

EN

Annex 4

Horizon Europe

Work Programme 2021-2022

4. Health

DISCLAIMER

Draft version 5.1 – January 2021

This draft version 5.1 contains budget figures and updates with respect to version 3 discussed with the Programme Committee in November, taking up comments sent in December by the Programme Committee and Commission services.

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

Table of contents

| | |
|--|-----------|
| Introduction | 7 |
| Destination 1 – Staying healthy in a rapidly changing society..... | 10 |
| Call - Staying Healthy (2021) | 13 |
| Conditions for the Call | 13 |
| 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 . | 14 |
| HORIZON-HLTH-2021-STAYHLTH-01-03: Supporting digital empowerment and health literacy – Healthy citizens 2.0 | 17 |
| HORIZON-HLTH-2021-STAYHLTH-01-04: A roadmap for personalised prevention..... | 19 |
| HORIZON-HLTH-2021-STAYHLTH-01-05: Mobilising the network of National Contact Points in the Health Cluster..... | 20 |
| Call - Staying healthy (Two stage - 2022)..... | 22 |
| Conditions for the Call | 22 |
| HORIZON-HLTH-2022-STAYHLTH-01-01-two-stage: Boosting mental Health in Europe in times of change | 23 |
| HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage: Trustworthy AI tools to predict the risk of chronic non-communicable diseases and/or their progression..... | 27 |
| HORIZON-HLTH-2022-STAYHLTH-01-05-two-stage: Prevention of obesity through the life course | 29 |
| Call - Staying healthy (Single stage, 2022) | 32 |
| Conditions for the Call | 32 |
| HORIZON-HLTH-2022-STAYHLTH-02-01: Personalised blue print of chronic inflammation in health-to-disease transition | 33 |
| Destination 2. Living and working in a health-promoting environment | 36 |
| Call - Environment and health (2021) | 39 |
| Conditions for the Call | 39 |
| HORIZON-HLTH-2021-ENVHLTH-02-01: Exposure to electromagnetic fields (EMF) and health | 40 |
| HORIZON-HLTH-2021-ENVHLTH-02-02: Indoor air quality and health | 42 |
| HORIZON-HLTH-2021-ENVHLTH-02-03: Health impacts of climate change, costs and benefits of action and inaction | 44 |
| Call - Partnerships in Health (2021) | 47 |
| Conditions for the Call | 47 |
| HORIZON-HLTH-2021-ENVHLTH-03-01: European Partnership for the Assessment of Risks from Chemicals (PARC) | 48 |

| | |
|--|-----------|
| Call - Environment and health (Single Stage - 2022) | 53 |
| Conditions for the Call | 53 |
| HORIZON-HLTH-2022-ENVHLTH-04-01: Methods for assessing health-related costs to environmental stressors | 54 |
| | |
| Destination 3. Tackling diseases and reducing disease burden | 57 |
| | |
| Call - Tackling diseases (2021) | 61 |
| Conditions for the Call | 61 |
| HORIZON-HLTH-2021-DISEASE-04-01: Towards improved supportive, palliative, survivorship and end-of-life care of cancer patients | 62 |
| HORIZON-HLTH-2021-DISEASE-04-02: Building a European innovation platform for the repurposing of medicinal products | 64 |
| HORIZON-HLTH-2021-DISEASE-04-03: Innovative approaches to enhance poverty-related diseases research in sub-Saharan Africa | 66 |
| HORIZON-HLTH-2021-DISEASE-04-04: Clinical validation of artificial intelligence solutions for treatment and care | 68 |
| HORIZON-HLTH-2021-DISEASE-04-07: Personalised medicine and infectious diseases: understanding the individual host response to viruses (e.g., SARS-CoV-2) | 70 |
| HORIZON-HLTH-2021-DISEASE-04-05: A roadmap towards the creation of the European One Health antimicrobial resistance partnership (OH AMR)..... | 72 |
| HORIZON-HLTH-2021-DISEASE-04-06: Building a European Research and Innovation Partnership for Pandemic Preparedness | 74 |
| | |
| Call - Tackling diseases (Two Stage - 2022) | 76 |
| Conditions for the Call | 76 |
| HORIZON-HLTH-2022-DISEASE-06-02-two-stage: Pre-clinical development of the next generation immunotherapies for diseases or disorders with unmet medical need | 77 |
| HORIZON-HLTH-2022-DISEASE-06-03-two-stage: Vaccines 2.0 - developing the next generation of vaccines | 79 |
| HORIZON-HLTH-2022-DISEASE-06-04-two-stage: Development of new effective therapies for rare diseases | 81 |
| | |
| Call - Tackling diseases (Single Stage - 2022) | 84 |
| Conditions for the Call | 84 |
| HORIZON-HLTH-2022-DISEASE-07-02: Pandemic Preparedness - Placeholder | 85 |
| HORIZON-HLTH-2022-DISEASE-07-03: Non-communicable diseases risk reduction in adolescence and youth..... | 85 |
| HORIZON-HLTH-2022-DISEASE-07-01: GloPID R secretariat - Placeholder | 87 |
| | |
| Call - Partnerships in Health (2022) | 87 |
| Conditions for the Call | 87 |
| HORIZON-HLTH-2022-DISEASE-03-01: European Partnership Fostering an ERA for Health research - Placeholder..... | 88 |

Destination 4. Ensuring access to innovative, sustainable and high-quality health care 90

Call - Ensuring access to innovative, sustainable and high-quality health care (2021) ... 93

| | |
|--|----|
| Conditions for the Call | 93 |
| HORIZON-HLTH-2021-CARE-05-01: Enhancing quality of care and patient safety | 94 |
| HORIZON-HLTH-2021-CARE-05-02: Data-driven decision-support tools for better health and care delivery and policy-making | 96 |
| HORIZON-HLTH-2021-CARE-05-04: Health and care innovation procurement network | 99 |

Call - Ensuring access to innovative, sustainable and high-quality health care (Single Stage - 2022) 102

| | |
|--|-----|
| Conditions for the Call | 102 |
| HORIZON-HLTH-2022-CARE-08-02: Innovation procurement (PCP) for building the resilience of health and care systems in the context of recovery | 103 |
| HORIZON-HLTH-2022-CARE-08-03: Innovation procurement (PPI) for building the resilience of health and care systems in the context of recovery | 106 |
| HORIZON-HLTH-2022-CARE-08-04: Better economic foresight, financial planning and procurement/contractual strategies for health systems..... | 108 |

Call - Partnerships in Health (2022) 111

| | |
|--|-----|
| Conditions for the Call | 111 |
| HORIZON-HLTH-2022-CARE-10-01: European Partnership on Transforming Health and Care Systems | 112 |

Destination 5. Unlocking the full potential of new tools, technologies and digital solutions for a healthy society 117

Call - Tools and technologies for a healthy society (2021)..... 119

| | |
|---|-----|
| Conditions for the Call | 119 |
| HORIZON-HLTH-2021-TOOL-06-01: Smart medical devices and their surgical implantation for use in resource-constrained settings | 120 |
| HORIZON-HLTH-2021-TOOL-06-02: Next generation advanced therapies to treat highly prevalent and high burden diseases with unmet needs..... | 121 |
| HORIZON-HLTH-2021-TOOL-06-03: Innovative tools for use and re-use of health data (in particular electronic health records and/or patient registries)..... | 123 |

Call - Tools and technologies for a healthy society (Single Stage - 2022)..... 125

| | |
|---|-----|
| Conditions for the Call | 125 |
| HORIZON-HLTH-2022-TOOL-11-01: Optimising effectiveness in patients of existing prescription drugs for major diseases (except cancer) with the use of biomarkers..... | 126 |
| 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 | 127 |

| | |
|---|------------|
| Call - Tools and technologies for a healthy society (2022) | 130 |
| Conditions for the Call | 130 |
| HORIZON-HLTH-2022-TOOL-12-01-two-stage: Computational models for new patient stratification strategies..... | 131 |
| | |
| Destination 6. Maintaining an innovative, sustainable and globally competitive health industry | 134 |
| | |
| Call - A competitive health-related industry (2021) | 136 |
| Conditions for the Call | 136 |
| HORIZON-HLTH-2021-IND-07-01: Green pharmaceuticals..... | 137 |
| HORIZON-HLTH-2021-IND-07-02: Development procurement and responsible management of new antimicrobials..... | 139 |
| 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” .. | 140 |
| | |
| Call - A competitive health-related industry (2022) | 142 |
| Conditions for the Call | 142 |
| HORIZON-HLTH-2022-IND-13-01: Enhancing Cybersecurity of connected Medical Devices | 144 |
| HORIZON-HLTH-2022-IND-13-02: Scaling up multi-party computation, data anonymisation techniques and synthetic data generation | 145 |
| HORIZON-HLTH-2022-IND-13-03: New payment models for cost-effective and affordable health innovations/new models of pricing | 147 |
| HORIZON-HLTH-2022-IND-13-04: Setting up a European Smart Health Innovation Hub | 149 |
| HORIZON-HLTH-2022-IND-13-05: Setting up a European Electronic Health Record Exchange Format Ecosystem | 151 |
| | |
| Other Actions not subject to calls for proposals | 155 |
| | |
| Grants to identified beneficiaries | 155 |
| 1. Grant to the Global Alliance for Chronic Diseases..... | 155 |
| 2. European registry for human pluripotent stem cell lines | 155 |
| 3. CEPI 3 - Contribution to the Coalition for Epidemics Preparedness Initiative - Placeholder | 156 |
| | |
| Other Instruments | 157 |
| 1. Studies, conferences, events and outreach activities..... | 157 |
| 2. Mobilisation of research funds in case of Public Health Emergencies | 157 |
| 3. Subscription to the Human Frontier Science Program Organization..... | 159 |
| 4. External expertise..... | 159 |
| | |
| Budget | 160 |

DRAFT

Introduction

The European Union and the world are challenged by the first pandemic since a century. 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 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 European 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 European Union leaders have agreed on a Recovery Plan that will lead the way out of the crisis and lay the foundations for a modern and more sustainable European Union. The Health cluster will put the focus of this work programme mainly to this endeavour, which will benefit from financial resources from the next Multiannual Financial Framework and from NextGenerationEU (NGEU), the European 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 health systems better prepared to any future public health emergency. The Recovery Plan aims the European 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 European 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 such that research and innovation activities are adjusted to the users' particular expectations, needs, constraints and potential.

The pandemic shows the importance of coordination among European Union countries in the area of health. The European Commission is building a strong European Health Union, in which all European Union countries prepare and respond together to health crises, medical supplies are available, affordable and innovative, and countries work together to improve prevention, treatment and aftercare for diseases such as cancer. Stronger common preparedness and response will rely on greater input from European Union agencies including the newly created EU Health Emergency preparedness and Response Authority (EU-HERA).

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, such as EU4Health, Digital Europe Programme (DEP), InvestEU, European Regional Development Fund (ERDF), European Social Fund (ESF+) and Structural Reform Support Programme (SRSP). Both 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.

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, special attention will be given to ensuring cooperation between universities, scientific communities and industry, including small and medium 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. Project proposers should consider and actively seek synergies with, and where appropriate possibilities for further funding from, other R&I-relevant EU, national or regional programmes (such as ERDF, ESF+, JTF, EMFF, EAFRD and InvestEU), where appropriate, as well as private funds or financial instruments. 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 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 health cluster will also benefit from participation of health-related European research infrastructures which can offer tailored research support services to activities across all destinations under the health cluster.

The EU's Recovery and Resilience Facility (RRF) [currently available in all Member States] aims at financing projects that directly tackle the economic and social impacts from the coronavirus crisis and support the green and digital transition. For project ideas that directly contribute to these objectives and that have a strong focus in one Member State it is advisable to check access to the RRF for a fast and targeted support.

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 and enabling 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 healthcare; A resilient EU prepared for emerging threats; High quality digital services for all; and Competitive and secure data-economy. More specifically, cluster 1 aims to contribute to six expected impacts as set by the strategic plan, which are the destinations of this work programme.

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 healthcare'* and in particular to the expected impact 1 of cluster 1 *'health'*: 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 and 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. 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.

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.

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.

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.

Key to achieving the expected impact 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 and AI solutions, and robust and transparent methodologies for analysis and reporting.

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 in young age), resulting in increased engagement in and adherence to effective strategies for health promotion, diseases prevention and treatment, including increased vaccination rates and patient safety.
- Health policies and actions for health promotion and disease prevention are knowledge-based, targeted 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- | | 50.00 | 21 Apr 2022 |

*Horizon Europe - Work Programme 2021-2022 Vs. 5.1 for PC, Jan '21
Health*

| | | | |
|---------------------------|-------|--------|--|
| STAYHLTH-02 | | | |
| Overall indicative budget | 69.00 | 220.00 | |

DRAFT

Call - Staying Healthy (2021)

HORIZON-HLTH-2021-STAYHLTH-01

Conditions for the Call

Indicative budget(s)¹

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ² | Number of projects expected to be funded |
|---|----------------|-----------------------|---|--|
| | | 2021 | | |
| Opening: na Deadline(s): 21 Sep 2021 | | | | |
| HORIZON-HLTH-2021-STAYHLTH-01-02 | RIA | 60.00 | 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. |

¹ 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.

² Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | |
|---|---|
| <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 EU 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 more) 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. The latter make use of this knowledge 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 individualising preventive and therapeutic treatment decisions. As a result, patients receive more targeted therapies and relapse less frequently. They moreover experience less stigma as more objective diagnoses increase 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 predisposition to mental illnesses and are given timely evidence-based guidance on individualised preventive measures that ensure their active engagement and adherence to effective strategies for mental health promotion.

- 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 illness, 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, depending on the chosen expected outcome(s) to be addressed:

- Significantly advance the molecular and neurobiological understanding of how genetic, epigenetic and environmental risk and resilience factors (including 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 illness³ 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 data⁴.
- 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

³ 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.

⁴ 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 of combination (bio)markers for all of the following purposes:
- development of robust quantitative, clinical measures of mental health
- identification of signatures, for example genetic and epigenetic blueprints, conferring susceptibility to and protection against mental illnesses
- 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
- 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 medications⁵ 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 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

⁵ Going beyond monoaminergic neurotransmitter systems by targeting novel pathways and addressing also the challenge of getting drugs pass through the blood-brain barrier

the proposed research is expected to be multidisciplinary including medical sciences, psychological sciences and social sciences and humanities.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices. Successful proposals will be also encouraged to exchange with other relevant proposals funded under other topics and other clusters to ensure synergies on cross-cutting challenges of common interest. Therefore, proposals are expected to include a budget to cover those joint coordination and dissemination activities without the prerequisite to define concrete joint activities at this stage. The details of these joint activities will be defined during the grant preparation phase with the Commission.

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

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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:

1. European citizens are educated, motivated and empowered to use digital tools for managing their own health (physical and mental) and well-being (including social). As a result, they have a more active role in achieving their health potential and are able to monitor their health, adopt healthy lifestyles at home, in the community and at work and interact better with their doctors and carers (receiving and providing feedback). Citizens who are digitally health literate have a higher quality of life and are more autonomous, they participate more in social life and have better employment opportunities and have a more active role in achieving their health potential. Member States actively contribute to health literacy efforts, monitor and evaluate them.

2. Health care and social services are better integrated, affordable, open to diversity and inclusion: they comply with the 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.

3. 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 healthcare.

Scope: Digital technologies are a driving force for empowering citizens in taking an active role in the management of their own health and well-being as well as 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, digital health literacy of the citizens is an essential element for the successful transformation of health and care systems.

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

1. Map health literacy research in the EU (and beyond).
2. Develop a comprehensive and inclusive European strategy on (Digital) Health Literacy – focusing on health promotion, disease prevention, treatment and (self-)care as well as its impact on quality of life, wellbeing, productivity and the economy - for the benefit of all citizens, taking into account the geographic, social and economic determinants of digital health literacy inequities.
3. 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.
4. Create a network of Digital Health Literacy champions across the EU (and beyond) to foster exchange and uptake of best practices.
5. Set concrete targets as well as areas for improvement on health literacy levels across Europe.
6. Develop monitoring mechanisms and indicators to assess health literacy levels and their evolution across Member States.
7. Include stakeholders from all the relevant sectors (including but not limited to education, social innovation, healthcare, Medtech, media and citizens) in the co-creation, design, planning, implementation and evaluation of the strategy.

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 EU 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*” and 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:

- Exploitation of a Strategic Research and Innovation Agenda by the research community, research funders and policy makers.
- Policy makers, public health services, industrial stakeholders and citizen associations will be empowered to act by a coordinated, harmonised and comprehensive approach to personalised prevention research for all, across Europe.
- Public health services and systems, and citizen associations will be aware and possibly adopt personalised prevention strategies.
- Evidence based policy decisions for insurers and authorities 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 the healthcare practice. Thanks to personalised approaches and the development of targeted interventions, several medical conditions which until recently were very serious or even fatal, can now be cured, attenuated or turned to a chronic condition. However, more could be achieved if we could identify early on individuals at higher risk of developing a particular condition, before symptoms occur. As an indicator, 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 healthcare 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 healthcare system.

Applicants should propose activities that address all the following areas:

- Identification and networking of key stakeholders for co-creation of personalised prevention.
- Literature mapping and research gap analysis, including of existing preventative research programmes in Europe and beyond.
- Identification of the existing bottlenecks and analysis of evidence and examples of successful implementation of personalised prevention approaches for transferability.
- Analysis of how personalised prevention can be most effectively and efficiently delivered, as well as cost effective.
- Robust, professional communication strategy to maximise the impacts 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 the candidate Partnership on Personalised Medicine and the funders (at all levels).

The CSA should engage with related initiatives (e.g. IC Permed) and provide input for the candidate EU partnership on personalised medicine.

HORIZON-HLTH-2021-STAYHLTH-01-05: Mobilising the network of National Contact Points in the Health Cluster

| Specific conditions | |
|---|---|
| <i>Expected EU contribution per project</i> | The EU 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 and admissibility conditions</i> | <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</p> |

| | |
|-----------------------------|--|
| | (SC1) nominated for Horizon 2020 would be eligible. |
| <i>Evaluation Procedure</i> | The granting authority can fund a maximum of one project |

Expected Outcome: Project results under this topic are expected to contribute 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) supporting the implementation of the EU Health programmes will be closely collaborating based on identified synergies with the Research and Innovation Health NCPs.
- 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.
- NCPs representing third countries, in particular those neighbouring the European Research Area should benefit from dense collaboration with the NCP Health network.

Proposals should describe a credible pathway from their project results and outcomes towards the following expected impacts:

- Staying healthy in a rapidly changing society;
- Living and working in a health-promoting environment;
- Tackling diseases and reducing disease burden;
- Ensuring access to innovative, sustainable and high-quality health care;
- Unlocking the full potential of new tools, technologies & digital solutions for a healthy society;
- Maintaining an innovative, sustainable and globally competitive health industry.

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

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 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 funding programmes providing funding available for health-related actions (DEP, ESF+, etc). 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)⁶

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ⁷ | Number of projects expected to be funded |
|--|----------------|-----------------------|---|--|
| | | 2022 | | |
| Opening: 06 Oct 2021 | | | | |
| Deadline(s): 01 Feb 2022 (First Stage), 06 Sep 2022 (Second Stage) | | | | |

⁶ 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.

⁷ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

*Horizon Europe - Work Programme 2021-2022 Vs. 5.1 for PC, Jan '21
Health*

| | | | | |
|--|-----|--------|--------------|----|
| HORIZON-HLTH-2022-STAYHLTH-01-01-two-stage | RIA | 50.00 | Around 7.00 | 7 |
| HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage | RIA | 60.00 | Around 6.00 | 10 |
| HORIZON-HLTH-2022-STAYHLTH-01-05-two-stage | RIA | 60.00 | 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):

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 EU 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 the following impact areas: ‘Good health and high-quality accessible healthcare’ as well as ‘high quality digital services for all’. More specifically, this topic aims at supporting activities that are enabling or contributing to the expected impact 1 of cluster 1 ‘health’: citizens of all ages stay healthy and independent in a rapidly changing society thanks to healthier lifestyles and behaviours, improved evidence-based health policies, and more effective solutions for health promotion and disease prevention. 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 and care professional, national/regional public authorities and other relevant actors in key settings (e.g. schools, workplace, etc.):
 - o Have access to evidence-based, innovative, cost-effective/cost-neutral, large-scale, comprehensive strategies and interventions for mental health promotion and mental ill health prevention, targeting the most vulnerable populations, which they may choose to uptake;
 - o 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, energy transition, demographic and migration factors and exponential technological advancements);
- The scientific community together with the public authorities anticipate new and emerging risks to mental health associated with this transformation contributing to a better and inclusive public mental health preparedness.
- Citizens have access to and make use of new tools and services to make 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 individuals 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 environment change.

On the other hand, digital technologies and the achievement of the Digital Single Market – one of Europe’s key priorities – are transforming our economy, our industries as well as our culture and lifestyle. Digitalisation, including ICT-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 workplaces, working practices, the workforce and how we perceive work as well as the way we live. However, the exponential incorporation of technology in our daily lives has 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, for example, 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”⁸.

1. A comprehensive knowledge base of how Europe’s transformation(s) 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 digital life, climate change and/or other factors highlighted in the “Expected outcomes”. 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 conditions and comorbidities and other high-risk groups such as socio-economic disadvantaged groups, migrants, etc.). Integration of care and coordination among different settings from communities to healthcare 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:
 - o Evidence based guidelines for healthcare 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 a schools (including higher education) and/or via eLearning.

⁸ For instance, the socio-economic consequences of the Covid-19 pandemic, climate change, energy transition, demographic and migration factors and exponential technological advancements.

- o Consultation during school time to educate students (e.g. on coping with change) and to detect students at risk early.
 - o Educational material and campaigns targeting the most vulnerable groups, (e.g. children and seniors), 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 mental occupational health in the workplace, in particular in small and medium-sized enterprises, e.g.: i) understanding the impact of 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 society (e.g. digital technologies, climate change, etc); and/or ii) the effects of a transforming 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 and social sciences and humanities, and also 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 strongly consider involving end-users (including civil society organisations) and/or strategic partners by 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.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices. Successful proposals will be also encouraged to exchange with other relevant proposals

funded under other topics and other clusters to ensure synergies on cross-cutting challenges of common interest. Therefore, proposals are expected to include a budget to cover those joint coordination and dissemination activities without the prerequisite to define concrete joint activities at this stage. The details of these joint activities will be defined during the grant preparation phase with the Commission.

HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage: Trustworthy 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 EU 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 validated disease risk assessment AI tools and hence citizens are better informed to manage their own health.
- Healthcare professionals can 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 and hence citizens can benefit from improved health outcomes.
- Healthcare professionals can develop evidence-based recommendations and guidelines for the implementation of AI-based personalised prevention strategies and citizens can benefit from optimized healthcare measures superior to the standard-of-care.
- Healthcare professionals can employ quantitative indicators in order to identify and follow-up of individuals with high risk for the development and/or risk for 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 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 trustworthy⁹ AI tools to enable timely personalised prevention approaches for chronic non-communicable diseases/disorders. The topic does not exclude any diseases/disorders, provided that the proposals address the requirements of the topic.

The 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.)

The projects 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/healthcare 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. 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.

The proposals should address all of the following areas:

- Leverage of 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
- Develop the adequate performance metrics to assess the technical robustness of the developed AI disease-risk tools and in particular their accuracy, reliability, reproducibility and generalisability. The 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 disease-risk tools in terms of improving health outcomes and enabling personalised prevention strategies.

⁹ The High Level Expert Group on Artificial Intelligence nominated by the European Commission publication: Ethics Guidelines for Trustworthy AI; <https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines#Top>

- Implement proof of concept and/or feasibility studies to validate the AI tools in a relevant end-users environment and/or real-world setting and assess their performance in comparison to the standard-of-care

The proposals should adhere to the FAIR¹⁰ data principles and apply good practices for GDPR-compliant personal data protection. The proposals are encouraged to implement best practices of international standards 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.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices. Furthermore, successful proposals will be also encouraged to exchange with other relevant proposals funded under other topics and other clusters, such as cluster 4, to ensure synergies on cross-cutting challenges of common interest. Therefore, proposals are expected to include a budget to cover those joint coordination and dissemination activities without the prerequisite to define concrete joint activities at this stage. The details of these joint activities will be defined during the grant preparation phase with the Commission.

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

| Specific conditions | |
|---|---|
| <i>Expected EU contribution per project</i> | The EU 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 |

¹⁰ FAIR: findable, accessible, interoperable and reusable

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*”. Researchers, healthcare professionals and developers of medical interventions will have a much better understanding of 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. 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 and care professionals have improved understanding of basic biological pathways (genetic and epigenetic blueprints) conferring susceptibility to and protecting against overweight/obesity.
- Health and care professionals, national/regional/local public authorities and other relevant actors (e.g. schools, canteens, hospitals, work places, shopping malls, sport centres):
 - 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 comorbidities throughout the life course.
 - 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 comorbidities at population level across European regions and countries.
 - Adopt tailor-made prevention campaigns to tackle overweight/obesity, including campaigns for improving integration of health education into academic learning and raising awareness for health care providers and citizens.
- Citizens have access to and make use of new tools and services to make informed decisions about evidence-based lifestyle choices that will enable them to avoid 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 also develop related diseases (diabetes, cardiovascular disease, 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.

The 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 behavior 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 casual links between overweight/obesity and sedentary behaviour, quality, 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, including cost-effectiveness of obesity management strategies 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.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices. Successful proposals will be also encouraged to exchange with other relevant proposals funded under other topics and other clusters to ensure synergies on cross-cutting challenges of common interest [such as topics HORIZON-CL6-SFO-2021-00-00: “*Enabling the transition to healthy and sustainable dietary behaviour*” and HORIZON-CL6-SFO-2022-00-00: “*Integrated surveillance system to prevent and reduce diet-related non-communicable diseases (NCDs)*”]. Therefore, proposals are expected to include a budget to cover those joint coordination and dissemination activities without the prerequisite to define concrete joint activities at this stage. The details of these coordination activities will be defined during the grant preparation phase with the Commission.

Call - Staying healthy (Single stage, 2022)

HORIZON-HLTH-2022-STAYHLTH-02

Conditions for the Call

Indicative budget(s)¹¹

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ¹² | Number of projects expected to be funded |
|--------|----------------|-----------------------|--|--|
| | | 2022 | | |
| | | | | |

¹¹ 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.

¹² Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | | | | |
|----------------------------------|-----|-------|-------------|---|
| 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 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 blue print of chronic inflammation in health-to-disease transition

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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 most of the following expected outcomes:

- Researchers and medical professionals utilise effectively the knowledge of the individual’s chronic inflammatory factors triggering the health-to-disease transition and subsequently can provide optimal counseling to the citizens for improving their health status.
- Healthcare professionals have access to and/or employ objective personalised health indicators linked to chronic inflammation with respect to monitoring of the health status and improving the health outcomes of the citizens.
- Health care professionals have the scientific evidence to develop and/or use improved guidelines for personalised prevention strategies to tackle chronic diseases.
- Citizens are better informed to actively manage their own health and have the tools to maintain their healthy status, improve their health and reduce their risk for chronic diseases

Scope:

Personalised approaches for disease prevention seek to determine the predisposition to disease and deliver timely and targeted prevention. Understanding the risk factors that trigger the health-to-disease transition is essential for delivering personalized preventive measures to reduce the chronic diseases burden.

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.

The 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.

The proposals are expected to develop and implement data-driven, personalised approaches to identify the chronic inflammation drivers 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, provided that the proposals address the requirements of the topic. The human studies and human data utilised/generated should be compatible to an age range as representative as possible to the (pre)-disease onset of the diseases to be studied, in order to boost the fast translation of the research results into proof-of-concept studies.

The applicants 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 the state-of-the-art knowledge and the 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 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 utilize robust sensors, devices and/or mobile apps and other innovative technologies to dynamically monitor the individual's health status and to identify chronic inflammation indicators correlative to the health-to-disease transition
- Pilot proof-of-concept human studies to assess the beneficial effect of diverse prevention and/or interventions strategies with the aim to demonstrate quantifiable 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 local inflammation.

The proposals should adhere to the FAIR¹³ data principles and adopt wherever relevant, data standards and data sharing/access good practices developed by existing European health research infrastructures.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices. Furthermore, successful proposals will be also encouraged to exchange with other relevant proposals funded under other topics and other clusters to ensure synergies on cross-cutting challenges of common interest. Therefore, proposals are expected to include a budget to cover those joint coordination and dissemination activities without the prerequisite to define concrete joint activities at this stage. The details of these joint activities will be defined during the grant preparation phase with the Commission.

¹³ FAIR: findable, accessible, interoperable and reusable

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 expected impact 2 of cluster 1 *'health'*: 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 and 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 decision-making. Furthermore, agreed methodologies to estimate health-related costs of exposure to environmental stressors are lacking.

Therefore, this work programme 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 such as 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 creating of a European Partnership for the Assessment of Risks from Chemicals to establish the EU as an internationally recognised driver of innovative chemical risk assessment with 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. All topics will be 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:

- Solid scientific evidence and systematic uptake of research results into relevant environmental, occupational, social, economic, fiscal and health policies and practices at the EU, national and regional level, including implementation in 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;
- 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;
- 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;
- 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- | 200.00 | | 21 Sep 2021 |

*Horizon Europe - Work Programme 2021-2022 Vs. 5.1 for PC, Jan '21
Health*

| | | | |
|----------------------------------|--------|-------|----------------|
| ENVHLTH-03 | | | |
| HORIZON-HLTH-2022- ENVHLTH-04 | | 20.00 | 21 Apr 2022 |
| Overall indicative budget | 330.00 | 20.00 | |

DRAFT

Call - Environment and health (2021)

HORIZON-HLTH-2021-ENVHLTH-02

Conditions for the Call

Indicative budget(s)¹⁴

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ¹⁵ | Number of projects expected to be funded |
|--|----------------|-----------------------|--|--|
| | | 2021 | | |
| Opening: 22 Apr 2021 Deadline(s): 21 Sep 2021 | | | | |
| HORIZON-HLTH-2021-ENVHLTH-02-01 | RIA | 30.00 | Around 8.00 | 4 |
| HORIZON-HLTH-2021-ENVHLTH-02-02 | RIA | 40.00 | Around 8.00 | 5 |
| HORIZON-HLTH-2021-ENVHLTH-02-03 | RIA | 60.00 | 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. |
| <i>Award criteria</i> | The criteria are described in General Annex D. |

¹⁴ 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.

¹⁵ 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-2021-ENVHLTH-02-01: Exposure to electromagnetic fields (EMF) and health

| | |
|---|--|
| Specific conditions | |
| <i>Expected EU contribution per project</i> | The EU 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 the 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 guidelines¹⁶ for limiting exposure to electromagnetic fields; Public authorities improve their risk assessment, management and communication through access to FAIR¹⁷ data and robust evidence on the exposure to EMF, in particular for new generation radio-communication networks (e.g. 5G networks), and on the causal links between level and duration of exposures and health effects;

¹⁶ HEALTH PHYS 118(5): 483–524; 2020

¹⁷ 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/ISO¹⁸) 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 new generation radiocommunication 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 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 have also increased such as security scanners, smart meters and medical equipment. This has resulted in an increase in manmade 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 follows 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 shall provide forward-looking information on potential hazards and risks of existing and emerging EMF exposures through innovative monitoring techniques, experimental evidence and modelling and shall include all of the following activities:

¹⁸ https://www.cencenelec.eu/news/brief_news/Pages/TN-2017-057.aspx

- Monitoring of exposures of the general population and specific groups at risk such as children and workers using innovative technologies;
- 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 3Rs¹⁹ principle, and taking into account combined exposures and changing patterns of device use;
- Delivering FAIR²⁰ data on the causal links between level and duration of exposures and potential health (biological) effects, including potential mechanisms, in living and working environment, considering also vulnerable groups, particularly children;
- Proposing new quality criteria and standards (CEN/ISO ²¹) 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 and promoting trust.

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

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices.

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

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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. |

¹⁹ Replacement, reduction and refinement
²⁰ https://www.cencenelec.eu/news/brief_news/Pages/TN-2017-057.aspx
²¹

| | |
|--------------------------|---|
| <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 the 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 FAIR²² 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.

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

²² FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability

- Identification and characterisation of sources and routes of exposure and dispersion of chemical and biological indoor air pollution²³, 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;
- 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 for interventions, supporting health promotion and disease prevention in various sectors, e.g. construction and transport, and in various socio-economic settings;
- Delivery of FAIR²⁴ 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.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices.

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

Specific conditions

²³ All chemical exposure data resulting from the selected projects shall be shared via IPCHEM (<https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>).

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

| | |
|---|---|
| <i>Expected EU contribution per project</i> | The EU 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 the 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 policies, the EU Observatory for Climate and Health²⁵, 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 environmental-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 environment-related risks and impacts. In addition to aiming for climate neutrality by 2050, the Commission will adopt a more ambitious EU strategy on adaptation to climate change. 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 is expected to cause at least 250000 additional deaths per year globally between 2030 and 2050²⁶. Climate change, together with other natural and human-made health stressors, can influence human health and pattern of disease in numerous ways. Some existing health threats will intensify and new

²⁵ https://climate-adapt.eea.europa.eu/observatory/evidence/indicators_intro

EU Adaptation Strategy under development

²⁶ <https://www.who.int/news-room/fact-sheets/detail/climate-change-and-health>

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 globally influencing the epidemiology 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 health impacts, including in occupational settings, and related risk factors correlated to climate change, especially in vulnerable population groups 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.

Applicants shall choose one of the following areas of research:

1. Research on relationships between changes in environmental pollution induced by climate change, and subsequent impacts on interrelated ecosystems and their influence on human health;
2. Climate induced emergence and transmission of pathogens and spread of zoonotic pathogens using Eco-health²⁷ and One Health²⁸ approaches;

The proposals should include all of the following activities:

- i. Development of suitable indicators and monitoring mechanisms to assess the health-relevant outcomes of climate policies and actions;
- ii. Development of predictive models and early warning systems for exposure and health impacts of climate change based on transparent assumptions and architecture;
- iii. Development of tools for health impact and cost-benefit assessment of climate-change adaptation and mitigation measures;
- iv. Investigation of health co-benefits of adaptation and mitigation policy measures outside the health sector;
- v. Demonstration of the validity of tools and methods developed in the above listed activities in policy-relevant case studies;
- vi. Determination of the societal implications of climate change on health systems, including occupational health, and development of adaptation measures;

²⁷ 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

²⁸ 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

- vii. Development of training materials and guidelines to educate relevant actors in our daily life on climate change health impacts and to facilitate adaptation of health systems and practices;
- viii. Delivery of FAIR²⁹ 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 target to support international climate policies.

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

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices. Successful proposals will be also encouraged to exchange with other relevant proposals funded under other topics and other clusters to ensure synergies on cross-cutting challenges of common interest [such as under cluster X the call topic YYY - to be deleted if not applicable]. Therefore, proposals are expected to include a budget to cover those joint coordination and dissemination activities without the prerequisite to define concrete joint activities at this stage. The details of these joint activities will be defined during the grant preparation phase with the Commission.

Call - Partnerships in Health (2021)

HORIZON-HLTH-2021-ENVHLTH-03

Conditions for the Call

Indicative budget(s)³⁰

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

²⁹ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability. Data can include exploitation of information and data from European data infrastructures and programmes such as Copernicus, European Space Agency and the GEO initiative.

³⁰ 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.

| | | 2021 | (EUR million) ³¹ | expected to be funded |
|--|--------|--------|-----------------------------|-----------------------|
| Opening: 22 Apr 2021 Deadline(s): 21 Sep 2021 | | | | |
| HORIZON-HLTH-2021-ENVHLTH-03-01 | COFUND | 200.00 | 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. |
| <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-03-01: European Partnership for the Assessment of Risks from Chemicals (PARC)

| Specific conditions | |
|-------------------------------------|---|
| <i>Expected EU contribution per</i> | The EU 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 |

³¹ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | |
|----------------------------------|--|
| <i>project</i> | 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> | Cofund Actions |
| <i>Exceptional funding rates</i> | Funding rate will be 50% |

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to the 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 innovative chemicals risk assessment over the seven-year timeframe of the Partnership, 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 (R&I) platform for chemicals risk assessment, as identified in the Council Conclusions³² of June 2019 ‘Towards a Sustainable Chemicals Policy Strategy of the Union’ and in the ‘Chemicals Strategy for Sustainability’, to provide joint new knowledge and innovate risk assessment processes.
 - 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 FAIR (findable, accessible, interoperable, reusable) data on chemicals in line with the European Strategy for Data³³.
- 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 chemical 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’ and the ‘New Circular Economy Action Plan’, are supported with innovation in chemicals risk assessment.

³² <https://www.consilium.europa.eu/en/press/press-releases/2019/06/26/council-conclusions-on-chemicals/>
³³ https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

- Workers are better protected from chemical risks as set out in the ‘EU Strategic Framework on Health and Safety at Work 2014-2020’ 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 sensibly prioritise risk assessments and capture risks from existing and emerging substances across regulatory domains. The lack of available and accessible information increases the risk of ‘regrettable’ substitutions and slows down the design of safer chemicals. Lack of interaction between the different sectors carrying out risk assessment of chemicals for their specific purpose has resulted in a fragmented approach, inconsistencies and duplication of efforts. Risks to human and environmental health are still considered separately, while in reality they are inherently interrelated.

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

Activities of the Partnership shall not substitute for obligations under existing regulatory frameworks or replace routine monitoring obligations, but shall coordinate with these as relevant. The Partnership should become a reference point 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’³⁴ as well as to explore collaborations with other relevant activities at EU and international level. The Partnership shall align with EU-wide initiatives on open access and FAIR (findable, accessible, interoperable, reusable) data.

The Partnership’s governance structure shall enable an upfront steering by risk managers and risk assessors to frame the research activities and ensure the use and uptake of the results in a regulatory context. The Partnership’s governance and operational structures shall 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 shall be established, bringing together European regulatory entities and risk assessment agencies to develop a strategic research and innovation agenda for chemical risk assessment in collaboration with the scientific community. This

³⁴ https://ec.europa.eu/info/horizon-europe/european-partnerships-horizon-europe_en#synergies

process shall also facilitate access and uptake by policy-makers of new scientific knowledge that can contribute to regulatory science.

Relevant synergies shall be fostered with other initiatives at national, EU or international level and targeted communication and dissemination shall be implemented to ensure openness and transparency of this partnership towards all concerned stakeholders. The Partnership shall build on and extend the concept of National Hubs developed under the European Joint Programme on Human Biomonitoring, HBM4EU³⁵. Targeted citizen actions shall be envisaged to increase their understanding of risks related to chemical exposures and reinforce trust in risk assessment and risk management processes.

2. Carry out joint EU research and innovation activities responding to the priorities identified in common strategies supporting the current regulatory risk assessment processes and responding to emerging challenges.

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

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, will be designed and performed taking into account the Reduce-Refine-Replace (3Rs) principle and the regulatory requirements to assess their relevance. Innovative methods for toxicological hazard assessment aligned with identified needs shall be developed, including methods that can reliably screen (groups of) substances allowing to select the substances for which a full safety assessment are required. New Approach Methodologies shall be integrated within 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 shall 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 shall be supported to encourage their use in regulatory risk assessment. Integrated Approaches to Testing and Assessment (IATA), integrative exposure models and practical approaches for regulatory risk assessment of aggregated and combined exposure shall be developed and their

³⁵ www.hbm4eu.eu

uptake promoted. Causal associations between (combined) exposures to chemicals and health outcomes shall 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 GDPR related challenges, shall be developed and implemented in the Partnership for data management, harmonisation, interoperability and exchange. Building on existing data platforms³⁶ solutions to collect, store, manage and permit access to new data generated by R&I activities in the partnership shall be proposed. Access and linkage to existing data collections shall be facilitated. Innovative methods for data analysis shall be pursued, including uncertainty analysis, data mining, and machine learning.

Innovative approaches in chemical risk assessment shall 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 shall in cooperation with laboratory networks established through EU regulations identify, and when needed, enhance existing networks and develop new networks. These networks shall aim at standardising methods, making available QA/QC schemes and promote the uptake of new methods and tools through training and peer-to-peer learning. In addition, specific training shall 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 Partnerships lifetime.

Grant signatories shall be:

- National institutions in charge of chemical risk assessment and carrying out related research and innovation activities.
- Exceptionally, if the national risk assessors do not have the capacities to act as grant signatories and manage a network of linked third parties, other solutions can be envisaged but must be duly justified and the national risk assessor must be a linked third party.

³⁶ Examples of relevant EC data platforms: IPCHEM (<https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>), eChemPortal (<https://www.echemportal.org/echemportal/>)

To encourage national coordination and avoid an excess of grant signatories, these should be limited to two per country and the use of linked third parties is mandatory.

Linked third parties shall be:

- Academia and research organisations part of the national networks on research for chemical risk assessment and with established links to the risk assessing institutions.
- National risk assessors in the exceptional case they cannot be grant signatories as mentioned above.

Depending on their individual legal and operational frameworks and agreement with their partner DGs, EU Agencies involved in chemical risk assessment and/or producing knowledge on chemicals' safety may also join the Partnership, e.g. as grant signatories.

Programme owners, such as authorities or ministries in charge of chemical safety policies shall mandate the grant signatories to engage the national programmes in the Partnership. The minimum number of participants is five independent legal entities from different Member States or associated countries. In addition to the minimum conditions, other legal entities than mandated entities may participate if justified by the nature of the action.

Up to one proposal will be funded under this topic. The Commission considers that proposals requesting a contribution from the EU of EUR 200 million for a duration of seven years would allow the challenges set-out to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. 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 conditions related to this topic are provided at the end of this call and in the General Annexes.

Call - Environment and health (Single Stage - 2022)

HORIZON-HLTH-2022-ENVHLTH-04

Conditions for the Call

Indicative budget(s)³⁷

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

³⁷ 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.

| | | 2022 | (EUR million) ³⁸ | expected to be funded |
|--|-----|-------|-----------------------------|-----------------------|
| Opening: 06 Oct 2021 Deadline(s): 21 Apr 2022 | | | | |
| HORIZON-HLTH-2022-ENVHLTH-04-01 | RIA | 20.00 | Around 4.00 | 5 |
| Overall indicative budget | | 20.00 | | |

| 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-ENVHLTH-04-01: Methods for assessing health-related costs to environmental stressors

| Specific conditions | |
|---|---|
| <i>Expected EU contribution per project</i> | The EU 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 |

³⁸ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | |
|--------------------------|---|
| | 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 the 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)³⁹ 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 Analysis⁴⁰ and Health Impact Assessment (HIA)⁴¹ are methodologies, which can be useful in linking scientific knowledge with environmental-economic analysis for informing policy action in diverse sectors such as transport, energy, chemicals, occupational health etc.

The main aim of the research will be to improve the calculation of the socio-economic costs (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.

³⁹ While introducing relevant changes, it should be ensured that metrics respect the UN Convention on the Rights of Persons with Disabilities.

⁴⁰ <http://arirabl.org/untitled/>

⁴¹ 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.

The proposals should consider all of the following specific 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 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 FAIR 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 resulting from this call will be invited to share and discuss their case studies amongst themselves and with relevant stakeholders at the EU level, and necessary resources should be allocated to this task.

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 expected impact 3 of cluster 1 *'health'*: 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 too often dying prematurely. Non-communicable diseases, including mental illnesses and neurodegenerative diseases, are responsible for up to 80% of EU health care costs⁴². These costs are spent on the treatment of such diseases that are, to a large extent, preventable. Furthermore, although there is a huge potential for prevention, only around 3% of the health care budgets are currently spent on preventive measures. Infectious diseases, including antimicrobial resistant infections, remain a major threat to health in the EU and global health security. Deaths caused by antimicrobial resistance (AMR) could exceed 10 million per year worldwide according to some predictions⁴³.

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 antibiotics, 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 health research and innovation cooperation. 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 needs for global health security, including the global burden of non-communicable diseases, and to strengthen patient safety.

⁴² 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).

⁴³ 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.

This destination in the first Horizon Europe Work Programme will address major societal challenges linked to Commission priorities such as fight against cancer and other non-communicable diseases, better diagnosis and treatment of rare diseases, 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).

Opportunities for potential synergies of the research and innovation actions under this destination with other clusters should be explored through broad cross-sectoral collaboration. For example, with cluster 3 “Civil security for society” 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” 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” on health security and AMR (one-health: human/animal/plant/soil/water health).

The relevant Horizon Europe’s research activities under Destination 3 should provide relevant complementary measures to the announced “Europe’s Beating Cancer Plan”⁴⁴, 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. Furthermore, synergies and complementarities will be sought between the Destination 3 and the implementation of EU4Health Programme (2021-2027)⁴⁵. These synergies and complementarities could be achieved, notably through feedback loops mechanisms, enabling on the one hand policy needs to be prioritised in research and innovation activities and on the other hand, facilitating the implementation of available

⁴⁴ <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan>

⁴⁵ https://ec.europa.eu/health/funding/eu4health_en

research results into policy actions, 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 and 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)^{46,47,48}.
- 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^{49, 50}. In particular, the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases are contained and hepatitis, water-borne diseases and other communicable diseases are being combated⁵¹.
- 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).

⁴⁶ 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/ against the 2010 baseline);

⁴⁷ 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.

⁴⁸ 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.

⁴⁹ WHO global action plan on antimicrobial resistance, 2015.
⁵⁰ EU One Health Action Plan against AMR, 2017.

⁵¹ SDG 3 target 3.3

*Horizon Europe - Work Programme 2021-2022 Vs. 5.1 for PC, Jan '21
Health*

- 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 | 262.50 | | 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 | 262.50 | 227.00 | |

Call - Tackling diseases (2021)

HORIZON-HLTH-2021-DISEASE-04

Conditions for the Call

Indicative budget(s)⁵²

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ⁵³ | Number of projects expected to be funded |
|--|----------------|-----------------------|--|--|
| | | 2021 | | |
| Opening: 22 Apr 2021 Deadline(s): 21 Sep 2021 | | | | |
| HORIZON-HLTH-2021-DISEASE-04-01 | RIA | 50.00 | Around 6.00 | 8 |
| HORIZON-HLTH-2021-DISEASE-04-02 | RIA | 50.00 | Around 25.00 | 2 |
| HORIZON-HLTH-2021-DISEASE-04-03 | RIA | 40.00 | Around 8.00 | 5 |
| HORIZON-HLTH-2021-DISEASE-04-04 | RIA | 60.00 | Around 6.00 | 10 |
| HORIZON-HLTH-2021-DISEASE-04-05 | CSA | 0.50 | Around 0.50 | 1 |
| HORIZON-HLTH-2021-DISEASE-04-06 | CSA | 2.00 | Around 2.00 | 1 |
| HORIZON-HLTH-2021-DISEASE-04-07 | RIA | 60.00 | Around 7.00 | 9 |
| Overall indicative budget | | 262.50 | | |

General conditions relating to this call

| | |
|---------------------------------|--|
| <i>Admissibility conditions</i> | The conditions are described in General Annex A. |
|---------------------------------|--|

⁵² 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.

⁵³ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | |
|---|--|
| <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: Towards improved supportive, palliative, survivorship and end-of-life care of cancer patients

| | |
|---|--|
| Specific conditions | |
| <i>Expected EU contribution per project</i> | The EU 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:

1. Reduced health-related suffering and improved well-being and quality of life of cancer patients in need of supportive, palliative, survivorship and end-of-life care and their professional and family caregivers.
2. Cancer patients independently of their age have early and better access, higher quality and (cost-) effectiveness of supportive or palliative or end-of-life care services.

3. Reduced societal, healthcare and economic burden associated with increasing demands of palliative, supportive or end-of-life care services that is beneficial for citizens and preserves sustainability of the health care systems.
4. Health care providers and health policy makers have access to and use the improved clinical guidelines and policy with respect to pain management, psychological and/or spiritual support, survivorship, palliative or end-of-life care of cancer patients.
5. Cancer patients and their professional and family caregivers use the improved palliative and supportive care decision-making process through an information driven management of patients with the end-stage disease.

Scope: The complexity of health conditions related to cancer and late or long-term side effects as consequences of its treatments affect quality of life of cancer patients and their families and pose a significant societal and economic burden. Palliative⁵⁴, supportive⁵⁵, survivorship, and end-of-life care approaches improve quality of life of 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. 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 multimorbidities. Therefore, a need exists to strengthen the evidence base for patient-centred, effective interventions improving quality of life and outcomes of cancer patients and cancer survivors of all ages in the domains of palliative, supportive, survivorship, and end-of-life care.

Applicants should propose activities that address all of the following:

- Demonstrate the effectiveness and cost-effectiveness of newly proposed or specifically adapted pharmacological and/or non-pharmacological interventions to improve well-being and 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 cancer survivors should be considered. The legal and ethical aspects of the proposed interventions should be taken into consideration and fully addressed.
- Prove the feasibility of integrating the proposed interventions in current pain management, palliative, supportive 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 patients' as well as their professional and family caregivers' perspectives. The views and values of patients and their caregivers (including families, volunteers, nurses and others) should also be appropriately taken into account in patient-centred care decisions.

⁵⁴ <https://www.who.int/cancer/palliative/definition/en/>

⁵⁵ <https://www.mascc.org/about-mascc>

- 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 equity⁵⁶ to the proposed interventions.
- Analyse the barriers and opportunities to re-invigorating and enhancing timely social inclusion and active engagement of cancer patients in need of palliative, supportive and end-of-life care and their carers.
- Provide guidelines for patient-centred communication as well as standards for evidenced based communication trainings for caregivers.
- When relevant, provide policy recommendations for pain management, psychological and/or spiritual support, palliative, supportive or end-of-life care of cancer patients or cancer survivors afflicted by late and long-term side effects of cancer treatments.

Randomized 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 the effective contribution of sciences and humanities (SSH) disciplines and the involvement of SSH experts, 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.

The Commission will ensure an overall coordination mechanism between the projects funded under this topic to catalyse the exchange of knowledge, as well as the development and adoption of best practices. Proposals are expected to budget for the attendance to regular meetings. Projects resulting from this call will be invited to share and discuss their case studies amongst themselves and with relevant stakeholders at the EU level, and necessary resources should be allocated to this task.

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 EU 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. |

⁵⁶ https://www.who.int/topics/health_equity/en/

| | |
|-----------------------|---------------------------------|
| <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:

1. Researchers continue to use the platform as an effective and sustained approach to coordinate and manage their efforts on repurposing of medicines, making the best use of scientific knowledge and resources.
2. Patients have new and effective therapeutic options addressing unmet medical needs, both for communicable and non-communicable diseases.
3. Healthcare systems and payers have available more cost-effective treatments that reduce financial burden in the medium/long term.
4. The public sector and the pharmaceutical industry can engage in new models of sustainable collaboration, within a global dimension.
5. Policy makers adjust the EU pharmaceutical regulatory landscape towards further harmonisation and fitness for purpose.

Scope: Development of therapeutics is a lengthy process that requires a large amount of efforts 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 products⁵⁷ and repositioning of investigational products⁵⁸, beyond their original indication. This approach has already proved successful⁵⁹ in several instances, but its potential is far from having been fully exploited.

Applicants should propose activities that address all of the following:

- Set up a platform⁶⁰ 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.

⁵⁷ Medicinal products with a market authorisation in the EU.

⁵⁸ Investigational products without a market authorisation in the EU.

⁵⁹ Notable examples are thalidomide and sildenafil.

⁶⁰ 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.

- Provide robust and transparent selection mechanisms for prioritising repurposing projects, 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 AI approaches, and deliver new computational tools.
- Resolve the fragmentation and lack of ownership of the repurposing approach that greatly impedes the efficient exploitation of its potentials, networking existing projects and initiatives.
- Devise and test a model 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.
- Special attention should be given to investigator-driven projects.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices. Successful proposals will be also encouraged to exchange with other relevant proposals funded under other topics and other clusters to ensure synergies on cross-cutting challenges of common interest. Therefore, proposals are expected to include a budget to cover those joint coordination and dissemination activities without the prerequisite to define concrete joint activities at this stage. The details of these joint activities will be defined during the grant preparation phase with the Commission. In order to achieve the expected outcomes, international cooperation is advised.

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 EU 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:

1. 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.
2. 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.
3. 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.
4. 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 Africa and/or establish themselves as scientific leaders in Africa.
5. More clinicians and researchers in 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 between the EU and sub-Saharan Africa in infectious disease clinical research. 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 be employed to advance prevention, treatment or diagnosis of PRDs in this part of the world.

Proposals should address all of the following:

1. Any PRD disease or group of PRDs affecting sub-Saharan Africa (within the scope of EDCTP2⁶¹ or EDCTP3⁶²).

⁶¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0556&from=GA>

⁶² https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/edctp3_draft_proposal_14_august_2020.pdf

2. Combine medical and/or pharmaceutical technologies with other scientific areas such as mobile technologies and digital technologies (mHealth and eHealth), big data processing, and other emerging technologies.
3. Implement one or more medium-scale clinical trials and/or clinical research studies that can deliver proof-of-concept or validation of smart, highly innovative technologies or concepts to prevent, treat or diagnose PRDs in sub-Saharan Africa, drawing lessons from the COVID-19 experience.
4. Increase collaboration with (development) partners to create solutions for improved development or delivery of medical interventions for vulnerable populations in low resource settings.
5. Proposals involving pharmaceutical partners and small- or medium-sized enterprises (SMEs) are encouraged.
6. 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.
7. Include activities that promote collaboration with EDCTP projects in the area.
8. Promote the integration of research work and health care service delivery.

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

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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:

- Healthcare professionals employ safer and evidence-based clinical decision support for affordable treatment including home-based care.
- Healthcare professionals better predict patients’ (long-term) response, including side effects, to a personalised specific treatment.

- Patients and carers have access to an information communication package about the disease and the proposed treatment.
- Clinical guidelines are enhanced thanks to novel clinically validated and (cost-) effective AI solutions.

Scope: Applying trustworthy-AI⁶³ in healthcare contexts generate a multitude of benefits, including 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 clinically AI-based solutions comparing their benefit versus standard-of-care treatments in non-communicable diseases. The proposals should pay special attention to the usability, performance and safety of the developed AI solutions, 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.

Applicants should propose activities that address all the following:

1. Supporting the clinical development, testing and validation of AI-driven treatment and care options, hereby assisting in clinical decision making
2. Timely end-user inclusion (e.g. patient, caregiver and healthcare professional) along the AI clinical development lifecycle and validation process
3. Enhancing accurate prognosis for, and response to, a personalised specific 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)
4. Inclusion of sex and gender aspects, age, socio-economic, lifestyle and behavioural factors and other social determinants of health, at early stages
5. Assessing potential manual or automated biases for large uptake
6. Integration of an extensive information and communication package about the disease, highlighting their relevance for the patients and carers
7. Measuring the (cost-)effectiveness of AI-driven development of therapeutic concepts and implementation in clinical practice

Proposals shall pave the way for establishing standard operating procedures for the integration of AI in health and care (e.g. for clinical decision-making treatment and care). Proposals are encouraged to consider multidisciplinary approaches to allow for intersectoral representation,

⁶³ High Level Group on Artificial Intelligence, set up by the European Commission, Ethics Guidelines for Trustworthy AI, document made public on 8 April 2019

and have to ensure that the health data are FAIR⁶⁴ according to 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 and 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 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 EU 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 |

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 healthcare value chain dispose of enhanced knowledge of risk factors, symptoms expression, disease progression and clinical outcomes in relation 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 healthcare 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.

⁶⁴ FAIR: findable, accessible, interoperable and reusable (FAIR)

- 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 can use biomarkers⁶⁵ in the broad sense for personalised patient management.
- Clinicians and other stakeholders along the healthcare value chain have access to guidance on preventive measures and 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, comorbidities, treatments offered and other relevant characteristics. The sample should be geographically representative of 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 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 ORCHESTRA⁶⁶. Proposals should pay special attention and link to the newly established European COVID-19 data sharing platform⁶⁷ and collaborate with the existing network of H2020 COVID-19 projects⁶⁸.

⁶⁵ *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))

⁶⁶ <https://cordis.europa.eu/project/id/101016167>

⁶⁷ <https://www.covid19dataportal.org/>

⁶⁸ https://cordis.europa.eu/programme/id/H2020_SC1-PHE-CORONAVIRUS-2020

Collaboration with other relevant initiatives, such as the International Consortium for Personalised Medicine (ICPerMed)⁶⁹, the 1+ Million Genomes initiative⁷⁰ and the EBrains⁷¹ network is encouraged where relevant.

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

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU estimates that an EU contribution of around EUR 0.50 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 0.50 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:

1. Research funders, policy makers and the research community have a Strategic Research and Innovation Agenda (SRIA) to be implemented for the candidate European OH AMR partnership.
2. Research funders, policy makers 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.
3. Academics, innovators, end-users, researchers, public health authorities and citizens have a strong ecosystem to improve the implementation of the European One Health AMR strategy and to progress towards Sustainable Development Goal No. 3 ‘Ensure healthy lives and promote well-being for all at all ages’.
4. Research funders, policy makers and the research community are in a position to close the current gaps and break existing silos on AMR in accordance with in the European One Health Action Plan against AMR⁷².

⁶⁹ <https://www.icpermed.eu/>

⁷⁰ <https://ec.europa.eu/digital-single-market/en/news/roadmap-1-million-genomes-initiative-now-clearly-illustrated-new-brochure>

⁷¹ <https://ebrains.eu>

⁷² https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf

Scope: The increasing levels of AMR present a major threat to human 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. 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 diagnosis, prevention and treatment of drug resistance infections in humans.

Accordingly, the proposals should cover all of the following activities:

- Development of a Strategic Research and Innovation Agenda (SRIA) for a comprehensive approach to inform the future candidate Partnership on One Health antimicrobial resistance.
- 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 – patients, clinicians, veterinarians, pharmacists, food producers and representatives of the pharmaceutical industry, policy makers and researchers (including those working on human and social sciences).

In order to achieve the expected outcomes, international cooperation, including with low and middle income countries where AMR is highly prevalent and prone to be spread to Europe, is strongly advised. The successful CSA should build on, be complementary to and go beyond existing initiatives such as the JPIAMR⁷³[1], the One Health EJP⁷⁴ [2] and ICARS⁷⁵[3]. It should also implement collaborative activities with International organisations such as the World Health Organisation, 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.

⁷³ <https://www.jpiamr.eu/>

⁷⁴ <https://onehealthjp.eu/>

⁷⁵ <https://www.icars-global.org/>

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

The successful CSA is expected to provide input for the candidate EU partnership on OH AMR. The proposals are also expected to explore links with the following relevant Horizon Europe partnership candidates: Innovative Health Initiative; EU-Africa Global Health; Personalised medicine; Animals and Health; Safe and Sustainable Food Systems for People; Planet and Climate; Towards more sustainable farming: agro-ecology living labs and research infrastructures; Water4All – Water security for the planet.

The successful proposal will be also encouraged to interact with other relevant proposals funded under other topics and other clusters to ensure synergies on cross-cutting challenges of common interest such those from destination 2: Living & working in a health-promoting environment.

HORIZON-HLTH-2021-DISEASE-04-06: Building a European Research and Innovation Partnership for Pandemic Preparedness

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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:

1. Research funders, policy makers and the research community have established a consolidated research and innovation framework that provides the foundation of a Pandemic Preparedness Partnership, having developed the Partnership’s objectives, its governance and ways of working/operationalisation;
2. Research funders, policy makers and the research community benefit from a long-term Strategic Research and Innovation Agenda for the Partnership, developed in consultation with future partners and relevant stakeholders;

3. Healthcare providers, European and international stakeholders can 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 potential new European R&I Partnership for Pandemic Preparedness could aim to improve the EU's preparedness to predict and respond to emerging infectious health threats by better coordinating funding for R&I at EU, national (and regional) level towards jointly agreed objectives and an agreed strategic R&I agenda.

Such a partnership will contribute to building a coherent European Research Area (ERA) enabling Member States, Associated Countries and the European Commission to rapidly and jointly support R&I in pandemic preparedness. Aligned around a multi-annual agenda with common objectives for R&I actions in pandemic preparedness, the partners – in close collaboration with ECDC, EMA and other relevant actors – will define research needs in the medium and 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)⁷⁶. Collaboration with the private sector is anticipated.

The specifics of the Pandemic Preparedness Partnership 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, 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, Eco-health and One Health approach.

Proposals should foresee the establishment of a secretariat to coordinate the creation a potential Partnership for Pandemic Preparedness.

Proposals should include all of the following activities:

1. Perform the preparatory groundwork to inform an innovative, visionary and strategic research agenda for pandemic preparedness;
2. Actively engage with all partners of the foreseen Partnership to support alignment around its objectives and scope, as well as its governance and ways of working;
3. 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&I Blueprint, ACT-Accelerator, etc.
4. Implement strong communication and dissemination activities on the Partnership's purpose, foreseen activities and outputs, both outside and during epidemic/pandemic episodes.

⁷⁶ 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.

5. Establish coordination and collaboration with relevant initiatives related to pandemic preparedness such as the future HERA to ensure complementarity and avoid overlaps.
6. As relevant, apply a cross-cutting, interdisciplinary, Eco-health and One Health approach.
7. 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 CSA is expected to engage with other relevant initiatives, such as the new Partnership on Transforming Health and Care Systems, the Partnership on Animal Health and Welfare, or relevant newly selected research projects.

Call - Tackling diseases (Two Stage - 2022)

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

Conditions for the Call

Indicative budget(s)⁷⁷

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ⁷⁸ | 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 | Around 6.00 | 10 |
| HORIZON-HLTH-2022-DISEASE-06-03-two-stage | RIA | 40.00 | Around 8.00 | 5 |
| HORIZON-HLTH-2022-DISEASE-06-04-two-stage | RIA | 60.00 | Around 8.00 | 8 |

⁷⁷ 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.

⁷⁸ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | | | | |
|---------------------------|--|--------|--|--|
| 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 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-06-02-two-stage: Pre-clinical development of the next generation immunotherapies for diseases or disorders with unmet medical need

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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:

1. The scientific and clinical communities make effective use of the pre-clinical validation of next generation immunotherapies for high burden communicable and/or non-communicable diseases or disorders with unmet medical needs.
2. New knowledge of mode of action of the novel immunotherapies and/or combinatorial treatments is published and used by the scientific and clinical communities for further development.
3. New high burden disease or disorder personalized models (*in vitro* and *in vivo*) and next generation immunotherapies protocols are available to the scientific and clinical communities.
4. Health care professionals have access to and use the new evidence-based safety and efficacy guidelines for immunotherapies and/or proof-of-clinical concept as single or combinatorial treatments as compared to existing approaches.

Scope: Immunotherapy is defined as a treatment able to stimulate or restore the ability of the immune (defense) system to fight infection, disease or disorder.

Immunotherapy has proved to be a valuable medical solution notably when preventive treatments 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. The 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.

Next generation immunotherapies are needed in order to improve and diversify the health standards of care of several communicable or non-communicable diseases⁷⁹ that cannot be effectively tackled with the current available treatments.

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

1. 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 HTA strategy should be in place at the start of the proposal.

⁷⁹ **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. Therapeutic vaccines are included.

2. Off-the-shelf therapies, including the cell-based therapies, will be considered as assets during the evaluation.
3. Proposals could include proof-of-concept/first-in-human studies for testing the new therapies, with a clear regulatory and clinical path⁸⁰ and should address as appropriate the therapy-related potential adverse effects. Proposals should take sex, gender, age and socio-economic factors into account when appropriate. Phase II studies or higher phases trials will not be supported.
4. Leverage the development of standardised framework of assays and data usage for a robust assessment of the safety and efficacy.
5. 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.
6. The proposed action should include a pathway of the necessary steps to ensure sustainable therapeutic agent production and uptake by health systems and rapid access to patients.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices. Successful proposals will be also encouraged to exchange with other relevant proposals funded under other topics and other clusters to ensure synergies on cross-cutting challenges of common interest such as under cluster 5 the topic 5.2 or some EIC topics. Therefore, proposals are expected to include a budget to cover those joint coordination and dissemination activities without the prerequisite to define concrete joint activities at this stage. The details of these joint activities will be defined during the grant preparation phase with the Commission.

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 EU 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. |

⁸⁰ Template for essential information for proposals including clinical studies https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_2018-2020_en.pdf

| | |
|----------------|---------------------------------|
| Type of Action | 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:

1. The scientific and clinical communities can better use the Increased knowledge of pathogens and the role of immune system in infectious diseases to improve vaccine efficacy.
2. Vaccine manufacturers benefit from utilization of Increased number of innovative manufacturing technologies and GMP manufacturing capacity for the production of second generation of vaccines.
3. Policy makers and funders can base decisions on application of diversified portfolio of vaccine candidates that are ready for testing in clinical trials.
4. Clinical community and regulators will have Increased number of preventive interventions tested in early stages of clinical studies.
5. Whole society will benefit from improved prevention of infectious diseases.

Scope: Infectious diseases, including antimicrobial resistant (AMR) infections, remain a major threat to health in the EU and to global health security. The availability of accessible and affordable new, improved 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. First generation vaccines against some of the pathogens have proven to be suboptimal and not effective enough to reach the targets. 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 novel, effective and affordable vaccines against all major infectious diseases become a reality, it is essential to sustain a diverse and modernised vaccine development pipeline. This collaborative research and innovation action aims to diversify and accelerate the global vaccine R&D pipeline, and to strengthen the current leading role of EU in technological development and vaccine research & innovation. The action is intended to cover those pathogens, which lack sufficiently efficacious vaccines, but where earlier efforts have already produced 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 and back-translation steps) to allow exploitation and integration of novel findings between clinical, preclinical and discovery. Integrative analysis of data.
- 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 should 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 EU 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 |

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 employ robust preclinical models, methods, technologies, validated biomarkers, reliable patient reported outcomes and/or innovative clinical trials designs to increase the development success rate of therapies for rare diseases.
- Developers and regulators have access to an increased number of interventions successfully tested in late stages of clinical development and move faster towards market approval of new therapies for rare diseases with no approved option.

- Healthcare professionals and people living with a rare disease have access as early as possible 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 evaluation⁸¹ 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 R&D development in areas of greatest unmet medical need. Therefore there is an urgent need for EU support for the development of novel therapies for rare diseases, where there is no approved therapeutic option available.

The topic will support proposals aiming to develop therapies for rare diseases with no approved therapeutic option. The 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 landscape⁸². This topic is not meant to address a single disease (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 existing therapies, including non-pharmacological interventions and/or their combinations, as relevant. Sex and gender aspects should be considered, wherever 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 is strongly encouraged. Rare infectious diseases and rare cancers will not be considered in this call.

The topic will support proposals covering several different stages in the continuum of the innovation path (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.

⁸¹ https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/orphan-regulation_eval_swd_2020-163_part-3.pdf

⁸² Medical areas such: 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 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 proof-of-concept (PoC) preclinical studies and/or multinational interventional clinical studies⁸³ to demonstrate the safety and efficacy of the therapeutic interventions under study. Preclinical PoC should implement 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.

The 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 advice⁸⁴ or protocol assistance from EMA. In particular, the 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.

The proposals should adhere to the FAIR⁸⁵ data principles and take stock, wherever relevant, of the data standards, harmonisation guidelines and data sharing/access good practices developed by existing European health research infrastructures (i.e. ESFRI infrastructures etc.). The proposals should take stock, whenever relevant, of the FAIR guidance, of good practices for analytical methods and preclinical models and of good exploitation strategies for the translation of the research results into high impact interventions, developed by the European Joint Programme on Rare Diseases⁸⁶ (EJP RD) and other relevant EU-funded consortia. Proposals utilising data from registries may adopt whenever relevant, the European standards, such as the "set of common data elements"⁸⁷ developed by the European Platform on Rare Disease Registration. In addition, synergies should be sought with the European Reference Networks, whenever relevant.

⁸³ [Template for essential information for proposals including clinical studies](#)

⁸⁴ <https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance>

⁸⁵ FAIR: findable, accessible, interoperable and reusable

⁸⁶ <https://www.ejprarediseases.org/>

⁸⁷ https://eu-rd-platform.jrc.ec.europa.eu/set-of-common-data-elements_en

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 where relevant may take stock of the IRDiRC Orphan Drug Development Guidebook⁸⁸.

Call - Tackling diseases (Single Stage - 2022)

HORIZON-HLTH-2022-DISEASE-07

Conditions for the Call

Indicative budget(s)⁸⁹

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ⁹⁰ | Number of projects expected to be funded |
|--|----------------|-----------------------|--|--|
| | | 2022 | | |
| Opening: 06 Oct 2021 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 | N/A | Not relevant |
| HORIZON-HLTH-2022-DISEASE-07-03 | RIA | 25.00 | 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. |

⁸⁸ <https://irdirc.org/orphan-drug-development-guidebook-materials/>

⁸⁹ 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.

⁹⁰ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | |
|---|---|
| <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 - Placeholder

| | |
|---|---|
| Specific conditions | |
| <i>Expected EU contribution per project</i> | The EU estimates that an EU contribution of around EUR N/A 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 |

HORIZON-HLTH-2022-DISEASE-07-03: Non-communicable diseases risk reduction in adolescence and youth

| | |
|---|--|
| Specific conditions | |
| <i>Expected EU contribution per project</i> | The EU 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 25.00 million. |
| <i>Type of Action</i> | Research and Innovation Actions |

Expected Outcome: The GACD funding agencies aim to harmonise the research and 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 the current call, use of the following measures are encouraged:

- Evidence of uptake of promoted healthy behaviours;
- Evidence of reduction in harmful behaviours;
- Proxy mental and/or physical health outcomes, if appropriate (pre- and post-intervention PHQ-9 scores, blood pressure, HbA1C, etc.)

All teams 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).

All projects should be gender-responsive and consider socioeconomic, racial or other factors that relate to equitable impacts of the intervention or barriers to equitable implementation.

Scope: We propose a Global Alliance for Chronic Diseases (GACD) funding call focused on implementation research on 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. Adolescents 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 structural,* 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 noncommunicable 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; *Not all funding agencies will support projects that focus on structural-level interventions. 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 (8). Projects will require 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.

The intended beneficiaries of the project can be powerful assets to the projects. 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: GloPID R secretariat - Placeholder

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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:

Call - Partnerships in Health (2022)

HORIZON-HLTH-2022-DISEASE-03

Conditions for the Call

Indicative budget(s)⁹¹

⁹¹ 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.

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ⁹² | Number of projects expected to be funded |
|--|----------------|-----------------------|--|--|
| | | 2022 | | |
| Opening: 06 Oct 2021 Deadline(s): 21 Apr 2022 | | | | |
| HORIZON-HLTH-2022-DISEASE-03-01 | COFUND | 30.00 | 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 Agreements</i> | The rules are described in General Annex G. |

Proposals are invited against the following topic(s):

HORIZON-HLTH-2022-DISEASE-03-01: European Partnership Fostering an ERA for Health research - Placeholder

| Specific conditions | |
|----------------------------|--|
| <i>Expected EU</i> | The EU estimates that an EU contribution of around EUR 30.00 million |

⁹² Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | |
|---------------------------------|--|
| <i>contribution per project</i> | 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> | Cofund Actions |

Expected Outcome:

DRAFT

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 area '*A resilient EU prepared for emerging threats*' and in particular to the expected impact 4 of cluster 1 '*health*': 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 evidence-based health policies. 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*', '*High quality digital services for all*' and '*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 sustainable and resilient, in order to cope with epidemics/pandemics, to address environmental crises like climate change and to contribute to social cohesion. Therefore, the consolidation 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 approaches and developing more resilient, flexible and dynamic health systems that are prepared to deal with future crises, while ensuring equitable access to high-quality health care.

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. Planned activities will support the development of innovative, feasible, implementable, financially sound scalable solutions in the various dimensions of health and care systems (e.g. governance, financing, human and physical resources, health service provision, and patient empowerment). Ultimately, these activities will provide decision-makers with new evidence, methods, tools and technologies for uptake into their health and care systems. Consequently improving governance of the European health and care systems, supporting healthcare professionals and providers and allocating resources according to citizens' health needs and preferences, while ensuring fiscal sustainability to assure those needs can be met on the long-term.

The topics for this destination in this WP 2021-22 will focus on the following issues:

- Modernisation of health care systems, especially through the foreseen partnership on Transforming Health and Care Systems;

- Innovative solutions improving the quality of health and care along the entire health care continuum and being people-centred;
- New tools and methods to take better informed health care decisions both for health care providers and policy-makers and to enable improved foresight and planning of health care resources;
- Pilots in the form of procurement actions for uptake of innovative health solutions, including environmentally sustainable ones that contribute to addressing the climate change.

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, with health promotion and disease prevention 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 and 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 and care activities.
- Citizens are supported to play a key role in managing their own health and 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 and 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

*Horizon Europe - Work Programme 2021-2022 Vs. 5.1 for PC, Jan '21
Health*

contribute to its goal(s) of [add most relevant 1-2 objective(s) of the EU4Health programme]***.

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 |
| Overall indicative budget | 70.00 | 170.00 | |

Call - Ensuring access to innovative, sustainable and high-quality health care (2021)

HORIZON-HLTH-2021-CARE-05

Conditions for the Call

Indicative budget(s)⁹³

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ⁹⁴ | Number of projects expected to be funded |
|--|----------------|-----------------------|--|--|
| | | 2021 | | |
| Opening: 22 Apr 2021 Deadline(s): 21 Sep 2021 | | | | |
| HORIZON-HLTH-2021-CARE-05-01 | RIA | 25.00 | Around 5.00 | 5 |
| HORIZON-HLTH-2021-CARE-05-02 | RIA | 40.00 | 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. |
| <i>Award criteria</i> | The criteria are described in General Annex D. |

⁹³ 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.

⁹⁴ 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-2021-CARE-05-01: Enhancing quality of care and patient safety

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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 understand how to 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 accept and adhere to recommendations for improved patient safety.

Scope: Patient safety remains an issue of increasing concern for EU health systems. The Commission estimates (COM (2008) 836) that between 8% and 12% of patients admitted to hospitals in the EU suffer from adverse effects of health care.

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 preventable (Schwendimann et al., 2018). According to the OECD (Health Working Papers No. 106, 2018), more than 7 million admissions in the OECD countries result from safety lapses in primary and ambulatory care. Diagnostic errors persist throughout all settings of care and contribute to increased risks and harms from the treatment (Erin P. Balogh et al., 2015). 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 3 (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. The issue 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.
- To 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 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.

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.

The Commission will ensure an overall coordination mechanism between the projects funded under this topic to catalyse the exchange of knowledge, as well as the development and adoption of best practices. Proposals are expected to budget for the attendance to regular meetings. Projects resulting from this call will be invited to share and discuss their case studies amongst themselves and with relevant stakeholders at the EU level, and necessary resources should be allocated to this task.

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

| Specific conditions | |
|---|---|
| <i>Expected EU contribution per project</i> | The EU 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, tailored towards and contributing to some of the following expected outcomes:

- Healthcare 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 and care decision-making processes;
- Healthcare providers, caregivers (formal and informal), citizens, and other relevant stakeholders take better informed decisions;
- Health system owners and other relevant stakeholders conduct evidence-based participative decision-making processes, taking into consideration diverse values, needs and perspectives;
- Policymakers get access to evidence-based decision support tools for public health policy-making and health and care delivery.

Scope: This call topic will contribute to Europe's Beating Cancer Plan⁹⁵. For this reason, proposals must focus on one or more 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 and 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, evaluating decisions and feedback into decision-making processes and policy strategies.

In this topic, research and innovation actions should aim at optimising and/or transforming health and 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 policy makers), and represent both a support-base and scientific evidence for data-driven innovation. Design thinking and other relevant design methodologies should be considered.

The proposals should adhere to the FAIR 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, anthropology) to ensure more equitable, innovative and sustainable health and care systems.

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

⁹⁵ <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan>

- 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 policy-makers make data-driven decisions. These can be foreseen to be used solely for health and 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, models) helping healthcare 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, among others), and availability of and access to health and 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 and care systems, including feedback mechanisms, guidance on health and care pathways and on managing healthcare data, supporting patients in making healthcare decisions and treatment adherence;
- The development of digital toolkits and indicators to improve the reporting and assessment of outputs from end-user involvements including of patient-reported outcomes measures (PROMs) and patient-reported experience measures (PREMs), and help gauge the actual impact in health and care (including interaction between patients and health care providers).

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 budgetary impact of health and care interventions (i.e. innovative solutions, digital services and health and 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 and care delivery and policy-making.

Projects involving earth observation, positioning, or navigation data, services or technologies should make use of Copernicus and/or Galileo/EGNOS data, services and technologies.

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

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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 5.00 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 4 “*Ensuring access to innovative, sustainable and high-quality health care*”. 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. 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/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 healthcare structures caused by the covid-19 pandemic.
- Procurers and decision makers in procurement organisations mainstream health and care-related Innovation Procurement best practices in their respective policy and investment strategies.
- Health and 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.

- Stakeholders involved in the demand side of health/care innovations (i.e. procurement agencies, healthcare providers, payers/health insurers, public authorities, healthcare professionals, citizens, etc.) reach a common understanding that reflects their key clinical, procurement/supply, organisational and coordination priorities.

Scope: This call aims to support the creation of a network of public⁹⁶ and private procurers that are responsible for deploying health and care innovations across the EU, in order to identify potential areas of interest for innovation procurement and support the European Commission in building needs-driven investment opportunities.

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 and experience sharing, the network should offer the opportunity to less experienced procurers in health innovation to build up capacity on innovation procurement.

Another aim of this initiative is to help procurers coordinate Innovation Procurement initiatives in the area of health/care across Europe and build the capacity of its members, by disseminating innovation procurement instruments, exchanging best practices, preparing areas for future collaborative actions on innovation procurement and addressing potential regulatory hurdles within specific contexts.

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 or the contribution of digital solutions to the safety of patients, health professionals and citizens. The ongoing pandemic has demonstrated that new critical challenges for health and 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/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 and 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);

⁹⁶ 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.

- facilitate and coordinate the procurement of R&D (including pre-commercial procurement) and the procurement of innovative solutions addressing existing public needs in the health / care sector by involving all relevant stakeholders in each stage of procurement implementation;
- set the ground for mainstreaming (cross-border) Innovation Procurement implementation in Europe's health sector (EU-funded or not), while engaging, in an appropriate way, other stakeholders who are important for Innovation Procurement activities in the health/care area, such as patients, healthcare providers, industry (including SMEs/start-ups), policy makers (local, regional and/or national authorities) or investors (e.g. private investors, National Promotional Banks and Economic Development Agencies etc.).

The proposals should be composed primarily by participants that are public or private procurers, interested in the purchase of health and care innovations. In addition, participants can also include health authorities or innovation procurement competence centres, which support these health and care procurers in implementing innovation procurements⁹⁷.

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 & 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 cooperation models for implementing Pre-Commercial Procurement and Public Procurement of Innovative solutions, which overcome potential differences among the legal public procurement frameworks of the participating procurers in health and social care;
- conduct a market analysis and propose solutions to overcome potential barriers (standardisation, certification, regulatory requirements, intellectual property rights, contracting models, payment/reimbursement models);

⁹⁷ 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.

- consult with relevant stakeholders, end-users (consumer organisations, reimbursement bodies) to prepare for a future market uptake of the solutions;
- 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.

The proposals should provide appropriate indicators to measure progress towards successful implementation of the action's activities, including Dissemination & Exploitation.

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)⁹⁸

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ⁹⁹ | 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

⁹⁸ 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.

⁹⁹ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | |
|---|--|
| <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-08-02: Innovation procurement (PCP) for building the resilience of health and care systems in the context of recovery

| | |
|---|--|
| Specific conditions | |
| <i>Expected EU contribution per project</i> | The EU 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 |

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*”, by mitigating the economic and social impact of the coronavirus pandemic and similar future health emergencies and by making the EU health sector more sustainable, competitive, resilient and better prepared. A means for achieving this is through strengthened dialogue between procurers (demand side) and EU industry (supply side) so that R&D leads to innovative solutions tailored to the needs of the former. This is expected to reinforce EU’s strategic autonomy and strengthen the security of the supply chain in the health care sector. Furthermore, the engagement of demand- and supply-side stakeholders and communities contributes to a holistic approach in decision-making, when

deploying innovation to the benefit of patient, citizens and 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:

- Public and private procurers in the area of health/care procure the competitive development of market-ready, sustainable, innovative solutions (materials, technologies and systems / practices) which are made in Europe and can improve the preparedness and resilience of health and care systems in the context of the recovery;
- European health & technology industry actors (incl. start-ups/SMEs) bring to the market secure, interoperable digital health and 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 and 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 and care systems.

Scope: Pre-commercial procurement (PCP) can boost innovation in health and 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 healthcare 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 and 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 and care gather relevant public and private procurers to address a common, unmet need through the cross-border public and private procurement of R&D for demand-driven innovative solutions. Specific guidance on

PCP actions and minimum eligibility requirements can be found in General Annex I¹⁰⁰ 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 R&D 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 and 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.

A wide variety of settings are potentially relevant for the implementation of such innovative solutions, such as: primary healthcare settings, hospitals, specialised centres, and long-term health and 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 foresee the transfer and adaptation of solutions and/or interventions from other sectors to health and 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.

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 Instrument¹⁰¹ and the European Structural and Investment Fund are encouraged.

The proposals should provide appropriate indicators to measure progress towards successful implementation of the action's activities, including Dissemination & Exploitation.

¹⁰⁰ Link not yet available

¹⁰¹ 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.

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

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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 |

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*”, by mitigating the economic and social impact of the coronavirus pandemic and similar future health emergencies and by making the EU health sector more sustainable, competitive, resilient and better prepared. A strengthened dialogue between procurers (demand side) and EU industry (supply side) can lead to the uptake and deployment of innovative solutions tailored to the needs of the former. This is expected to reinforce EU’s strategic autonomy and strengthen the security of the supply chain in the health care sector. Furthermore, the engagement of demand- and supply-side stakeholders and communities contributes to a holistic approach in decision-making, when deploying innovation to the benefit of patient, citizens and 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 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 and care systems;
- European health & technology industry actors (incl. start-ups/SMEs) bring to the market secure, interoperable digital health and 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 and 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 and care systems.

Scope: Public procurement of innovative solutions (PPIs) can boost the wider market uptake of high impact innovations in health and 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 and 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 and 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 and 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 I¹⁰² of 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 and 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 policy makers to reinforce the national policy frameworks and mobilise substantial additional national budgets for the PPIs, searching support and collaborating with respective coordination and networking projects. Likewise, awareness raising, technical assistance and/or capacity building beyond the project

¹⁰² Link is not yet available

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 healthcare settings, hospitals, specialised centres, and long-term health and 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 and 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 Instrument¹⁰³ and the European Structural and Investment Fund are encouraged.

The proposals should provide appropriate indicators to measure progress towards successful implementation of the action's activities, including Dissemination & Exploitation.

HORIZON-HLTH-2022-CARE-08-04: Better economic foresight, financial planning and procurement/contractual strategies for health systems

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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 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 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, with health promotion and disease prevention 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.

¹⁰³ 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.

- 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 and 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 policy-makers 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 policy-makers make use of cost-effective spending strategies based on the optimisation of benefits packages, in the appropriate care service model, while maintaining or improving health outcomes in an equitable way;
- Decision- and policy-makers have access to tools enabling them to better remunerate, contract and incentivise health and care professionals and providers;
- Decision- and policy-makers are enabled to take evidence-based and socially equitable health and care financial decisions

Scope: In 2017, spending on healthcare in the European Union 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.¹⁰⁴

Due to demographic changes in the EU with a population projected to continue ageing and higher expectations regarding provision of health and care services, public health threats with relevant repercussions for society and the introduction of innovative and digital solutions to improve healthcare systems' functioning, the demand for health- and care services as well as the budgetary pressures on healthcare 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 and care services in the EU by addressing one or more of the following:

- **Economic modelling and foresight of health system performance and sustainability** – development of effectiveness, access, resilience and sustainability indicators in order to benchmark EU health systems versus each other and the EU average; foresight at regional, national, European and global level; application of economic modelling and assessment of different indicators; evidence that inform where to invest and when.

¹⁰⁴ Health at a Glance: Europe 2018 - STATE OF HEALTH IN THE EU CYCLE

- **Financing of healthcare systems** – development of new models for financing and reimbursement, including incentive mechanisms and outcome-based financing in order to promote good performance of the healthcare systems.
- **Financing of preventive healthcare** – 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 in order to ensure that the funding of preventive care is not displaced due to its long-run timescales; also the assessment of personal health risk behaviour and its potential impact on health costs.
- **Cost-effective healthcare delivery with focus on optimisation of benefits packages** – efficient spending and cost-optimized delivery of high quality services, balanced projected benefits packages ensuring that patients have access to the highest value for money and where the performance evaluation is appropriately contextualised.
- **New or improved cost-effective and transparent procurement methods** – development of new, or improved, procurement models that contribute to an increased understanding of, and potentially solution to, challenges faced by health system procurers, such as price variation between health systems or actors that can not be explained by differences in quality, competition aspects regarding more centralised purchasing, ways of assessing and mitigating unintended consequences of the suggested practices and contributing to stimulate the implementation of regulatory instruments that favour accountability.
- **Innovative purchasing and contract methods** – new strategies for contracting provision of healthcare 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 remuneration or non-financial incentives for healthcare professionals** – fostering of better healthcare planning, optimized use of health and care services, avoiding overconsumption and waste, minimising differentiation between services and minimising cream skinning of patients. It can also comprise better ways of monitoring and developing comparative effectiveness frameworks for assessing cost-effectiveness of models, or development of case studies on what does and does not work, including implementation of positive results.

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 healthcare systems, by taking into account relevant factors (for example cross-border emergency procurement coordination, quality of supplies, access to and diversification of supply chains for medical products and solutions).

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.

Call - Partnerships in Health (2022)

HORIZON-HLTH-2022-CARE-10

Conditions for the Call

Indicative budget(s)¹⁰⁵

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ¹⁰⁶ | Number of projects expected to be funded |
|--|----------------|-----------------------|---|--|
| | | 2022 | | |
| Opening: 06 Oct 2021 Deadline(s): 21 Apr 2022 | | | | |
| HORIZON-HLTH-2022-CARE-10-01 | COFUND | 100.00 | 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. |

¹⁰⁵ 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.

¹⁰⁶ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | |
|---|---|
| <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 EU 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> | Cofund 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*”.

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 have impact in areas relevant to the following EC objectives:

- 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)

The partnership should lay the ground for the transformation of health and care systems in Europe that will make them more sustainable, resilient, innovative and efficient in providing citizens with equal access to the highest quality services for prevention, diagnosis, treatment and people-centred care overall. This should be accomplished based on evidence provided by research and innovation activities, as well as by building of ecosystems and multi-actor value chains. Thus, the partnership should provide better knowledge and best practices to guide all relevant stakeholders.

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;
- Researchers, policymakers and other stakeholders use widely disseminated research results based on Open Science principles;
- Health and care authorities, policymakers and other stakeholders develop evidence-based strategies and policies on transforming health and care systems and learn from good practices of European countries and regions;
- Health and care providers and professionals know how to implement innovative ways of delivering care and maintaining population health;
- Health and care authorities, policymakers and other stakeholders know how to plan and carry out efficient investments in health and care systems at national/regional level;
- Critical mass of innovators and stronger local/regional ecosystems of stakeholders are in place and know how to facilitate uptake of successful innovations;
- Citizens and health and care professionals have increased digital and health literacy;
- Countries know and understand how to better cooperate 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 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. 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.

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 Health and Care Systems Transformation¹⁰⁷ 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 development of SRIA;
- Joint annual calls for R&I activities, applied R&I, pilots, twinning projects;

¹⁰⁷ More information on the planned European Partnerships is available on the Horizon Europe Webpage: [\[https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme/european-partnerships-horizon-europe_en#partnership-candidates-and-contact-details/xxx\]](https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme/european-partnerships-horizon-europe_en#partnership-candidates-and-contact-details/xxx).

- 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 and 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 such countries wanting to join. It will 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;
- 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 engage 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 shall 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.

The minimum number of participants is five independent legal entities from different Member States or Associated Countries. In addition to the minimum conditions, other legal entities may participate if justified by the nature of the action.

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 must collaborate closely and establish synergies with ongoing EU and nationally funded R&I actions, the potential future Cancer mission and the following potential European Partnerships:

- The European Partnership for Innovative Health Initiative;
- The Pandemic Preparedness Partnership;
- The European Partnership for Personalised Medicine;
- The European Partnership on Rare Diseases.

The above list is not exhaustive and synergies with other European partnerships must be considered. On top of this, the proposal should consider and include synergies with EU programmes, including but not limited to EU4Health, DEP, ESF+, ERDF, InvestEU, RRF and TSI.

The Partnership shall align with EU-wide initiatives on access and sharing of data.

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. Proposers are expected to describe in their proposal the methodology for their collaboration and the aims they want to achieve with this kind of collaboration.

The proposal should include a roadmap describing the key priorities for the entire duration of the partnership, the governance structures and processes, as well as the first annual work plan.

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 objectives. Therefore, the 60 000 EUR threshold provided for in Article 204 (a) of the Financial Regulation No 2018/1046 does not apply.

Up to one proposal will be funded under this topic.

Indicative budget: the total indicative budget for the topic is EUR 100 million committed in annual instalments over the seven years, 2021-2027. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts. 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.***

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

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 and enabling 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 expected impact 5 of cluster 1 *'health'*: 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: *'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 and care sector. It can provide better and more cost-efficient solutions with high societal impact, tailored to the specific health and 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 and 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. Opportunities for potential synergies of the research and innovation actions under this destination with other clusters such as Cluster 4 (Digital, Industry and Space) and other Pillars such as Pillar III (EIC and EIT) will be explored through broad cross-sectoral collaboration.

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 and 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).¹⁰⁸
- The EU gains high visibility and establishes leadership in terms of 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 and care.
- Researchers, innovators and health care providers use 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 and 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 |
| HORIZON-HLTH-2022-TOOL-11 | | 95.00 | 21 Apr 2022 |
| HORIZON-HLTH-2022-TOOL-12 | | 60.00 | 21 Apr 2022 |
| 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)¹⁰⁹

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ¹¹⁰ | Number of projects expected to be funded |
|--|----------------|-----------------------|---|--|
| | | 2021 | | |
| Opening: 22 Apr 2021 Deadline(s): 21 Sep 2021 | | | | |
| HORIZON-HLTH-2021-TOOL-06-01 | IA | 25.00 | Around 6.00 | 4 |
| HORIZON-HLTH-2021-TOOL-06-02 | RIA | 60.00 | Around 6.00 | 10 |
| HORIZON-HLTH-2021-TOOL-06-03 | RIA | 30.00 | 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. |
| <i>Award criteria</i> | The criteria are described in General Annex D. |

¹⁰⁹ 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.

¹¹⁰ 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-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 EU 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 can provide sustainable and affordable smart active implants validated in the operational environment.
- Medical professionals in resource-constrained clinical settings have at their disposal sustainable and affordable surgical procedures for smart active implants.
- Sustainable smart medical devices suitable for minimally-invasive implantation are available to patients 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 shall at the start of the proposed work be at a TRL of minimum 4 and will necessitate appropriate tailored surgical procedures and interventions. Surgical conditions account for app. 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 intervention 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, R&I activities should comprise medical device design, regulatory work, clinical stages and developmental iterations, reaching a TRL of at least 7, and involve key medical specialists (e.g. surgeons) and/or other healthcare professionals, developers, patients and relevant regulatory bodies as appropriate. The work proposed shall take into account the new EU legal framework on medical devices with the targeted implants meeting all the essential requirements as defined in the new EU legal framework on medical devices.

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

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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 have at their disposal 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 burden¹¹¹ that tackle the following bottlenecks currently encountered in the field, ensuring that promising advanced therapies can reach the market within the next decade. Applicants should justify the disorder chosen to be targeted with the level its prevalence, the related burden and unmet needs. Applicants should propose activities in one or several of the following areas, taking into consideration the Oviedo Convention, eligible actions and ethical principles as defined by the regulation:

- Method development for the production and differentiation of pluripotent stem cells¹¹² (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, talens, zinc-finger nucleases, CRISPR). 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.

¹¹¹ As defined by www.who.int/medicines/areas/priority_medicines/en/

¹¹² 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 electronic health records and/or patient registries)**

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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, interoperability and re-use of health data by health professionals, researchers and health authorities, data analytics and metadata from different repositories across countries, in compliance with FAIR data management principles, in compliance with national and EU legal (in particular personal data protection) and ethical requirements.
- 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.
- Better data portability due to the standardization of meta knowledge (meta data, ontologies and reference repositories) and clinical data, especially data coming from different clinical services / sites and/or from multiple countries and consequently better data use by patients, researchers and clinicians.
- More efficient and cost-effective healthcare procedures and workflows that contribute to improved disease prevention, early detection, diagnosis and treatment by healthcare professionals.

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, quality of data and various representations of unstructured data in healthcare 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 and 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 format¹¹³.
- 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 EHR 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. Proposers should focus on health data coming from a number of EU Member States and EEA countries, constituting as representative a sample of the European healthcare landscape as possible, 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

¹¹³ <https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format>

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, 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)¹¹⁴

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ¹¹⁵ | 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 | Around 10.00 | 6 |
| HORIZON-HLTH-2022-TOOL-11-02 | RIA | 35.00 | 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. |

¹¹⁴ 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.

¹¹⁵ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | |
|---|---|
| <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 EU 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 are enabled to move towards market approval for companion diagnostics.
- Regulatory authorities can approve companion diagnostics and make recommendations for the prescription of existing drugs.
- Health care providers make use of biomarkers to treat with existing pharmaceuticals 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 EU 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 |

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 HTA bodies adopt optimised data-driven methodologies for the effective use of real-world data (including omics data)¹¹⁶, and/or synthetic data derived from digital twins and advanced computational methods (such as modelling &

¹¹⁶ 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 (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)

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) have at their disposal 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), synthetic data by the pharmaceutical industry and medical devices industry, regulators and health technology assessment (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’” and its associated DARWIN (Data Analysis and Real World Interrogation Network) project.

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, synthetic data can inform regulatory decision-making throughout the product lifecycle, and namely: 1) support product development (e.g. scientific advice, PRIME), 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:

- Develop a set of evidentiary standards to be pre-specified and used in the analysis of real-word 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 to 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 healthcare digital innovation products and services. Proposals should involve national competent authorities (national healthcare 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 the 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. Additionally, the EMA will review all successful proposals and may join the projects in which their expertise would be best suited to, based upon relevant policy priorities.

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

HORIZON-HLTH-2022-TOOL-12

Conditions for the Call

Indicative budget(s)¹¹⁷

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ¹¹⁸ | Number of projects expected to be funded |
|--|----------------|-----------------------|---|--|
| | | 2022 | | |
| Opening: 06 Oct 2021 Deadline(s): 21 Apr 2022 | | | | |
| HORIZON-HLTH-2022-TOOL-12-01-two-stage | RIA | 60.00 | 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. |
| <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. |

¹¹⁷ 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.

¹¹⁸ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

| | |
|---|--|
| <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 EU 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 most of the following expected outcomes:

- Clinical researchers have access to effective health data integration solutions for the classification of the clinical phenotypes.
- Researchers and/or health care professionals have at their disposal 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 research and care 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 data 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 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.

The Commission will ensure an overall coordination mechanism between the projects funded under this topic to catalyse the exchange of knowledge, as well as the development and adoption of best practices. Proposals are expected to budget for the attendance to regular

meetings. Projects resulting from this call will be invited to share and discuss their case studies amongst themselves and with relevant stakeholders at the EU level, and necessary resources should be allocated to this task. In addition, the proposals will be encouraged to exchange with other successful proposals developing AI algorithms and in-silico models under other relevant topics.

DRAFT

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 and enabling 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 '*Competitive and secure data-economy*' and in particular to the expected impact 6 of cluster 1 '*health*': 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 and 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

The portfolio of actions within this destination may find synergies with Cluster 4 “Digital, Industry and Space” and with Pillar III, “Open Innovation”, in particular the scheme of the European Innovation Council that supports breakthrough and risky innovations.

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 benefit 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.

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)¹¹⁹

| Topics | Type of Action | Budgets (EUR million) | Expected EU contribution per project (EUR million) ¹²⁰ | Number of projects expected to be funded |
|--|----------------|-----------------------|---|--|
| | | 2021 | | |
| Opening: 22 Apr 2021 Deadline(s): 21 Sep 2021 | | | | |
| HORIZON-HLTH-2021-IND-07-01 | RIA | 40.00 | 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 D. |

¹¹⁹ 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.

¹²⁰ 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-2021-IND-07-01: Green pharmaceuticals

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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 6 “*Maintaining an innovative, sustainable and globally competitive health industry*”. More specifically, this topic aims at supporting activities that are contributing to the following impact area “*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.*” To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to the following expected outcome: Pharmaceutical industries will have a better understanding of the environmental impact of pharmaceuticals. They will support the development of greener by design that are intrinsically less harmful for the environment, and use greener and economically more sustainable manufacturing processes for active pharmaceutical ingredients and medicinal products.

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 environment (COM(2019) 128 final; Section 5.2) and the Pharmaceutical strategy for Europe (COM(2020) 761) called for diversifying and secure

supply chains and environmentally sustainable pharmaceuticals¹²¹. 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 as regards 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 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 reason for pharmaceutical manufacturing leaving 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 address the risk of impurities.

Applicants should propose activities at least 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;
- Explore innovative uses of digital transformation or robotic for competitive and scalable methods of production;

Results of the projects must be widely disseminated via open publication. The project should favour 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 at the same time integrate the academic and public health perspective

¹²¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0761&from=EN>

HORIZON-HLTH-2021-IND-07-02: Development procurement and responsible management of new antimicrobials

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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*”. More specifically, this topic aims at supporting activities that are contributing to the following impact areas: “*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*” and “*Good health and high-quality accessible 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:

- Health care providers use new antimicrobials or their alternatives to improve treatments for patients.
- Patients benefit from optimised treatments and the responsible use of new antimicrobials will lower the threat of antimicrobial resistance.
- The pharmaceutical industry profit from catalysing market-based reforms through a pull incentive for antimicrobial development.
- Health care systems reduce the number of patients with resistant infections, that cannot be treated with the currently available antimicrobials but that can benefit from new antimicrobials.

Scope: The aim is to establish an innovation partnership as a pull incentive for new antimicrobials where there is an unmet medical need and a market failure. This would allow for the combination of development of new antimicrobials and procurement elements tailored to public health needs. It would catalyse the integration of science, technology and development with public health needs in new medicines.

The Innovation partnership process takes place in three phases:

- In the **competitive phase** at the very beginning of the procedure, the most suitable partner(s) are selected on the basis of their capacity. The contracts establishing the innovation partnership are awarded using the criteria of the best price-quality ratio proposed.
- In the **research and development phase**, the partner(s) will develop the new solution in collaboration with the contracting authority. This phase can be divided into several stages during which the number of partners may be gradually reduced, depending on whether they meet predetermined criteria.
- In the commercial phase, the partner(s) provide the final results.

Proposals of this topic should follow the specific requirements for the Innovation partnership.

Procurers of the antimicrobials to be developed together with the Commission are forming the contracting authority that sets out the requirements and conditions for the product(s) to be developed through this partnership. This will be guided by public health needs and should be based on priority pathogens such as those identified by WHO¹²². These requirements and conditions will form the basis of this call topic. The call will invite developers to partner with contracting authority to develop antimicrobials that meet the requirements.

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.
- Market failures and the challenges of availability and accessibility of therapeutics.
- Development and purchase of new antimicrobials.
- Requirements of the innovation partnership process.

“Sex and gender, as well as other categories, like disability, ethnicity, and age should be considered, where relevant”

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 EU 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. |

¹²² 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*”. More specifically, this topic aims at supporting activities that are contributing to the following impact area: “*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:

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 and 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)¹²³. CEN¹²⁴, 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.

¹²³ <https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth>

¹²⁴ <http://www.ehealth-standards.eu/quality-reliability-for-health-and-wellness-apps/> due to be completed in 2020

Applicants should propose activities that bring together app developers, health and care system representatives, a diverse range of users (citizens/patients, health and care providers), , and certification bodies in order to promote and stimulate the use and up-take of the health app 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 and care system.

The proposals are expected to address all of the followings:

- Set up a structured dialogue on the uptake of the Technical Specifications between app developers, health and care system representatives, app stores, medical societies, patient organisations, users (incl. health and 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 and 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 and care settings, covering the entire European Union.
- 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 involved actors.
- Interests of different age groups, sex and gender, as well as other categories like persons with disability, ethnicity and 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)¹²⁵

| Topics | Type | Budgets | Expected EU | Number |
|--------|------|---------|-------------|--------|
|--------|------|---------|-------------|--------|

¹²⁵ 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 Vs. 5.1 for PC, Jan '21
Health**

| | of Action | (EUR million) | contribution per project (EUR million) ¹²⁶ | 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 | Around 6.00 | 3 |
| HORIZON-HLTH-2022-IND-13-02 | RIA | 30.00 | Around 7.00 | 4 |
| HORIZON-HLTH-2022-IND-13-03 | RIA | 15.00 | 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. |

Proposals are invited against the following topic(s):

¹²⁶ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

HORIZON-HLTH-2022-IND-13-01: Enhancing Cybersecurity of connected Medical Devices

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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*”. More specifically, this topic aims at supporting activities that are contributing to the following impact area: “*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 some of the following expected outcomes:

- Stakeholders (e.g. manufacturers, suppliers, healthcare 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) 2017/745¹²⁷ on medical devices and Regulation (EU) 2017/746¹²⁸ 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.

¹²⁷ OJ L 117, 5.5.2017, p. 1–175

¹²⁸ OJ L 117, 5.5.2017, p. 176–332

- Proposals are expected to address some or all of the followings: 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 devices 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 devices¹²⁹, to connected medical device, including software.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, or the development and adoption of best practices. Successful proposals will be also encouraged to exchange with other relevant proposals funded under other topics and other clusters to ensure synergies on cross-cutting challenges of common interest such as under cluster 3 the topic HORIZON-CL3-CS-2022-01-01: Improved monitoring of threats, intrusion detection and response in complex and heterogeneous digital systems and infrastructures (the application scenarios described in the scope include cybersecurity of communication systems and networks and their components, e.g. 5G networks, Internet of Things (IoT) devices, medical devices, etc.). Therefore, proposals are expected to include a budget to cover those joint coordination and dissemination activities without the prerequisite to define concrete joint activities at this stage. The details of these joint activities will be defined during the grant preparation phase with the Commission.

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 EU estimates that an EU contribution of around EUR 7.00 million would allow these outcomes to be addressed appropriately. Nonetheless, |

¹²⁹ <https://ec.europa.eu/docsroom/documents/41863>

| | |
|--------------------------|---|
| <i>project</i> | 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*”. More specifically, this topic aims at supporting activities that are contributing to the following impact area: “*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:

- European Union 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 have at their disposal 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 and 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 grants third parties access to analysis outcomes but not to the underlying data. The developers should have access to

distributed testing data sources 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 and 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 payment models for cost-effective and affordable health innovations/new models of pricing

Specific conditions

| | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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*”. More specifically, this topic aims at supporting activities that are contributing to the following impact areas: “*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*” and “*Good health and high-quality accessible 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:

- 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 proposal 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.

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.

Sex and gender, as well as other categories, like disability, ethnicity, and age should be considered, where relevant.

HORIZON-HLTH-2022-IND-13-04: Setting up a European Smart Health Innovation Hub

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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*”. More specifically, this topic aims at supporting activities that are contributing to the following impact area: “*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:

- Empowered patients and citizens of all age, gender, social and economic background iadopt 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)¹³⁰, European Reference Sites of the EIP-AHA¹³¹ 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 Interest¹³², 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.

Applicant 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

¹³⁰ <https://ec.europa.eu/digital-single-market/en/digital-innovation-hubs>

¹³¹ https://ec.europa.eu/eip/ageing/reference-sites_en

¹³² <https://ec.europa.eu/docsroom/documents/37824>

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, EDIHs¹³³, Reference Sites of the EIP-AHA¹³⁴ and Knowledge Hubs, such as eHealth Hub¹³⁵ or mHealth Hub¹³⁶ – working on innovation of digital health solutions, including training to end-users, e.g. citizens, patients, health and 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, also through synergies with other relevant initiatives, like the Digital Transformation Accelerator that will manage the network of European Digital Innovation Hub.
- 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 Ecosystem

| Specific conditions | |
|---|--|
| <i>Expected EU contribution per project</i> | The EU 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 |

¹³³ <https://ec.europa.eu/digital-single-market/en/digital-innovation-hubs>

¹³⁴ https://ec.europa.eu/eip/ageing/reference-sites_en

¹³⁵ <https://www.ehealth-hub.eu/>

¹³⁶ <https://mhealth-hub.org/>

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*”. More specifically, this topic aims at supporting activities that are contributing to the following impact area: “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:

- Development of interoperable cross-border digital health solutions for use by individuals, researchers, health services and the workforce across borders in the EU Digital Single Market will be significantly improved and supported by a 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 will be provided with 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 Network¹³⁷ will be provided with substantiated recommendations regarding potential evolutions of the EEHRxF and its extension to other uses cases.
- Different target populations such as designers, developers, healthcare professionals, and individuals will be provided with 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 EEHRxF¹³⁸. 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 projects¹³⁹ 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

¹³⁷ https://ec.europa.eu/health/ehealth/policy/network_en

¹³⁸ <https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format>

¹³⁹ E.g. from the H2020 topics PHC 34 – 2014, HCO-14-2016, HCO-15-2016, SC1-DTH-08-2018, SC1-HCC-07-2020.

specifications of its information domains (i.e. medical imaging, discharge letters, laboratory results etc.). This infrastructure must provide a REST API¹⁴⁰ 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 Regulation¹⁴¹, the Network and Information Systems Directive¹⁴² and the operation in a European Digital Single Market.

- 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 Network¹⁴³ 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.

¹⁴⁰ <https://joinup.ec.europa.eu/collection/api4dt>

¹⁴¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation): <http://eur-lex.europa.eu/eli/reg/2016/679/oj>

¹⁴² 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>

¹⁴³ https://ec.europa.eu/health/ehealth/policy/network_en

- 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, healthcare professionals, policy makers, SMEs etc.

DRAFT

Other Actions not subject to calls for proposals

Grants to identified beneficiaries

1. Grant to the Global Alliance for Chronic Diseases

The European Commission will make a contribution towards activities of the Global Alliance for Chronic Diseases (GACD)¹⁴⁴. 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. 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 cooperation¹⁴⁵ in research and innovation.

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 - Coordination and support action

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. 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.

Legal entities:

FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V., HANSASTRASSE 27C, 80686, Muenchen, Germany

¹⁴⁴ <https://www.gacd.org/>

¹⁴⁵ COM(2012)497

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 195
- Coordination and support action

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 - Placeholder

Results under this action are expected to contribute to all of the following expected outcomes:

1. Health care providers have access to newly developed medical countermeasures against prioritised pathogens with epidemic potential
2. Citizens benefit from improvements in prevention and containment of epidemics
3. Research funders, policy makers and the research community will have better means to achieve the Sustainable Development Goal 3.3¹⁴⁶, “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:

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 cooperation¹⁴⁷ in resersearch 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

¹⁴⁶ <https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals>
¹⁴⁷ COM(2012)497

- 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 - Programme co-fund action

Indicative timetable: 2021 and 2022

Indicative budget: EUR 25.00 million from the 2021 budget and EUR 25.00 million from the 2022 budget

Other Instruments

1. Studies, conferences, events and outreach activities

A number of specific contracts will be signed under existing framework contracts in order: (i) to support the dissemination and exploitation of project results; (ii) to contribute to the definition of future challenge priorities; (iii) to undertake citizen surveys such as Eurobarometers, (iv) to carry out specific evaluations of programme parts (v) to organise conferences, events and outreach activities. Should existing framework contracts prove unsuitable or insufficient to support the abovementioned activities, one or more calls for tender may be launched as appropriate.

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

Form of Funding: Procurements

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))

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

These grants will be awarded without a call for proposals according to Article 195 (a, b, c, d, f, g) of the Financial Regulation and Article 20 of the Horizon Europe Framework Programme and Rules for Participation.

In case of a public health emergency¹⁴⁸ (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), Article 195(b) of the Financial Regulation 2018/1046 applies¹⁴⁹, allowing for:

1. The award of grants without a call for proposals in exceptional and duly substantiated emergencies. At that time, the Funding & Tenders Portal will open a dedicated section where research applications can be received. This will be communicated to the National Contact Points. The invitation to apply for funding may also be limited to targeted entities, taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances.
2. The award of additional funding for ongoing grant agreements to cover additional activities specifically linked to the public health emergency. 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.

Beneficiaries of grants awarded under actions relating to public health emergencies must make available their research data, at the latest within 30 days after it has been generated, through open access or, if agreed by the Commission, by giving access rights to those third parties that need the research data to address the public health emergency. Therefore, the relevant option of Article 29.3 will be applied. It is expected that quality-controlled data are shared in accordance with the FAIR¹⁵⁰ principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

The standard eligibility and admissibility criteria, evaluation criteria, thresholds, weighting for award criteria, maximum rate of co-financing and conditions for providing financial support to third parties, are provided in the General Annexes.

Specific derogations and additional conditions may be announced or directly communicated to the potential applicants and to the beneficiaries which would like to receive additional funding to the grant agreements. Such conditions are likely to include additional exploitation obligations to ensure that the resulting products will be available and accessible as soon as possible including an obligation to license on a non-exclusive basis and at fair and reasonable conditions, additional dissemination obligations and the right of the Commission to object to the transfer or licensing of the results. It may also include justified derogations from the standard limits to financial support to third parties. Where applicable, the relevant grant agreement options will be applied.

Form of Funding: Grants not subject to calls for proposals

¹⁴⁸ Should there be no Public Health Emergency in 2021 or 2022, the indicative budget may be reallocated.

¹⁴⁹ 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;"

¹⁵⁰ <https://www.openaire.eu/how-to-make-your-data-fair>

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 195
- Research and innovation action

Indicative timetable: 2021 and 2022

Indicative budget: EUR 20.00 million from the 2021 budget and EUR 20.00 million from the 2022 budget

3. Subscription to the Human Frontier Science Program Organization

An annual subscription to the international Human Frontier Science Program Organization (HFSPPO)¹⁵¹ 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

Indicative timetable: 2021 and 2022

Indicative budget: EUR 5.30 million from the 2021 budget and EUR 5.30 million from the 2022 budget

4. 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

Indicative budget: EUR 2.00 million from the 2021 budget

¹⁵¹ The European Commission is a member of the HFSP Organization (HFSPPO) and has funded HFSP under previous Framework Programmes

Budget¹⁵²

| | Budget line(s) | 2021 Budget (EUR million) | 2022 Budget (EUR million) |
|---|---------------------------------|---------------------------|---------------------------|
| Calls | | | |
| HORIZON-HLTH-2021-STAYHLTH-01 | | 69.00 | |
| | <i>from</i> <i>01.020210</i> | <i>69.00</i> | |
| HORIZON-HLTH-2022-STAYHLTH-01-two-stage | | | 170.00 |
| | <i>from</i> <i>01.020210</i> | | <i>170.00</i> |
| HORIZON-HLTH-2022-STAYHLTH-02 | | | 50.00 |
| | <i>from</i> <i>01.020210</i> | | <i>50.00</i> |
| HORIZON-HLTH-2021-ENVHLTH-02 | | 130.00 | |
| | <i>from</i> <i>01.020210</i> | <i>130.00</i> | |
| HORIZON-HLTH-2021-ENVHLTH-03 | | 200.00 | |
| | <i>from</i> <i>01.020210</i> | <i>200.00</i> | |
| HORIZON-HLTH-2022-ENVHLTH-04 | | | 20.00 |
| | <i>from</i> <i>01.020210</i> | | <i>20.00</i> |
| HORIZON-HLTH-2021-DISEASE-04 | | 262.50 | |
| | <i>from</i> <i>01.020210</i> | <i>262.50</i> | |
| HORIZON-HLTH-2022-DISEASE-06-two-stage | | | 160.00 |
| | <i>from</i> | | <i>160.00</i> |

¹⁵²

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.

**Horizon Europe - Work Programme 2021-2022 Vs. 5.1 for PC, Jan '21
Health**

| | | | |
|------------------------------|---------------------------|---------------|---------------|
| | <i>01.020210</i> | | |
| HORIZON-HLTH-2022-DISEASE-07 | | | 37.00 |
| | <i>from 01.020210</i> | | <i>37.00</i> |
| HORIZON-HLTH-2022-DISEASE-03 | | | 30.00 |
| | <i>from 01.020210</i> | | <i>30.00</i> |
| HORIZON-HLTH-2021-CARE-05 | | 70.00 | |
| | <i>from 01.020210</i> | <i>70.00</i> | |
| HORIZON-HLTH-2022-CARE-08 | | | 70.00 |
| | <i>from 01.020210</i> | | <i>70.00</i> |
| HORIZON-HLTH-2022-CARE-10 | | | 100.00 |
| | <i>from 01.020210</i> | | <i>100.00</i> |
| HORIZON-HLTH-2021-TOOL-06 | | 115.00 | |
| | <i>from 01.020210</i> | <i>115.00</i> | |
| HORIZON-HLTH-2022-TOOL-11 | | | 95.00 |
| | <i>from 01.020210</i> | | <i>95.00</i> |
| HORIZON-HLTH-2022-TOOL-12 | | | 60.00 |
| | <i>from 01.020210</i> | | <i>60.00</i> |
| HORIZON-HLTH-2021-IND-07 | | 44.00 | |
| | <i>from 01.020210</i> | <i>44.00</i> | |
| HORIZON-HLTH-2022-IND-13 | | | 69.00 |
| | <i>from 01.020210</i> | | <i>69.00</i> |

**Horizon Europe - Work Programme 2021-2022 Vs. 5.1 for PC, Jan '21
Health**

| Other actions | | | |
|---|---------------------------|---------------|---------------|
| Grant to identified beneficiary according to Financial Regulation Article 195 | | 47.20 | 45.00 |
| | <i>from 01.020210</i> | <i>47.20</i> | <i>45.00</i> |
| Public procurement | | 3.00 | 3.00 |
| | <i>from 01.020210</i> | <i>3.00</i> | <i>3.00</i> |
| Subscription action | | 5.30 | 5.30 |
| | <i>from 01.020210</i> | <i>5.30</i> | <i>5.30</i> |
| Expert contract action | | 2.00 | |
| | <i>from 01.020210</i> | <i>2.00</i> | |
| Estimated total budget | | 948.00 | 914.30 |

DRAFT