial Regulation Article 195(e) under Part 12 of the work programme		0.02	
	<i>from</i> <i>01.020210</i>	0.02	
Estimated total budget		1039.80	936.30