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Annex 4

Horizon Europe

Work Programme 2023-2024

4. Health

DISCLAIMER

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DRAFT

Introduction

The Union and the world is gradually learning how to live with the COVID-19 pandemic. The pandemic laid bare the vulnerabilities of our societies, economies and health care systems and made evident the need for a strong European crisis preparedness and response in which Europe is now decidedly investing. The European Health Emergency Preparedness and Response Authority (HERA) created in September 2021 is key to this endeavour. The present work programme will support HERA and Europe's pandemic preparedness by investing in research into better management of epidemics, adaptable clinical networks for drugs and vaccines and better comprehension of the emergence of cross-border health threats. Particular attention is paid to translational research, to facilitating the development and implementation of new ways to prevent, diagnose, and treat infectious diseases, including the growing problem of antimicrobial drug resistance. Focus is not only on immediate health threats, but also on the wider societal impacts of health crises e.g. on peoples' mental health and wellbeing and on health care system resilience. Research conducted during the pandemic and following its sequels is pivotal to inform preparedness for potential similar events in the future. The pandemic has also demonstrated the downside of globalisation in which the dependence on global value chains can quickly result in shortages of critical supplies, such as essential medicines or other health technologies.

To help repair the economic and social damage caused by the coronavirus pandemic, the European Commission, the European Parliament and EU Member States leaders agreed on a Recovery Plan for Europe that will lead the way out of the crisis and lay the foundations for a modern and more sustainable Union. The Health cluster will continue to benefit from financial resources of this Multiannual Financial Framework and from NextGenerationEU (NGEU), the Union's financing instrument to boost the recovery. It requires research and innovation supporting the recovery of people and communities from COVID-19 but also for making society more resilient and national health systems better prepared to any future public health emergency.

The Recovery Plan aims the Union to building back better, including through support for 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 help increase the capacity of health care systems to deliver more personalised and effective health and care with less resource wasting. It will contribute, but is not sufficient, for making the Union the first climate-neutral continent by 2050, with zero pollution and zero waste. Additional efforts are needed to make also the delivery of health care, the design of health technologies and their manufacturing more sustainable by reducing energy consumption, waste, pollution and the release of harmful substances, including pharmaceuticals, into the environment.

Even though research and innovation has the power to uncovering the knowledge and developing the technologies to serve societal well-being, economic prosperity and

environmental sustainability, it only can succeed through cooperation of the best research teams with the prospective users of such knowledge and technologies. It is thus of outmost importance to involve those users - like patients and healthy citizens, health care professionals providers and payers, public health authorities and regulators, researchers or innovators from academia and industry - early in the knowledge generation or technology development process, including through patient/citizen engagement, community involvement or other forms of social innovation approaches, such that research and innovation activities are adjusted to the users' particular expectations, needs, constraints and potential. Any cooperation would benefit from adequate intellectual property management strategies.

Beyond cooperating along the value chain of knowledge and know-how production and valorisation or within the knowledge triangle (research-education-innovation), it is in the EU's strategic interest to also reach out and cooperate with other countries outside the EU and on other continents. This applies in particular for multi-lateral cooperation on (global) health issues with countries associated to Horizon Europe but also with other partner countries and regions in the world. In line with the EU's Global Approach to Research and Innovation¹, participation in Cluster 1 of Horizon Europe is open to third countries. In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under the Health cluster. However following Russia's unprovoked and unjustified military aggression against Ukraine and Belarus' involvement in Russia's military aggression entities established in Russia, Belarus or in non-government controlled territories of Ukraine are not eligible to participate in any capacity (or receive, as third parties, financial support from grant beneficiaries) except in specific duly justified cases. In support of the Global Gateway Strategy², projects involving international partners should lead to increased scientific knowledge and transfer of technology among partner countries allowing to address global health challenges across the world, thus creating sustainable growth and jobs. Cooperation should take place in a value-based way, creating linkages, not dependencies”.

The pandemic has demonstrated the importance of effective coordination among EU Member States in the area of health. The European Commission is building a strong European Health Union, in which all EU Member States work together to improve prevention, diagnosis, treatment and aftercare for any diseases, including cancer. Research and innovation actions under the Health Cluster will deliver relevant complementary inputs to “Europe's Beating Cancer Plan”³, contributing to actions covering the entire cancer care pathway, including prevention, early detection, diagnosis, treatment, cancer data monitoring, as well as quality of life of cancer patients and survivors.

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

¹ *COM(2021) 252 final*

² *JOIN(2021) 30 final*

³ <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan>

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

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

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

The ERDF focuses, amongst others, on the development and strengthening of regional and local research and innovation ecosystems and smart economic transformation, in line with regional/national smart specialisation strategies. It can support investment in research infrastructure, activities for applied research and innovation, including industrial research, experimental development and feasibility studies, building research and innovation capacities

and uptake of advanced technologies and roll-out of innovative solutions from the Framework Programmes for research and innovation through the ERDF.

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

Notwithstanding the synergies mentioned above, the work programme 2023-2024 of cluster 1 'Health' captures synergies with other clusters based on the challenges and areas of intervention of each destination. Further synergies are encouraged with regard to complementary funding opportunities provided by topics in other clusters and other pillars of Horizon Europe, notably in the European Research Infrastructure work programme (under pillar I) and the European Innovation Council work programme (under pillar III). Additional synergies could also be explored at project-level, i.e. between the portfolio of projects funded either under the same topic or by establishing a portfolio of projects funded under different topics (of the health cluster, of the other clusters 2-6, or of the pillars I/III of Horizon Europe). In particular, applicants to calls of the health cluster are encouraged to consider, where relevant, the services offered by the current and future EU-funded European Research Infrastructures, including the European Open Science Cloud.^{4 5} Moreover, if projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, they must make use of European space technologies and services provided by Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).⁶

In the context of the work programme 2023-2024 of cluster 1 'Health', a clinical study covers clinical studies/trials/investigations/cohorts and is defined as any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by

⁴ 2018 Roadmap of the European Strategy Forum on Research Infrastructures (ESFRI) with the ESFRI research infrastructures list (pp 15-17), https://ec.europa.eu/info/sites/info/files/research_and_innovation/esfri-roadmap-2018.pdf; European Research Infrastructures, Commission website: https://ec.europa.eu/info/research-and-innovation/strategy/european-research-infrastructures_en; List of entities legally established as European Research Infrastructure Consortium (ERIC) <https://www.eric-forum.eu/the-eric-landscape>.

⁵ European Open Science Cloud (EOSC) <https://www.eosc-portal.eu>; European COVID-19 Data Platform / COVID-19 Data Portal <https://www.covid19dataportal.org>.

⁶ European space technology based earth observation, positioning, navigation and timing services provided by: Copernicus, the European Union's Earth observation programme <https://www.copernicus.eu/en/copernicus-services>; Galileo, the European Global Satellite Navigation System (GNSS) <https://www.gsc-europa.eu/galileo/services/galileo-initial-services>; and the European Geostationary Navigation Overlay Service (EGNOS) <https://www.gsa.europa.eu/egnoss/services>.

Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

Where relevant, applicants are encouraged to take advantage of synergies with the Euratom Research and Training Programme (2021-2025).⁷

The work programme 2023-2024 of cluster 1 ‘Health’ is directed towards two Key Strategic Orientations (KSOs) for research and innovation set by Horizon Europe’s strategic plan 2021-2024, notably to creating a more resilient, inclusive and democratic European society (KSO-D) and promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains (KSO-A). It aims to complete the targets set out in the Strategic Plan 2021-2024, mainly along the four impact areas: Good health and high-quality accessible health care; A resilient EU prepared for emerging threats; High quality digital services for all; and A competitive and secure data-economy. More specifically, cluster 1 strives to contribute to six expected impacts as set out by the Strategic Plan, which are the following six destinations of this work programme:

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

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

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

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

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

⁷ The Euratom programme supports research on the protection of citizens, including patients, benefiting from screening, early detection, diagnostics, cancer therapy and care involving radiation sources. It aims at better understanding the effects of medical exposure to ionising radiation, optimisation of radiological protection, and safe use and reliable supply of medical radionuclides.

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

DRAFT

Destination 1 – Staying healthy in a rapidly changing society

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

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

As set out in the Strategic Plan 2021-2024, destination 1 focuses on major societal challenges that are part of the European Commission’s political priorities. This is why destination 1 in the workprogramme 2021-2022 covered immediate urgencies, notably a better understanding and prevention of mental illness, prevention of obesity, digital empowerment in health literacy, understanding the transition from health to disease and making use of AI tools to predict the risk for onset and progression of chronic diseases. The workprogramme 2023-2024 will complete the ambitions of the Strategic Plan by focussing on holistic and integrated approaches to disease prevention and health promotion, notably healthy ageing, a life course approach to physical and mental health starting in early childhood and personalised disease prevention.

More specifically, research and innovation supported under destination 1 in 2023 will provide new tools, digitally enabled solutions and evidence-based health and care services to prevent and delay progression of age-related diseases. Research and innovation will also provide tailor made strategies and solutions to support children and adolescents adopting and maintaining person-centred healthy lifestyles. Specific measures will be developed to educate and

empower citizens of all ages and throughout their life to play an active role in the self-management of their own health and self-care, to the benefit of an active and healthy ageing. In 2024, this destination will call for proposals specifically aiming to develop integrated and holistic personalised disease prevention strategies, making use of multiple data sources, including real-world health data. This initiative will build on the impressive advances made in the area of personalised medicine to treat diseases, but here the focus will be on personalized approaches to prevent rather than treat diseases.

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 holistic approaches to health promotion and disease prevention and deliver improved evidence-based health for all.

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

Expected impacts:

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

- Citizens adopt healthier lifestyles and behaviours, make healthier choices and maintain longer a healthy, independent and active life with a reduced disease burden, including at old ages or in other vulnerable stages of life.

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

Horizon Europe - Work Programme 2023-2024
Health

- 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.
- Children and adolescents are empowered to better monitor and manage their physical, social and mental health with a view to lifelong healthy lifestyles.
- Society benefits from reduced economic and health burden from avoidable sickness, disease and premature death. Efficiency is increased by targeting scarce resources in appropriate, cost-effective ways, to areas of high social return, contributing to an improvement and optimisation of health and well-being of citizens and reduction of health inequalities.
- Citizens' trust in knowledge-based health interventions and in guidance from health authorities is strengthened, including through improved health literacy, resulting in increased engagement in and adherence to effective strategies for health promotion, disease prevention and treatment, while digital literacy inequalities are minimized.
- Health policies and actions for health promotion and disease prevention are knowledge-based, people-centred, personalized and thus targeted and tailored to citizens' needs, and designed to reduce health inequalities.

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

Call	Budgets (EUR million)		Deadline(s)
	2023	2024	
HORIZON-HLTH-2023-STAYHLTH-01	40.00		13 Apr 2023
HORIZON-HLTH-2024-STAYHLTH-01-two-stage		80.00	19 Sep 2023 (First Stage) 11 Apr 2024 (Second Stage)
Overall indicative budget	40.00	80.00	

Call - Staying Healthy (Single stage - 2023)

HORIZON-HLTH-2023-STAYHLTH-01

Conditions for the Call

Indicative budget(s)⁹

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁰	Indicative number of projects expected to be funded
		2023		
Opening: 12 Jan 2023 Deadline(s): 13 Apr 2023				
HORIZON-HLTH-2023-STAYHLTH-01-01	RIA	40.00 ¹¹	15.00 to 20.00	2
Overall indicative budget		40.00		

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.

⁹ The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2023 and 2024.

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

¹¹ Of which EUR 24.00 million from the 'NGEU' Fund Source.

Horizon Europe - Work Programme 2023-2024
Health

<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-2023-STAYHLTH-01-01: The Silver Deal - Person-centred health and care in European regions

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 15.00 and 20.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 40.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

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 at, tailored towards and contributing to all of the following expected outcomes:

- Citizens and patients will get effective, preventive, integrated, coordinated, evidence-based and people-centred high-quality health and care services to identify and tackle or prevent multi-morbidities, frailty, biologically or mentally reduced capacities, (sensory) impairments, dementia and/or neurodegeneration, fostering mental and physical health, wellbeing and quality of life. These could include, but are not limited to, assistive technologies, nutrition and physical activity, adaptation of work and workplace, health-promoting age-friendly working, home and community environments, better equality of access to health and care services through community-based and integrated care models, also digitally enabled.
- Primary and community based health and care services will be better equipped to early identify people at risk of developing non-communicable diseases (NCDs) and multi-morbidities. They will have integrated and cost-effective intervention tools to help prevent, monitor and manage progression of age-related diseases, conditions and disabilities, while promoting healthy lifestyles, ageing in place¹², as well as physical and mental wellbeing among the elderly.
- Older people, including those receiving long-term care, will be empowered to take an active role in the management of their own physical and mental health, as well as increase their social interactions and wellbeing through better health literacy, educational programmes, trainings and platforms, including with the help of innovative and digitally enabled solutions.
- Citizens, all relevant stakeholders, public authorities, cities and rural environments, as well as health care providers will be engaged to ensure the introduction to and the integration of age-friendly, mental and physical health promoting innovative care pathways and digitally enabled solutions into the daily life and wellbeing of the ageing population, with the aim of leaving no-one behind.

The proposals should provide appropriate indicators to measure performance and progress towards the relevant expected outcomes.

Scope: This topic aims to implement strategies and actions in line with the Green Paper on Ageing¹³, the EU Long-term care report¹⁴, the ‘Healthier Together’ – EU Non-Communicable Diseases Initiative¹⁵, the new EU Care Strategy¹⁶, which strive to address demographic change and enable better health and care for Europe’s growing ageing societies, as well as to harness the potential of the Silver Economy¹⁷. New tools and integrated care models are

¹² ‘The ability to live in one's own home and community safely, independently, and comfortably, regardless of age, income, or ability level’.

¹³ https://ec.europa.eu/info/sites/default/files/1_en_act_part1_v8_0.pdf

¹⁴ <https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8396>

¹⁵ https://ec.europa.eu/health/non-communicable-diseases/overview_en

¹⁶ <https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-european-care-strategy>

¹⁷ A new multi-policy approach is recommended by the “Silver Economy Study”: the ageing population promises more economic growth and jobs. <https://ec.europa.eu/digital-single-market/en/news/silver-economy-study-how-stimulate-economy-hundreds-millions-euros-year>

needed, reinforcing primary, community- and home based health and long-term care provision, through better early detection and management of diseases among older people in an increasingly ageing society and overburdened health and care systems.

The topic encourages the participation of small and medium-sized enterprises (SMEs), as well as of European, national and regional authorities and civil society, in order to strengthen the scientific and technological expertise of SMEs in the health and care domain, promote the European Health- and Age-Tech; and improve the uptake of innovative health and care solutions in the EU and Associated Countries.

The applicants should ensure that the developed solutions, technologies and adoption policies are driven by the needs of citizens and patients of old age and ensure their involvement. Co-creation, co-design with end-users and particular consideration of the diversity of the needs, mental and physical abilities, living and socio-economic conditions as well as life-situations of older people are required, including provision of training to citizens, patients, formal and informal carers.

The proposed research and innovation should focus on all of the following aspects:

- Consolidate high-quality effective, integrated, innovative and digitally enabled person-centred health and long-term care services and solutions, both in primary care, hospital and home settings, around older people's needs for physical and mental health, care and wellbeing, strengthened disease prevention, rehabilitation and for staying active and healthy as people age. Such integrated and holistic solutions could include, but are not limited to, integrated care solutions, serious games, connected wearables, ambient sensors, social robots, assistive technologies, age-friendly environments, diagnostic screenings, self-monitoring devices, robotics and others¹⁸, tackling age-related physical and mental diseases and co-morbidities.
- Develop and provide evidenced-based new approaches, coordinated care models and pathways, for delivering effective, person-centred health and long-term care solutions at the system and community level. These should be based on the needs of healthy and vulnerable older people for increased physical, mental and nutritional resilience vis-à-vis inequality of access to health and care, rapidly changing societies and health and care systems, and ensure better skills, empowerment and improved health and digital literacy through appropriate trainings and activities.
- Support adoption and market innovation of novel health and care solutions, co-created with and designed for older age related health conditions. The support could be provided through large-scale testing and deployment piloting, guidance on relevant HTA and CE procedures, demonstrating cost-effectiveness, as well as through stakeholder involvement and policy collaboration on European¹⁹, local, regional²⁰, and

¹⁸ EU-funded large-scale pilots on Active and Healthy Ageing <https://www.opendei.eu/healthcare-sector/>
¹⁹ <https://digital-strategy.ec.europa.eu/en/policies/eip-aha> and <http://www.aal-europe.eu/> and <http://www.rscn.eu/>
²⁰ Such as the Reference Sites Collaborative Network, <http://www.rscn.eu/>

international^{21,22} level, exchange of best practices (twinning), and, when relevant, collaboration with the EC-funded large-scale pilots on Active and Healthy Living²³ and the Reference Sites Collaborative Network.

This topic addresses consortia including research partners and innovative technology providers, such as SMEs and/or organisations that can offer the range of activities required to address the objectives of the topic; the latter could for example be based on Digital Innovation Hubs, digital health accelerators, incubators and knowledge hubs, Centres offering Pilot Lines or similar technology, business and/or knowledge transfer organisations.

The proposals should be highly integrated, ambitious, go beyond simple networking and provide appropriate indicators to measure progress, impact, cost-effectiveness and adoption in the Europe. Dissemination and involvement of policy makers, both at national and regional level, as well as civil society organisations in a European wide geographical balanced matter is essential, as the results of this action are expected to have European wide impact.

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, the development and adoption of best practices and adoption strategies on regional, national and European level. The details of these joint activities will be defined during the grant preparation phase with the European Commission. Applicants should plan a necessary budget to cover this collaboration.

This topic requires the effective contribution of social 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.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

Call - Staying Healthy (Two stage - 2024)

HORIZON-HLTH-2024-STAYHLTH-01-two-stage

Conditions for the Call

Indicative budget(s)²⁴

²¹ International cooperation EU-Japan: Digital health and ageing Smart living environments for ageing people. September 2021; DOI: 10.2759/13059; Luxembourg: Publications Office of the European Union: ISBN 978-92-76-38187-7

²² <https://idih-global.eu>

²³ <https://www.opendei.eu/healthcare-sector/>

²⁴ 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.

**Horizon Europe - Work Programme 2023-2024
Health**

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ²⁵	Indicative number of projects expected to be funded
		2024		
Opening: 30 Mar 2023				
Deadline(s): 19 Sep 2023 (First Stage), 11 Apr 2024 (Second Stage)				
HORIZON-HLTH-2024-STAYHLTH-01-02-two-stage	RIA	30.00	8.00 to 10.00	3
HORIZON-HLTH-2024-STAYHLTH-01-05-two-stage	RIA	50.00	8.00 to 12.00	5
Overall indicative budget		80.00		

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.

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 2023 and 2024.

²⁵ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2024-STAYHLTH-01-02-two-stage: Towards a holistic support to children and adolescents' health and care provisions in an increasingly digital society

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 8.00 and 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 30.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Admissibility conditions</i>	<p>The conditions are described in General Annex A. The following exceptions apply:</p> <p>Applicants submitting a proposal under the blind evaluation pilot (see General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in Part B of their first stage application (see General Annex E).</p>
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>
<i>Procedure</i>	<p>The procedure is described in General Annex F. The following exceptions apply:</p> <p>This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.</p>
<i>Legal and financial</i>	The rules are described in General Annex G. The following exceptions

<i>set-up of the Grant Agreements</i>	apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). ²⁶ .
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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 at, tailored towards and contributing to all of the following expected outcomes:

- Children, adolescents and their parents/carers are educated and empowered in prevention strategies involving personalised approaches and solutions (also through the use of digital tools) to manage, maintain and improve children’s and adolescents' own health, physical activity, nutrition habits, leisure needs, mental and social well-being, in full respect of the privacy of individuals.
- Children and adolescents, including those from vulnerable contexts, monitor their health risks, adopt healthy lifestyles at home, at school and in the community and interact with their doctors and carers (receiving and providing feedback), also through the means of digitally enabled solutions, better health literacy, training and critical thinking.
- Thanks to better co-creation, training, digital and health literacy, children, adolescents, parents and carers across Europe access and use person-centred, widely available solutions for children and adolescents’ health, care and wellbeing, appropriate to a rapidly changing and increasingly digitalised society, considering also the risk of digital addiction.

The proposals should provide appropriate indicators to measure the progress towards the relevant expected outcomes.

Scope: Laying the ground for a healthy life starts in childhood. Accordingly, and in line with the HealthyLifestyles4All Initiative²⁷, the ‘Healthier Together’ – EU Non-Communicable Diseases Initiative²⁸, and the Communication of the Commission on enabling the Digital Transformation of Health and Care^{29,30}, the main goal of the research and innovation should

²⁶ This [decision](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf) is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under ‘Simplified costs decisions’ or through this link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf

²⁷ <https://sport.ec.europa.eu/healthylifestyle4all>

²⁸ https://ec.europa.eu/health/non-communicable-diseases_en

²⁹ <https://digital-strategy.ec.europa.eu/en/policies/ehealth>

³⁰ <https://digital-strategy.ec.europa.eu/en/library/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering>

be to promote healthier societies by developing holistic solutions that foster healthy lifestyles from early age with long-term impact(s).

Digitalisation poses risks but can also be a driving force for empowering young citizens, who are growing up in an increasingly digitised world, in taking an active role in the management of their own health conditions, mental and social well-being, and promote healthy lives and disease prevention, through innovative solutions, coordinated person-centred care models and better health literacy.

The topic encourages the participation of small and medium-sized enterprises (SMEs), as well as of European, national and regional authorities and civil society, in order to strengthen the scientific and technological expertise of SMEs in the health and care domain to promote the uptake of innovative health and care solutions in Europe.

The proposed research and innovation should focus on several of the following aspects:

- Develop and advance person-centred, evidence-based and coordinated disease prevention intervention solutions to support children and adolescents' health and care in an increasingly digital society. The effectiveness of the intervention solutions should be evaluated, inter alia, in terms of health outcomes, (comparative) cost-effectiveness, implementation facilitators and barriers. The target group should include children and adolescents up to 25 years of age from different socio-economic backgrounds.
- Develop and integrate innovative, privacy preserving tools and technologies, such as (but not limited to) activity trackers, sensors, serious games, platforms and robotics, Massive Open Online Courses (MOOCs) in coordinated and integrated care models, to help children and adolescents lead healthy, active and social lifestyles, prevent diseases, as well as to better monitor and manage their physical, social and mental health. Empower children and adolescents to navigate the health and care systems, interact with their doctors, formal and informal carers, social circles, as well as better manage their own health at home, in the community and at school, taking into account specific youth psychiatric risk factors, the risk of addiction, as well as the geographic, social and economic determinants of health and digital literacy inequities.
- Stimulate the adoption of person-centred approaches and solutions for better health, care and well-being of children and adolescents, by including stakeholders from all the relevant sectors (including but not limited to education, leisure, social innovation, healthcare, Medtech, media and citizens) in the co-creation, design, planning and adoption of the solutions, as well as the training of their end-users.
- Develop and disseminate evidence-based guidance and tools for children and adolescents promoting healthy balance between a sedentary digitised lifestyle and a more active non-digitised lifestyle in support of their physical, mental and social health and well-being on short- and long-term basis.

- Develop, implement (pilot and/or scale-up) and promote person-centred tools and interventions for better physical and mental wellbeing, addressing the risks of digital addiction and overconsumption, isolation and mental illness, by promoting physical, intellectual or artistic activities, social interaction and providing mental health support and treatment.

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

This topic requires the effective involvement of youth throughout the project. Moreover, social sciences and humanities (SSH) disciplines and the involvement of SSH experts, institutions as well as the inclusion of relevant SSH expertise must be present in order to produce meaningful and significant effects enhancing the societal impact of the related research activities.

Moreover, greater involvement of non-health sectors directly affecting risk factors and determinants of health, for example (physical) environment, food and nutrition, security, education, sports, finance, industry is desirable/encouraged, as relevant.

Proposals should be highly integrated, ambitious, go beyond simple networking and provide appropriate indicators to measure progress and impact.

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, the development and adoption of best practices and adoption strategies on regional, national and European level. The details of these joint activities will be defined during the grant preparation phase with the Commission. Applicants should plan a necessary budget to cover this collaboration.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2024-STAYHLTH-01-05-two-stage: Personalised prevention of non-communicable diseases - addressing areas of unmet needs using multiple data sources

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 8.00 and 12.00 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

**Horizon Europe - Work Programme 2023-2024
Health**

<i>Admissibility conditions</i>	<p>The conditions are described in General Annex A. The following exceptions apply:</p> <p>Applicants submitting a proposal under the blind evaluation pilot (see General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in Part B of their first stage application (see General Annex E).</p>
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>
<i>Procedure</i>	<p>The procedure is described in General Annex F. The following exceptions apply:</p> <p>This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.</p>
<i>Legal and financial set-up of the Grant Agreements</i>	<p>The rules are described in General Annex G. The following exceptions apply:</p> <p>Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025).³¹.</p>

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

³¹ This [decision](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/lc-decision_he_en.pdf) is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under ‘Simplified costs decisions’ or through this link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/lc-decision_he_en.pdf

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

- Citizens have access to and use effective personalised prevention schemes and health counselling (including through digital means) that take into account their individual characteristics and situation. Individuals can be assigned to particular groups based on their characteristics, and receive advice adequate to that group. Stratification of a population into groups showing similar traits allows for effective personalised disease prevention.
- Health professionals use effective, tried and tested tools to facilitate their work when advising both patients and healthy individuals. Public health programme owners gain insight into the specificities and characteristics of disease clusters within the population through stratification. This can then be used to facilitate the identification of population groups with elevated risk of developing certain diseases and improve the programmes, update them and design effective strategies for optimal solutions and interventions.
- National and regional programmes make better use of funds, data infrastructure and personnel in health promotion and disease prevention, primary and secondary healthcare. They can consider the use of new or improved ambitious policy and intervention options, with expected high population-wide impact, for effective health promotion and disease prevention.
- Companies generate opportunities for new product and service developments to cater to the needs of the healthcare service and individuals.

Scope: Non-communicable diseases (NCDs) are responsible for the majority of the disease burden in Europe and are the leading cause of avoidable premature death. The human and financial cost of NCDs is high and expected to grow. Reducing the burden of NCDs requires a holistic approach and tackling health inequalities across the board. Preventing NCDs from developing in the first place will be at the core of successful public health programmes in the future.

Personalised approaches and the development of targeted interventions have led to an impressive progress in several fields of medicine and have been included in many treatments. However, the use of stratification and individualisation in guiding prevention strategies is still not widely in use even though examples of its potential are accumulating. Identifying people at risk of developing a particular disease before the disease starts to manifest itself with symptoms greatly improves treatment options. It is estimated that about two thirds of all NCDs are preventable, many affecting people who are unaware of their disease risks or do not have access to information pertaining to the management of the condition.

Personalised prevention is the assessment of health risks for individuals based on their specific background traits³² to recommend tailored prevention³³. This can include any

³² (Epi-)genetic, biological, environmental, lifestyle, social, behavioural, etc.

³³ Possibly along with digitally supported disease management schemes.

evidence based method³⁴. Personalised prevention strategies complement general public health prevention programmes without replacing them, optimising the benefit of both approaches. Personalised prevention is ideally suited to the use of large data sets, computational and omics approaches, with design and use of algorithms, integrating in-depth biological and medical information, machine learning, artificial intelligence (AI) and ‘virtual twin’ technology, taking into account explainable and transparent AI³⁵.

The funded projects will work towards reducing the burden of NCDs in line with the ‘Healthier Together’ – EU Non-Communicable Diseases Initiative³⁶. This does not limit the scope of projects under this topic to particular diseases as any disease area of interest, co-morbidities and health determinants³⁷ can be addressed.

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

- Enable the understanding of areas of unmet need in NCDs prevention, possibly also addressing disease mechanism, management of disease progression and relapse. Providing new approaches for prevention, focussing on the digitally supported personalised dimension, that can be adopted and scaled up.
- Devise new or improved ambitious policy and intervention options, with expected high population-wide impact on the target groups in question. To be proposed and made available for effective health promotion and disease prevention including targeted communication strategies to successfully reach out to the risk groups.
- Design an integrated, holistic approach that includes several of the following aspects: genetic predisposition to NCDs, meta-genomics, epigenomics, the microbiome, metabolomics, sleep disorders, large cohorts, molecular profiling in longitudinal health screening, impact of lack of physical activity, novel predictive biomarker candidates, diets and nutrition, eating habits for designing customized dietary patterns (geographical variation), and the influence of choice environment on personal choices.
- Study the ethical, legal and social aspects as well as health economics of the personalised prevention tools and programmes being developed. Consider optimal health counselling and communication to the patients/citizens. Address legal aspects of balancing the right not to know and the obligation of helping people in danger.

Furthermore, the proposed research is expected to deliver on several of the following points, while maintaining a reasonable focus:

- Develop and validate effective strategies to prevent NCDs and optimise health and well-being of citizens (including the most vulnerable). Propose the strategies to policy makers

³⁴ For example: medication, diet programmes, early diagnostics, monitoring, lifestyle advice and modification, specific training/exercise, psychosocial interventions, meditation, etc.

³⁵ See: European strategic research agenda in artificial intelligence: <https://www.elise-ai.eu/work/agenda-and-programs>

³⁶ https://ec.europa.eu/health/non-communicable-diseases/overview_en

³⁷ Social and economic environment; physical environment; individual characteristics; behaviour.

along with mechanisms to monitor their progress. The strategies need to be aligned with relevant national and European health laws and policies.

- Provide scientific evidence on interactions between the genetic predisposition to multifactorial diseases and environmental factors or environmental triggers. Propose scientifically supported personalised prevention strategies that ensure how to modify the environmental drivers of behavioural risk factors.
- Develop new computational tools combining and analysing comprehensive data with different dimensions³⁸ to identify risk factors and modifiers. Creating procedures and algorithms to combine information from different sources (with standardised common data models) to generate risk scores for several diseases and provide health promotion recommendations for the individual as advised by healthcare professionals. Furthermore, develop advanced computational modelling techniques³⁹ for predicting disease risk and predisposition (addressed together in an integrative approach) and identifying the optimal solution/intervention for different target groups and individuals.
- Develop tools and techniques to increase the efficiency and cost- effectiveness of on the one hand interventions, adjusting their scope, characteristics and resources, and on the other hand healthcare infrastructure and how it promotes and delivers health promotion, disease prevention, and care effectively to the different population groups.
- Design tools to collect various data to advance health promotion and disease prevention and strategies for providing omics essays for the general patient with a focus on cost-effectiveness and flexibility.
- Determine how to optimize the benefits of physical activity, smart monitoring of physical activity and sedentary behaviour with measurable data, addressing barriers to uptake and implementation of healthy lifestyles in daily life, understanding what promotion methods work and why, behavioural science to understand healthier choice environments. Balancing the ecosystem associated with the economic, social, and health consequences of NCDs.
- Conduct data mining of real world data and develop quantifiable and distinguishable indicators from wearables data, taking into account 'light-weight' AI means to ensure patient privacy and short reaction times.
- Demonstrate with a practical prototype on a given health challenge: from multimodal data collection to identification of an effective prevention strategy to be tested and validated for one or several NCDs.

Where relevant, the projects should contribute to and create synergies with ongoing national, European and international initiatives such as the European Partnership for Personalised

³⁸ For example, genomic, biomarkers, metagenomics, diet, synthetic data, lifestyle, wearables (physical activity), mental health, gender, age, physical and social environment.

³⁹ Computational techniques, e.g., virtual twin; deep, fair and/or federated machine learning; AI and symbolic AI.

Medicine, the 'Healthier Together' - EU Non-Communicable Diseases Initiative⁴⁰, Europe's Beating Cancer Plan and the Mission on Cancer, WHO's 9 targets for NCDs, the EMA 'Darwin' network etc.

This topic requires the effective contribution of social 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.

Where relevant, activities should build on and expand results of past and ongoing research projects. Selected projects under this topic are expected to participate in joint activities as appropriate, possibly including also related projects from other call topics. This can take the form of project clustering, workshops, joint dissemination activities etc. Applicants should plan a necessary budget to cover this collaboration.

Applicants of second stage envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

⁴⁰ https://ec.europa.eu/health/non-communicable-diseases_en

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

Calls for proposals under this destination are directed towards the Key Strategic Orientation KSO-D ‘*Creating a more resilient, inclusive and democratic European society*’ of Horizon Europe’s Strategic Plan 2021-2024. Research and innovation supported under this destination should contribute to the impact area ‘A resilient EU prepared for emerging threats’ and in particular to the following expected impact, set out in the Strategic Plan for the health cluster: ‘living and working environments are health-promoting and sustainable thanks to better understanding of environmental, occupational, social and economic determinants of health’. In addition, research and innovation supported under this destination could also contribute to the following impact areas: ‘Good health and high quality accessible health care’, ‘Climate change mitigation and adaptation’, and ‘Clean and healthy air, water and soil’. The environment we live and work in is a major determinant of our health and well-being. Environmental factors are estimated to account for almost 20% of all deaths in Europe. The impacting factors on both physical and mental health and wellbeing are not all identified nor their effects comprehensively understood and accounted for to support evidence-based policy- and decision-making. Therefore, Destination 2 aims at filling knowledge gaps in the understanding of the impacts on our health and well-being of those environmental, occupational and socio-economic risk factors that have the most significant or widespread societal impacts. In this work programme, Destination 2 focuses on pollution, disrupting chemicals, environmental degradation, climate and other environmental exposures in living and working environments. 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 EU Adaptation Strategy, the EU Biodiversity Strategy 2030, 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, biodiversity, mobility, security, urban planning, social inclusion and gender will be needed to ensure that maximal societal benefits are reached. Thus, in view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, development and adoption of best practices, or joint communication activities. All topics are open to international collaboration to address global environment and health challenges.

Expected impacts:

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

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- Policy-makers and regulators are aware and well informed about environmental, socio-economic and occupational risk factors as well as health-promoting factors across society;
- Environmental, occupational, social, economic, fiscal and health policies and practices at the EU, national and regional level are sustainable and based on solid scientific evidence. These include overarching policy frameworks such as the European Green Deal, the Chemical Strategy for Sustainability, the 8th Environment Action Programme, the EU Adaptation Strategy, the Farm to Fork Strategy, the EU Biodiversity Strategy 2030, the EU Strategic Framework on Health and Safety at Work and the European Environment and Health Process led by the World Health Organization;
- The upstream determinants of disease - related to choices in energy generation, agricultural and food processing practices, industrial production, land use planning, built environment and construction - are known, understood and reduced;
- The health threats and burden resulting from hazardous chemicals, biodiversity degradation 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 as well as unhealthy lifestyles are prevented;
- Citizens understand better complex environment and health issues, and effective measures to address them and support related policies and regulation.

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

Call	Budgets (EUR million)		Deadline(s)
	2023	2024	
HORIZON-HLTH-2023-ENVHLTH-02	103.00		13 Apr 2023
HORIZON-HLTH-2024-ENVHLTH-02-two-stage		60.00	19 Sep 2023 (First Stage) 11 Apr 2024 (Second Stage)

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Overall indicative budget	103.00	60.00	
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Call - Environment and health (Single stage - 2023)

HORIZON-HLTH-2023-ENVHLTH-02

Conditions for the Call

Indicative budget(s)⁴¹

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ⁴²	Indicative number of projects expected to be funded
		2023		
Opening: 12 Jan 2023 Deadline(s): 13 Apr 2023				
HORIZON-HLTH-2023-ENVHLTH-02-01	RIA	30.00 ⁴³	5.00 to 6.00	5
HORIZON-HLTH-2023-ENVHLTH-02-02	RIA	30.00 ⁴⁴	5.00 to 6.00	5
HORIZON-HLTH-2023-ENVHLTH-02-03	RIA	40.00 ⁴⁵	6.00 to 7.00	7
HORIZON-HLTH-2023-ENVHLTH-02-04	CSA	3.00 ⁴⁶	Around 3.00	1
Overall indicative budget		103.00		

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

⁴¹ 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 2023 and 2024.

⁴² Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

⁴³ Of which EUR 17.00 million from the 'NGEU' Fund Source.

⁴⁴ Of which EUR 17.00 million from the 'NGEU' Fund Source.

⁴⁵ Of which EUR 24.00 million from the 'NGEU' Fund Source.

⁴⁶ Of which EUR 1.50 million from the 'NGEU' Fund Source.

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	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-2023-ENVHLTH-02-01: Planetary health: understanding the links between environmental degradation and health impacts

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 5.00 and 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 30.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3</p>

	(Implementation). The cumulative threshold will be 12.
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Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 ‘Living and working in a health-promoting environment’. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to most of the following expected outcomes:

- Climate and environmental policies are supported with better knowledge on the Earth natural systems and human health interactions;
- Sustainable planetary health policies which foster co-benefits to human health and the health of ecosystems are supported with robust evidence;
- Policy-makers have better tools to improve the predictive capability and preparedness to deal with the impacts on human health of changes or degradation of ecosystems’;
- Cross sectorial and multidisciplinary scientific collaborations, including expertise in public health and One Health, are established;
- Public authorities rely on indicators about the impacts on human health of changes or degradation of natural systems to support adaptation and mitigation strategies to natural hazards;
- Policy-makers have better tools to improve the predictive capability and preparedness as well as to envision prevention strategies to deal with the impacts on human health of changes in natural ecosystems;
- Citizens are engaged and informed about the impact of natural systems’ degradation on human health and behaviours aiming at the conservation of ecosystems are promoted.

Scope: Globally, life quality and expectancy have increased to unprecedented levels over the last decades due to the significant public health, agricultural, industrial and technological achievements of the 20th century. On the other hand, the ongoing trend of environmental degradation and global climate and environmental changes has introduced new pressures, which involve large impacts on human health and might put at risk the recent public health gains.

Among others, climate change, biodiversity loss, biological invasions, environmental pollution, changes in land use and degradation, deforestation, thawing permafrost (in polar regions, and particularly in the Arctic), overfishing and acidification of water bodies can result in reduced food and water availability and safety and increased exposure to factors causing infectious and non-communicable diseases. Additionally, changes in weather and climate extremes have been observed across the globe, resulting in an increase of the frequency and intensity of extreme weather events such as heavy precipitation and floods, heat waves and hot extremes, droughts and tropical cyclones.

There is increasing evidence showing that many of these environmental stressors and changes can cause profound short- and long-term negative impacts on human health and well-being, contributing to increased morbidity and mortality worldwide. Understanding and acting upon these challenges calls for a multidisciplinary, cross-sectorial and trans-border approach ranging from the local to the global scale. The effects can be direct due to increases in floods, heatwaves, water shortages, landslides, exposure to ultraviolet radiation, exposure to pollutants, among others, or indirect and complex, as climate change -mediated or ecosystem-mediated. In addition, it is imperative that the solutions and initiatives chosen to prevent environmental degradation are safe for human health and the environment.

Planetary health is a concept focused on the interdependencies between human health and the state of earth's complex natural systems. A key focus is on understanding how the current trend of human-related environmental degradation can affect the health and well-being of current and future generations. The Rockefeller Foundation-Lancet Commission on Planetary Health⁴⁷ published a report in 2015, laying the foundation for the development of this important new field of study⁴⁸. In 2020 the Helsinki declaration⁴⁹ was published, resulting from a conference where participants discussed how to implement the planetary health approach in Europe in the context of the European Green Deal. Planetary health is also a priority topic in the research agenda in environment, climate and health proposed by the Coordination and support action HERA⁵⁰.

Applicants are invited to submit proposals providing actionable evidence for policy-makers to take preventive actions to protect the human health and wellbeing by exploring the links between human health and environmental degradation in an integrated and comprehensive manner. More fragmented contributions focused on less studied aspects such as the links between climate change and health and, between biodiversity and health, will also be considered.

To advance the knowledge on planetary health to support policy-making in this area, the applicants should address several of the following activities:

- Provide strengthened evidence for health and wellbeing impacts of planetary changes, considering a systems thinking framework or a fragmentary approach focused on the impacts of climate change and biodiversity loss on human health (for biodiversity loss, proposals should not focus on the connection between the biodiversity loss and ecosystem degradation with the prevention of zoonotic emerging diseases since this topic will be covered by CL6-2023-BIODIV: Interlinkages between biodiversity loss and degradation of ecosystems and the emergence of zoonotic diseases);

⁴⁷ [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(15\)60901-1.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60901-1.pdf)

⁴⁸ “Our definition of planetary health is the achievement of the highest attainable standard of health, well-being, and equity worldwide through judicious attention to the human systems—political, economic, and social—that shape the future of humanity and the Earth’s natural systems that define the safe environmental limits within which humanity can flourish. Put simply, planetary health is the health of human civilisation and the state of the natural systems on which it depends”

⁴⁹ Halonen et al. A call for urgent action to safeguard our planet and our health in line with the [Helsinki declaration](#)

⁵⁰ <https://www.heraresearch.eu/>

- Provide improved understanding and modelling of human–ecological systems interactions and ecosystem-mediated effects on human health and well-being, including the attribution of health outcomes to environmental change;
- Provide a methodology to identify and prioritise threats for public health caused by environmental degradation, with a view to improving preparedness of health systems to these threats, through structured processes that move from evidence to recommendations and decisions;
- Investigation how infections agents that might have the capacity to adapt to other host species can spread via the environment, and how this type of insight might lead to enhanced monitoring strategies;
- Lay the foundations for integrated surveillance systems considering already established monitoring systems (e.g. systematic wastewater monitoring) and using available and newly collected health, socioeconomic, and environmental data for defined populations over longer time periods. This would provide early detection of emerging disease outbreaks (e.g. zoonotic diseases, potential permafrost release of new and old pathogens) or changes in nutrition and non-communicable disease burden and support the assessment of the integrated health, environmental, and socioeconomic effect of policies and technologies.
- Explore strategies to reduce environmental damage and harmful emissions (e.g. air pollution) including assessment of health co-benefits through engagement with relevant HE partnerships and missions;
- Explore implications of planetary health for health systems and public health and identify opportunities to mitigate adverse health impacts of environmental degradation;
- Improve risk communication to policy makers, public authorities, industry and the public and support evidence-informed decisions by policy makers, by increasing capacity to do systematic reviews and provide rigorous policy briefs;
- Advance knowledge and actions to reduce the burden of non-communicable diseases while reducing the environmental pressure in areas like nutrition, physical activity, and mobility, and to assess the integrated health, environmental, and socioeconomic effect of those actions (i.e. behaviour change interventions, policies or new technologies);
- Provide better understanding on adaptation to climate and other environmental changes to protect human health, including the interactions between different planetary boundaries and the need to integrate adaptation and mitigation strategies;
- Improved health impact assessment approaches accounting for environmental externalities and estimating the cost and benefits of interventions versus no action.

This topic requires the effective contribution of social 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. Researchers should carefully integrate distributive considerations in their analysis by considering, where relevant, disaggregated effects for different socio-economic groups.

All projects funded under this topic are required to participate in networking and joint activities, as appropriate. These networking and joint activities can, for example, involve the exchange of knowledge, the development and adoption of best practices, the organization of common capacity building activities (e.g. joint workshops) and joint communication and dissemination activities. Therefore, proposals are required to allocate a sufficient budget for the attendance to regular joint meetings and to cover the costs of any other potential networking and joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission will take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate. Networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, can also be considered, if relevant (e.g. the projects funded by the Climate Adaptation Mission WP 2021-2022). Proposals should coordinate with the work being developed under EU4Health 2022 CP-g-22-04.01 Direct grants to Member States' authorities: setting up a coordinated surveillance system under the One Health approach for cross-border pathogens that threaten the Union⁵¹.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-ENVHLTH-02-02: Evidence-based interventions for promotion of mental and physical health in changing working environments (post-pandemic workplaces)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 5.00 and 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 30.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's

⁵¹ [21 11 19 Annex I - track changes \(europa.eu\)](https://europea.eu)

	programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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

- Public authorities and regulators are supported with evidence-based guidance to design occupational health policies;
- Public authorities, employers, organisations and social partners (e.g. trade unions and employer organisations) are better supported with tools, evidence-based intervention options and guidelines to promote mental and physical well-being and health in the workplace;
- Public authorities and the scientific community have access to FAIR data⁵² and robust evidence on direct links between psychosocial and physical risk factors at the workplace (considering also individual differences such as age, gender, cultural background, bodily/cognitive abilities) and specific health outcomes;
- Public authorities, regulators and social partners are informed by evidence on the costs, benefits, sustainability and expected challenges of available solutions;
- Public authorities and employers take advantage of the best available knowledge (including new innovations and ways for action) to support interventions and solutions on the design of the built working environment and promote healthier behaviours at the workplace;
- Public authorities and employers develop adequate measures to prevent and reduce the negative outcomes of exposure to psycho-social and physical risk factors in the work place and support recovery;
- Workers are more protected against work-related hazards and informed about effective prevention approaches based on specific and appropriate measures and health enhancing behaviours;

⁵² 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.

- Workers living with a chronic disease and/or recovering from a mental or physical health problem are supported to continue/return to work.

Scope: The digital and green transitions (referred to as ‘twin transition’) have been changing the workplace at a rapid pace, leading to new forms of work (e.g. hybrid work, gig economy jobs) or changes in the forms of management and work organisation (e.g. through algorithmic decision-making and digital worker performance monitoring) for workers across the spectrum. These changes have varying impacts on the working conditions, income and health and occupational safety both for skilled and unskilled workers. Furthermore, they contribute to the high costs of work-related illnesses and accidents for employers and the European economy in general.

Mental health and ergonomic-related problems affect a significant number of EU workers. Musculoskeletal disorders (MSDs) are one of the most common work-related health problems in the EU and workers and managers commonly identify stress, depression and anxiety as serious psychosocial outcomes of workplace exposures. Changes in the organisation of work can bring flexibility that allows more people to enter the labour force, but may also lead to psychosocial problems (for example, insecurity, compromised privacy and rest time, inadequate OSH and social protection, as well as stress due to excessive or atypical working hours, performance monitoring by algorithms and similar AI applications).

Some workplaces have either become exclusively virtual or they have evolved into a ‘hybrid’ model (e.g. multilocal working, home office), some work tasks and processes performed virtually and others requiring physical presence⁵³. A significant number of jobs are performed at clients’ premises or require workers to commute long distances and/or cross borders regularly. Such workers are facing additional legal, social, environmental and economic issues. Data on how these affect their mental/physical health and well-being is scarce.

The emergence and persistence of the Covid-19 pandemic has accelerated the pace of change, causing, in some cases, additional challenges for workers’ mental health (differentially affecting certain segments of the working force) and intensifying already existing physical risk factors (e.g. ergonomic risks). The European Pillar of Social Rights Action Plan⁵⁴ aims to promote a healthy, safe and well-adapted work environment in the EU and relies on Horizon Europe for research and innovation supporting economic and social resilience and sustainability. The EU strategic framework on health and safety at work 2021-2027⁵⁵ recognises the needs, challenges and opportunities that technological innovation and the pandemic bring for the working population and calls for strengthening the evidence-base for policymaking and implementation.

⁵³ The future of working in a virtual environment and occupational safety and health, <https://osha.europa.eu/en/publications/future-working-virtual-environment-and-occupational-safety-and-health>

⁵⁴ <https://op.europa.eu/webpub/empl/european-pillar-of-social-rights/en/>

⁵⁵ <https://osha.europa.eu/en/safety-and-health-legislation/eu-strategic-framework-health-and-safety-work-2021-2027>

To address the issues described above, research actions under this topic should include several of the following activities:

- Provide adequate and robust data on the impact (positive and negative) that the ongoing changes in the workplace are having on the mental and physical health of different categories of workers and working sectors (e.g. teleworkers, cross-border commuters, gig economy workers, and vulnerable groups such as women, migrants and young and older workers with increased demonstrated risk for MSDs), including gender and intersectional analyses, where appropriate;
- Generate evidence (including data) not only on mental health, but also on mental well-being at the workplace and how changing work organisation due to the twin transitions and the pandemic affects workers' work-life balance and work ability;
- Generate evidence (including data) on the importance of risk factors (such as stress caused by new working environments, static postures and physical inactivity, physically strenuous and highly repetitive work arising from the workplace design) in the development of chronic and acute diseases;
- Increase the understanding of the links between different health-promoting factors in the working built environment and physical and mental health outcomes, and how these may be mutually reinforcing;
- Explore the health impacts of changing working times, including excessive and atypical working hours and work in different time zones that blur work from leisure time, limiting recovery. Effects should consider a wide range of diseases;
- Provide recommendations for effective interventions to prevent occupational risks and support the mental and physical health and well-being at individual (worker), organisation (employer) and policy (government) levels for different sectors/types of work, including an analysis on their cost-effectiveness, sustainability and barriers to implementation at national and/or EU level;
- Advance the development of a scientific framework addressing Occupational safety and health (OSH) across policies and sectors and support new and sustainable (future-proof) tools, guidelines and policies concerning the evaluation and design of physical and psychosocial work environment;
- Provide tools and approaches to anticipate new OSH risks, also taking account of lessons learnt from the COVID-19 pandemic, for instance in relation to digital technologies and associated new ways of working.

This topic requires the effective contribution of social 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. Researchers should carefully integrate

distributive considerations in their analysis by considering, where relevant, disaggregated effects for different socio-economic groups.

Projects are expected to contribute to the New European Bauhaus (NEB) initiative⁵⁶ by interacting with the NEB Community, NEBLab and other relevant actions of the NEB initiative through sharing information, best practice, and, where relevant, results.

All projects funded under this topic are required to participate in networking and joint activities, as appropriate. These networking and joint activities can, for example, involve the exchange of knowledge, the development and adoption of best practices, the organization of common capacity building activities (e.g. joint workshops) and joint communication and dissemination activities. Therefore, proposals are required to allocate a sufficient budget for the attendance to regular joint meetings and to cover the costs of any other potential networking and joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission will take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate. Networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, can also be considered, if relevant.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-ENVHLTH-02-03: Health impacts of endocrine-disrupting chemicals: bridging science-policy gaps by addressing persistent scientific uncertainties

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 6.00 and 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 40.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.

⁵⁶ https://europa.eu/new-european-bauhaus/index_en

	The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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

- Public authorities and regulators are supported with scientific evidence to implement the comprehensive European Union Framework on Endocrine Disruptors⁵⁷, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment⁵⁸ and EU legislation on plant protection products⁵⁹;
- Public authorities improve their risk assessment, management and communication through access to FAIR⁶⁰ data and more robust evidence on the causal links between exposure to endocrine disruptors and health outcomes for which insufficient data exist;
- Research community has better data on the role of endocrine disruptors and other co-factors (e.g., life-style, behavioural, socio-economic) to enable a better understanding of their individual or combined health impacts;
- Public authorities and the scientific community take advantage of latest methodologies for advancing the understanding of health impact of exposures;
- Public authorities, employers and citizens rely on practical evidence-informed guidelines for exposure prevention and reduction;
- Citizens are engaged and informed about the health impact of exposures to endocrine disruptors and risk-preventing behaviours are promoted.

Scope: The function and regulation of the endocrine system in humans and other species is of high biological complexity. Endocrine disrupting chemicals (EDCs or endocrine disruptors) are chemical substances that alter the functioning of the endocrine system and negatively affect the health of humans and animals. They may either be of synthetic or natural origin. Exposure to endocrine disruptors can occur from different sources, such as residues of pesticides or consumer products used or being present in our daily life.

⁵⁷ https://ec.europa.eu/info/policies/endocrine-disruptors_en

⁵⁸ [Chemicals strategy \(europa.eu\)](https://ec.europa.eu/info/policies/chemicals-strategy_en)

⁵⁹ <https://www.efsa.europa.eu/en/efsajournal/pub/5311>

⁶⁰ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability

EDCs are of increasing importance in chemical regulations in the European Union. According to the Comprehensive European Union Framework on Endocrine Disruptors, adopted in 2018, the EU strategic approach on endocrine disruptors for the years to come should be based on the application of the precautionary principle. This approach would aim at, *inter alia*, minimising overall exposure of humans and the environment to endocrine disruptors, paying particular attention to exposures during important periods of development of an organism, such as foetal development and puberty, possibly integrating a life course approach, as well as accelerating the development of a thorough research basis for effective and forward-looking decision-making. This includes research for the further management of chemicals (including multi-constituent chemicals as well as chemical mixtures), the understanding of the mechanistic effects of endocrine disruptors (including at the molecular and cellular level through the use of new approach methodologies, such as ‘multiomics’, cheminformatics, *in vitro* 2D and 3D models, *in vivo* models and computational approaches), and the collection, sharing, harmonization and combination of robust data sources.

Closing existing knowledge gaps in the understanding of EDC effects will support more effective and evidence-based regulations at the European level.

Bringing together, *inter alia*, (molecular) epidemiologists, exposure scientists, toxicologists, endocrinologists, health care practitioners and risk assessors, research actions under this topic should focus on the understanding of the impact of exposures at critical life stages in diseases developing later in life, focusing on the several health endpoints for which there is currently less information available. Advantage should be taken of existing biobanks and disease registries and/or cohorts, with carefully planned measurement strategies and clearly worked-out hypotheses. The issues of non-monotonic dose-response relationships and whether effects are threshold-dependent should be addressed in the study designs. Similarities between endocrine systems and certain health outcomes across species should be exploited to improve understanding of endocrine functioning. Finally, research should attempt at identifying predictive biomarkers (e.g. from liquid biopsies such as saliva, urine, blood) that would allow the tracing of endocrine disrupter-mediated health effects in a shorter period of time than normally would be required for epidemiological studies.

Research actions under this topic should provide forward-looking mechanistic information on potential hazards and health risks of exposures to EDCs, through innovative molecular epidemiological, multifactorial models and systems biology approaches, exploiting the use of new approach non-animal methodologies when relevant, and should include several of the following activities:

- Studying the impact of EDCs on target organs and in multi-organ models, and physiological barriers, such as the placenta, the blood-brain barrier, the blood-saliva barrier, intestinal, pulmonary and immune cells as well as their interaction with microbiota;
- Elucidating health endpoints for which insufficient data exist, such as disturbances in the development and functioning of the nervous and cardiovascular systems, the immune

system, bone development and disease, obesity, diabetes, hormone-dependent cancers and fertility (e.g. minipuberty, prepuberty and puberty);

- Providing better biological and imaging biomarkers to predict EDC-mediated health outcomes;
- Gaining better insights into the developmental origins of health and disease, especially for those where less data are available. Assessing the occurrence and relevance of multi- and transgenerationally inherited effects, including molecular and epigenetic mechanisms that drive multigenerational effects;
- Gaining better insights into the most sensitive windows of susceptibility, during which exposure are of particular importance for health effects;
- Better understanding of the effects of chemicals and chemical mixtures on the underlying mechanistic crosstalk between endocrine axes, endocrine pathways and other key biological systems, including immune, neurological and metabolic functions;
- Improving the understanding of chemical mixture effects, including with other toxins and at low doses. The role of the microbiome in the activation or detoxification of these chemicals should be explored where relevant.
- Investigating biological effects of realistic mixtures to get a more detailed understanding of the endocrine effectome, taking advantage of computational toxicology and development of up-to-date models (including state of the art new approach non-animal models such as human organoids and organ-on-a-chip technology);
- Exploiting non-mammalian species as test organisms, e.g. non-mammalian vertebrates and invertebrates to predict effects or raise concern about potential effects in humans or vice versa and performing comparative analysis between species;
- Exploiting systems biology approaches in order to understand how exposure to an EDC results in an altered phenotype, a process that implies complex interactions across multiple levels of biological organization.

Aspects such as gender, regional variations, socio-economics and culture should be considered, where appropriate. Proposals should ensure that chemical monitoring data are shared in IPCHEM⁶¹ through involvement with the European Commission's Joint Research Centre (JRC). Proposals should also consider involving JRC with respect to the value it could bring in providing an effective interface between the research activities and regulatory aspects and/or to translating the research results into validated test methods and strategies fit for regulatory purpose. In that respect, the JRC will collaborate with any successful proposal and this collaboration, when relevant, should be established after the proposal's approval.

⁶¹ [IPChem Portal \(europa.eu\)](https://ipchem.europa.eu)

Proposers should be acquainted with planned activities under the European partnership for the assessment of risks from chemicals PARC⁶². PARC will be informed about successful proposals. Successful proposals will be invited to establish synergies with PARC and take advantage of the partnership as a facilitator for open data and methodology sharing with risk assessors and their scientific networks.

This topic requires the effective contribution of social 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.

All projects funded under this topic are required to participate in networking and joint activities, as appropriate. These networking and joint activities can, for example, involve the exchange of knowledge, the development and adoption of best practices, the organization of common capacity building activities (e.g. joint workshops) and joint communication and dissemination activities. Therefore, proposals are required to allocate a sufficient budget for the attendance to regular joint meetings and to cover the costs of any other potential networking and joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission will take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate. Networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, can also be considered, if relevant.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-ENVHLTH-02-04: Global coordination of exposome research

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 3.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 3.00 million.
<i>Type of Action</i>	Coordination and Support Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: Legal entities established in the United States of America may

⁶² <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2021-envhlth-03-01>

	<p>exceptionally participate in this Coordination and support action in a capacity other than Associated Partner.</p> <p>In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>Coordinators of projects must be legal entities established in an EU Member State or Associated Country.</p> <p>The following additional eligibility criteria apply:</p> <p>In order to achieve the expected objectives, namely the establishment of a forward looking cooperation framework in the area of the exposome, the consortium must include at least one legal entity established in a country other than a Member State or an Associated Country.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

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

- Environment and health research community, research-policy-making authorities, research funders and other relevant stakeholders work together at the European and international level towards establishing a medium-long-term Global Human Exposome Network;
- Environment and health research community, authorities working at the science-policy interface and research funders provide options for functioning, financing and governance of a medium-long-term Global Human Exposome Network considering also the strengthening of the coordination of the European Human Exposome Network;
- Relevant stakeholders profit from a strengthened coordination and collaboration globally among different fields of research and innovation with relevance to deciphering the human exposome;

- A roadmap and a R&I agenda for international cooperation in specified areas of exposome research and innovation, including, among others, recommendations for exchange of knowledge and data, policy uptake, technological and conceptual approaches and promotion of global level coordinated initiatives on the exposome are made available to the relevant international stakeholders;
- The coordination of research initiatives, infrastructures, facilities and resources in the area of the Exposome in Europe is supported and reinforced;
- The interoperability and harmonisation between data and studies is increased facilitating the exchange and use of information across research disciplines and groups.

Scope: The concept of the exposome refers to the totality of environmental exposures from conception onwards, including its external (e.g. diet, lifestyle, occupational and environmental factors) and internal components (e.g. epigenomics, metabolomics). Developing a comprehensive Human Exposome Project would present a fundamental shift in looking at health, by moving research away from ‘one exposure, one disease’ understanding to a more complex picture upon which to build solid, cost-effective preventive actions and policies. At its most complete, the efforts could resemble in scope the Human Genome Project.

The European Human Exposome Network (EHEN)⁶³, a cluster of 9 projects funded since 2020 for five years from Horizon 2020, is currently the world’s largest network of projects studying the impact of environmental exposure on human health with an exposome angle. Together, the network of projects aims to study the combination of exposures to pollutants and other stressors, across different life stages and socio-economic conditions, via a number of exposure vehicles such as consumption patterns, lifestyle and working and living environment, and their collective effect on human health.

At the international level, some related activities are ongoing in, e.g., the US (National Institute for Environmental Health Sciences) and Japan. Currently, there is only sporadic cooperation initiatives between the ongoing research at the EU level and important research groups outside Europe. However, in order to fulfil the promise of deciphering the human exposome, a large-scale effort similar to the Human Genome Project could be envisaged, for which a preparatory coordination and support action would be highly useful to identify and discuss the research needs and specific areas of potential cooperation at the global level. Additionally, both at the European and global level better coordination is essential to foster new opportunities to collect, harmonise, combine and analyse large data sets emanating from new and evolving technologies. This offers also new possibilities to understand the pathways leading from a multitude of environmental exposures to the global health burden of common chronic diseases. Standardization and interoperability of data is also needed to assure access to quality data sources at the European and global level.

On the policy side, the outcomes of advancing the exposome research can touch upon and contribute to a better implementation of a wide range of policies and EU priorities such as the

⁶³ <https://www.humanexposome.eu/>

EU Chemicals Strategy⁶⁴, Zero Pollution Action Plan⁶⁵, the European Green Deal⁶⁶ and climate policies⁶⁷, among others. The benefits of cooperation would also extend to international initiatives such as activities of the World Health Organization related to environment and health⁶⁸ and the United Nations activities on climate⁶⁹ and environment⁷⁰.

Accordingly, proposals should cover, among others, most of the following activities:

- Proposal for a common agreed conceptual framework for the exposome;
- Proposal for options for a global governance structure for a Global Human Exposome Network taking advantage of and connecting to the existing research infrastructures and services in the area of the Exposome at the European level;
- Agreed technologies needed to decipher the external and internal exposome, support longitudinal studies and potential for international cooperation;
- Proposal for data mining, analysis, opportunities for harmonisation, interoperability, and standardisation in data collection, knowledge storage and transfer, and bioinformatics needs at the European and global level;
- Cooperation between population and patient cohorts, integrating a large number of variables and comprehensive environmental datasets, and biobanks, covering also the perinatal period;
- Facilitation of the regulatory uses of results including for regulatory science and risk assessment.

Proposals should interact with existing research infrastructures, services and research projects in the area of the exposome (namely the European Human Exposome Network but also other related projects and actions supported through Horizon 2020 and Horizon Europe) and build on and integrate the work being developed in these initiatives. The composition of the applicant consortia should ensure a broad and balanced geographical representation of Member States and Associated Countries and the proposals should involve also Widening Member States and Associated Countries. International cooperation beyond EU with interested parties is required.

Call - Environment and health (Two stage - 2024)

HORIZON-HLTH-2024-ENVHLTH-02-two-stage

⁶⁴ https://ec.europa.eu/environment/strategy/chemicals-strategy_en

⁶⁵ https://ec.europa.eu/environment/strategy/zero-pollution-action-plan_en

⁶⁶ https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

⁶⁷ https://ec.europa.eu/clima/index_en

⁶⁸ <https://www.who.int/health-topics/environmental-health>; <https://www.euro.who.int/en/health-topics/environment-and-health>

⁶⁹ <https://www.un.org/en/climatechange>

⁷⁰ <https://www.unep.org/>

Conditions for the Call

Indicative budget(s)⁷¹

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ⁷²	Indicative number of projects expected to be funded
		2024		
Opening: 30 Mar 2023 Deadline(s): 19 Sep 2023 (First Stage), 11 Apr 2024 (Second Stage)				
HORIZON-HLTH-2024-ENVHLTH-02-06-two-stage	RIA	60.00	7.00 to 8.00	8
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.
<i>Procedure</i>	The procedure is described in General Annex F.

⁷¹ 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 2023 and 2024.

⁷² Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

**Horizon Europe - Work Programme 2023-2024
Health**

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

HORIZON-HLTH-2024-ENVHLTH-02-06-two-stage: The role of environmental pollution in non-communicable diseases: air, noise and light and hazardous waste pollution

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 7.00 and 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 60.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Admissibility conditions</i>	<p>The conditions are described in General Annex A. The following exceptions apply:</p> <p>Applicants submitting a proposal under the blind evaluation pilot (see General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in Part B of their first stage application (see General Annex E).</p>
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative</p>

	threshold will be 12.
<i>Procedure</i>	The procedure is described in General Annex F. The following exceptions apply: This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). ⁷³ .

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

- National and EU authorities apply user-friendly tools to produce and use generated data on the impact of pollutants on health;
- National and EU authorities benefit from access to robust and transparent indicators for health impact assessment to monitor efficacy of pollution-mitigating actions and policies;
- Policy-makers and other stakeholders, e.g. public authorities such as urban planners, health professionals, employers, civil society organisations and citizens, use developed guidelines to take action to prevent pollution-related illnesses and impairments, and choose healthier lifestyles and behaviours;
- EU, national and regional authorities receive guidance and recommendations for updates of (1) scientific evidence about health risks caused by environmental pollutants (2) advice on management and mitigation of these health risks and (3) guidance and recommendations for updates of limit values for different classes of pollutants in the environment; these recommendations should take into account vulnerable population groups and people with increased vulnerability because of pre-existing medical conditions;

⁷³ This [decision](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf) is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under ‘Simplified costs decisions’ or through this link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf

- The implementation of the Zero-Pollution Action Plan, the Chemical Strategy for Sustainability and the EU legislation on air quality, noise and waste continue to be supported by a strong evidence-base;
- Relevant actors in our daily lives, e.g. medical personnel, building engineers, teachers, urban planners etc., have access to information such as training courses on pollution and health impacts.

Scope: The European Green Deal set out by the European Commission recognises that man-made environmental pollution is an increasing threat for human health and wellbeing. Opinion polls⁷⁴ show that climate change, air pollution, and waste are the three most important environmental issues that European citizens are concerned about. Over three-quarters (78%) of respondents believe that environmental issues have a direct effect on their daily life and health.

Pollution affects a large number of people in Europe and beyond: A 2018 assessment attributed 16% of total global mortality to pollution-related disease. Over 7 million people die of exposure to polluted air every year worldwide⁷⁵. For 2019, the European Environment Agency has estimated that around 350 000 premature deaths in the EU can be attributed to air pollution (namely from particulate matter, nitrogen dioxide and ozone)⁷⁶. Today, more than 1 in 4 Europeans is exposed to traffic noise levels dangerous to their health in their homes, schools and workplaces⁷⁷. The increase of artificial light at night (ALAN) in cities has altered the natural light levels in the environment and extended human activities to the usually dark hours. It has been estimated that more than 80% of the world population is living under light polluted skies⁷⁸. Waste⁷⁹ continues to be a persistent environmental issue in Europe, and it is estimated that there are 2.5 million contaminated sites in Europe, with potentially significant adverse health effects⁸⁰.

The global burden from non-communicable diseases (NCDs) has consistently increased over the last decades, being now estimated to account for 70% of deaths globally (World Health Organization). The growing burden of chronic diseases will also be a challenge for Europe's healthcare systems, these diseases already accounting for an estimated 70-80% of healthcare costs. Currently, around 50 million European citizens suffer from two or more chronic conditions and most of these people are over 65.⁸¹ The most recent WHO environmental burden of disease estimations suggest that, annually, 13% of deaths (630 000) in the WHO Europe region are attributable to environmental stressors and an EEA report concluded that, 90% of deaths attributable to the environment result from non-communicable diseases,

⁷⁴ E.g. Eurobarometer 501 – 2020- https://ec.europa.eu/commission/presscorner/detail/en/ip_20_331

⁷⁵ [Air pollution \(who.int\)](#)

⁷⁶ For more details, see Briefing no. 19/2021: Health impacts of air pollution in Europe, 2021

⁷⁷ [EEA 2020 report on Healthy environment, healthy lives: how the environment influences health and well-being in Europe](#)

⁷⁸ [Evaluating the Association between Artificial Light-at-Night Exposure and Breast and Prostate Cancer Risk in Spain \(MCC-Spain Study\) | Environmental Health Perspectives | Vol. 126, No. 4 \(nih.gov\)](#)

⁷⁹ https://ec.europa.eu/environment/topics/waste-and-recycling_en

⁸⁰ Data presented at the Ministerial Meeting on Environment and Health, Ostrava, CZ (2017)

⁸¹ [European Commission 2020 Report on the Impact of Demographic Change](#)

including cancers, cardiovascular diseases, stroke, chronic obstructive pulmonary disease, mental, behavioural and neurological disorders, diabetes, kidney disease and asthma.⁷² While early childhood deaths have declined, the years lived with disability have increased, particularly with chronic disease.

The proposed research should strengthen the knowledge base available to policy-makers regarding pollution-disease associations and causal mechanisms at different phases of the life course, taking advantage of latest molecular, cellular and computational technologies to elucidate biological pathways from exposure (including combined exposures) to disease. The work should bring together toxicology, exposure science, public health engineering and environmental epidemiology, and build on data from sources such as pollution-related databases, disease registries, epidemiological studies and biobanks, environmental and human biomonitoring data and new generated data and could consider citizen science and other innovative approaches. All exposure routes should be considered where relevant (oral/digestive tract, inhalation, dermal).

The focus of this topic shall be on three areas where the understanding of and evidence on causality should be strengthened to overcome the current paucity of data and respond to calls from policy-makers. The applicants shall focus on at least one of the following three aspects:

- Air pollution, especially in the urban environment, taking into account existing evidence, notably the latest WHO air quality guidelines of 2021 and their recommendations on different pollutants⁸², including on pollutants of emerging concern, looking at e.g. ultrafine particles and interactions with aeroallergens, black carbon, sand and dust storms and impact on human health;
- Noise pollution and light pollution impact on human health;
- Pollution from hazardous waste (e.g. pharmaceuticals, illicit drugs, e-waste, plastics (including nano- and microplastics)) in heavily contaminated environments and adverse health outcomes.

Several of the following activities shall be included:

- Research activities to strengthen the evidence base for pollution-disease associations and underlying causality mechanisms and biological pathways, taking into account combined exposures and mechanisms of increased sensitivity in susceptible groups;
- Delivery of FAIR⁸³ data on causal associations between environmental risk factors and health outcomes, in particular for air pollutants of emerging concern, specifically ultrafine particles, black carbon, and others, taking into account vulnerable population

⁸² World Health Organization. (2021). WHO global air quality guidelines: particulate matter (PM2.5 and PM10), ozone, nitrogen dioxide, sulfur dioxide and carbon monoxide. World Health Organization. <https://apps.who.int/iris/handle/10665/345329>.

⁸³ 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.

groups and specific exposure situations in a life-course approach including vulnerable early-stages of life and transgenerational risks;

- Development of user-friendly tools for systematic mining and assessment of the knowledge generated and translation into best practices and to improve the assessment of individual life-exposure to pollutants;
- Proposals for environmental limit values for the studied pollutants and generation of health impact indicators, where relevant and taking into account existing standards and evidence;
- Development of guidelines and socio-economic and decision support tools for different actors including policy makers, health professionals and citizens to take action to prevent pollution-related illnesses and impairments, and to enable the choice of healthier lifestyles and behaviours;
- Identification of cross-sectoral interventions (case studies) with the potential for remediating pollution and risk of exposure and improving human health and well-being in the short/medium term;
- Development of training courses on pollution and health impacts to inform professionals impacting our daily lives e.g. medical personnel, engineers, teachers, urban planners;
- Design of best-practice evidence-based communication actions for fact-based risk and benefit communication and improving citizen awareness of pollution and preventive actions, offsetting dissemination of misinformation;
- Undertaking case studies to demonstrate the added societal value of tools, methodologies and guidelines developed and the implementation of resulting actions to decrease health impacts of exposures.

Aspects such as gender, regional variations, socio-economics and culture should be considered, where appropriate. Proposals should ensure that chemical monitoring data are shared in IPCHEM⁸⁴ through involvement with the European Commission's Joint Research Centre (JRC). In that respect, the JRC will collaborate with any successful proposal and this collaboration, when relevant, should be established after the proposal's approval.

This topic requires the effective contribution of social 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.

All projects funded under this topic are required to participate in networking and joint activities, as appropriate. These networking and joint activities can, for example, involve the exchange of knowledge, the development and adoption of best practices, the organization of

⁸⁴ [IPChem Portal \(europa.eu\)](https://ipchem.europa.eu)

common capacity building activities (e.g. joint workshops) or joint communication and dissemination activities. Therefore, proposals are required to allocate a sufficient budget for the attendance to regular joint meetings and to cover the costs of any other potential networking and joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission will take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate. Networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, can also be considered, if relevant.

Applicants of second stage envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

DRAFT

Destination 3. Tackling diseases and reducing disease burden

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

Communicable and non-communicable diseases cause the greatest amounts of premature death and disability in the EU and worldwide. They pose a major health, societal and economic threat and burden. Many people are still suffering from these diseases and too often dying prematurely. Non-communicable diseases, including mental illnesses and neurodegenerative diseases, are responsible for up to 80% of EU health care costs⁸⁵. These costs are spent on the treatment of such diseases that to a large extent are preventable. Furthermore, only around 3% of the health care budgets are currently spent on preventive measures although there is a huge potential for prevention. Infectious diseases, including emerging infectious diseases and infections resistant to antimicrobials, remain a major threat to public health in the EU but also to global health security. Deaths caused by antimicrobial resistance (AMR) could exceed 10 million per year worldwide according to some predictions⁸⁶.

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

⁸⁵ 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).

⁸⁶ 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.

global health security, including the global burden of non-communicable diseases, and to strengthen patient safety.

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

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

Based on needs that emerged during the management of COVID-19, some research and innovation actions under Destination 3 should support the mission of the European Health

Emergency and Response Authority (HERA) to strengthen Europe’s ability to prevent, detect, and rapidly respond to cross-border health emergencies by ensuring the availability and access to key medical countermeasures. Other actions should deliver relevant complementary inputs to the “Europe’s Beating Cancer Plan”⁸⁷ in order to cover the entire cancer care pathway, including prevention, early detection, diagnosis, treatment, cancer data monitoring, as well as quality of life of cancer patients and survivors. Furthermore, synergies and complementarities will be sought between Destination 3 and the implementation of the EU4Health Programme (2021-2027)⁸⁸. These synergies and complementarities could be achieved, notably through mechanisms based on feedback loops, enabling on the one hand to identify policy needs that should be prioritised in research and innovation actions and facilitating on the other hand the implementation of research results into policy actions and clinical practice, thereby providing an integrated response across sectors and policy fields.

Expected impacts:

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

- Health burden of diseases in the EU and worldwide is reduced through effective disease management, including through the development and integration of innovative diagnostic and therapeutic approaches, personalised medicine approaches, digital and other people-centred solutions for health care. In particular, patients are diagnosed early and accurately and receive effective, cost-efficient and affordable treatment, including patients with a rare disease, due to effective translation of research results into new diagnostic tools and therapies.
- Premature mortality from non-communicable diseases is reduced by one third (by 2030), mental health and well-being is promoted, and the voluntary targets of the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 are attained (by 2025), with an immediate impact on the related disease burden (DALYs)^{89,90, 91}.
- 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

⁸⁷ <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan>

⁸⁸ https://ec.europa.eu/health/funding/eu4health_en

⁸⁹ 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.

⁹⁰ 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.

⁹¹ 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.

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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^{92, 93}.
- Patients and citizens are knowledgeable of disease threats, involved and empowered to make and shape decisions for their health, and better adhere to knowledge-based disease management strategies and policies (especially for controlling outbreaks and emergencies).

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

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

Call	Budgets (EUR million)		Deadline(s)
	2023	2024	
HORIZON-HLTH-2023-DISEASE-03	224.00		13 Apr 2023
HORIZON-HLTH-2023-DISEASE-07	50.00		19 Sep 2023
HORIZON-HLTH-2024-DISEASE-03-two-stage		125.00	19 Sep 2023 (First Stage) 11 Apr 2024 (Second Stage)
HORIZON-HLTH-2024-DISEASE-08		52.00	11 Apr 2024
HORIZON-HLTH-2024-DISEASE-09		100.00	11 Apr 2024
Overall indicative budget	274.00	277.00	

⁹² WHO global action plan on antimicrobial resistance, 2015

⁹³ EU One Health Action Plan against AMR, 2017

Call - Tackling diseases (Single stage - 2023)

HORIZON-HLTH-2023-DISEASE-03

Conditions for the Call

Indicative budget(s)⁹⁴

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ⁹⁵	Indicative number of projects expected to be funded
		2023		
Opening: 12 Jan 2023 Deadline(s): 13 Apr 2023				
HORIZON-HLTH-2023-DISEASE-03-01	RIA	50.00 ⁹⁶	6.00 to 7.00	8
HORIZON-HLTH-2023-DISEASE-03-03	RIA	20.00 ⁹⁷	3.00 to 4.00	5
HORIZON-HLTH-2023-DISEASE-03-04	RIA	50.00 ⁹⁸	7.00 to 8.00	7
HORIZON-HLTH-2023-DISEASE-03-05	CSA	3.00 ⁹⁹	1.00 to 2.00	2
HORIZON-HLTH-2023-DISEASE-03-06	CSA	1.00 ¹⁰⁰	Around 1.00	1
HORIZON-HLTH-2023-DISEASE-03-07	RIA	30.00 ¹⁰¹	6.00 to 7.00	5
HORIZON-HLTH-2023-DISEASE-03-17	RIA	20.00 ¹⁰²	7.00 to 8.00	5
HORIZON-HLTH-2023-DISEASE-03-18	RIA	50.00 ¹⁰³	7.00 to 8.00	7

⁹⁴ 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 2023 and 2024.

⁹⁵ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

⁹⁶ Of which EUR 30.00 million from the 'NGEU' Fund Source.

⁹⁷ Of which EUR 11.00 million from the 'NGEU' Fund Source.

⁹⁸ Of which EUR 30.00 million from the 'NGEU' Fund Source.

⁹⁹ Of which EUR 1.50 million from the 'NGEU' Fund Source.

¹⁰⁰ Of which EUR 0.50 million from the 'NGEU' Fund Source.

¹⁰¹ Of which EUR 17.00 million from the 'NGEU' Fund Source.

¹⁰² Of which EUR 11.00 million from the 'NGEU' Fund Source.

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Overall indicative budget		224.00		
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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-2023-DISEASE-03-01: Novel approaches for palliative and end-of-life care for non-cancer patients

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 6.00 and 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
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the

¹⁰³ Of which EUR 30.00 million from the 'NGEU' Fund Source.

	United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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

- Reduced health-related suffering and improved well-being and quality of life of patients in need of palliative and end-of-life care and their professional and family caregivers.
- Patients have early and better access to palliative or end-of-life care services of higher quality and (cost) effectiveness.
- Patients and their professional and family caregivers are able to engage meaningfully with the improved evidence-based and information-driven palliative care joint decision-making process.
- Health care providers and health policy makers have access to and use the improved clinical guidelines and policy with respect to pain and/or other symptoms management, psychological and/or spiritual support, and palliative or end-of-life care for patients.
- Reduced societal, healthcare and economic burden associated with increasing demands of palliative or end-of-life care services that is beneficial for citizens and preserves sustainability of the health care systems.

Scope: The complexity of health conditions related to life-threatening and chronic diseases, acute and chronic pain, late or long-term side effects as consequences of diseases and also their treatments affect quality of life of patients and their families and pose an immense societal and economic burden. Palliative¹⁰⁴ and end-of-life care approaches improve quality of life of 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 factors such as physical, psychosocial and spiritual problems. Although a variety of interventions are in use, they are often not adequately validated or adapted to the specific needs of patients affected by complex diseases or their co- or multimorbidities. Therefore, a need exists to strengthen the evidence base for available patient-centred effective interventions improving quality of life and outcomes of patients of all ages in the domains of palliative and end-of-life care.

¹⁰⁴ <https://www.who.int/cancer/palliative/definition/en/>

Proposals should address all of the following activities:

- Demonstrate the effectiveness and cost-effectiveness of newly proposed or specifically adapted pharmacological and/or non-pharmacological interventions to improve well-being and quality of life of patients suffering from life-threatening and chronic diseases¹⁰⁵ (including disabilities). Whenever relevant, serious late and long-term side effects of disease treatments or symptoms that occur at the end of life of patients should be considered. The legal and ethical aspects of the proposed interventions should be taken into consideration and be fully addressed.
- Prove the feasibility of integrating the proposed interventions in current pain management, palliative 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 those of 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.
- 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 equity¹⁰⁶ to the proposed interventions, including equitable access.
- Analyse the barriers and opportunities to re-invigorating and enhancing timely social inclusion and active engagement of patients in need of palliative and end-of-life care and their caregivers.
- Provide implementation strategies and guidelines of patient-centred communication for health and social care professionals as well as standards for evidenced based communication trainings for caregivers, considering the potential of social innovation approaches or tools.
- When relevant, provide policy recommendations for pain management, psychological and/or spiritual support, and palliative or end-of-life care of patients.

Randomised clinical trials and observational studies, targeting different age groups, 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.

¹⁰⁵ Proposals focused on cancer-related research are not in the scope of this topic. The supportive, survivorship, palliation and end-of-life care of cancer patients was already covered by the specific topic in the Cluster Health Work Programme 2021-2022. Applicants are invited to check the Work Programme of the Mission on Cancer for further funding opportunities for this research areas.

¹⁰⁶ https://www.who.int/topics/health_equity/en/

This topic requires the effective contribution of social 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. Proposals should consider a patient-centred approach that empowers patients, increase health literacy in palliative and end of life care, promotes a culture of dialogue and openness between health professionals, patients and their families, and unleashes the potential for social innovation.

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

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-DISEASE-03-03: Interventions in city environments to reduce risk of non-communicable disease (Global Alliance for Chronic Diseases - GACD)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 3.00 and 4.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 20.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of</p>

	Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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 most of the following expected outcomes:

- Health care practitioners and providers in low- and middle-income countries (LMICs) and/or those in high-income countries (HICs) serving vulnerable populations have access to and use specific guidelines to implement health interventions that decrease risk factors of non-communicable diseases (NCDs) associated with city¹⁰⁷ environments.
- Public health managers and authorities have access to improved insights and evidences on the NCDs caused or impacted by city environments and which factors influence the implementation of preventive actions that address risk behaviours in concerned city populations. They use this knowledge to design improved city planning policies to diminish health associated risks.
- Adopting an implementation science approach to studying interventions in different city contexts, researchers, clinicians and authorities have an improved understanding how specific interventions can be better adapted to different city environments and how the interventions could be scaled within and across cities taking into account specific social, political, economic and cultural contexts.
- Public health managers and authorities use evidence-based strategies and tools for promoting population health in equitable and environmentally sustainable ways, enabling cities to better address the challenges of rapid urbanisation, growing social inequalities, and climate change.
- Communities, local stakeholders and authorities are fully engaged in implementing and taking up individual and/or structural level interventions and thus contribute to deliver better health.

¹⁰⁷ Non-rural settings; a densely populated urban or peri-urban environment. Cities may also include informal settlements and slums surrounding city centres. Applicants can justify why a particular context may be considered a city.

Scope: The European Commission is a member of the Global Alliance for Chronic Diseases (GACD)¹⁰⁸. This topic is launched in concertation with the other GACD members and aligned with the 8th GACD call.

The topic is focused on implementation research with the potential to reduce the risks of NCDs in cities in LMICs and/or vulnerable populations in 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 multi-morbidity.

Non-communicable diseases, such as diabetes, cardiovascular disease, neurological diseases, respiratory diseases, certain cancers, and mental health disorders, are the leading cause of morbidity and mortality in both LMICs and HICs¹⁰⁹. The COVID-19 pandemic has brought these chronic diseases further into the spotlight, as the majority of those who have experienced severe illness and/or death have had one or more underlying NCD. Reducing the burden of NCDs is therefore critical to building more resilient, equitable, and healthier societies.

Air, water, and soil pollution; lack of greenspace; urban heat islands; lack of safe infrastructure for walking, cycling, and active living; and wide availability of tobacco, alcohol, and unhealthy foods and beverages drive the NCD epidemic in city environments¹¹⁰. More than half of the world's population currently live in cities and this number is projected to rise to 68% by 2050. There is an urgent need to equip local authorities and policymakers with strategies for maximising the health-promoting potential of cities, while minimising or reversing environmental degradation and health inequities.

Cities provide tremendous social, cultural, and economic opportunity, and have the potential to become engines of good health and support climate change adaptation¹¹¹. Innovative health-focused programmes, policies, and infrastructure, such as public smoking bans, bikeable streets, greenspace, and vehicle emission laws, can shape the behaviours of millions of people and decrease exposure to environmental contaminants. Applicants to the current call are invited to conduct implementation research that leads to improved understanding of how specific interventions can be better adapted to different city environments and/or scaled within and across cities, taking into account unique local social, political, economic, and cultural contexts.

The proposed implementation research must be focus on addressing NCD risk factors associated with city environments and related health inequities. In all cases, the selected study population(s) must live in cities, which may include informal settlements near urban centres, peri-urban environments, and city centres. The study population may include people with existing NCDs, those without existing NCDs, or a combination of both. Applicants are

¹⁰⁸ <https://www.gacd.org/>

¹⁰⁹ WHO. Noncommunicable Diseases. 2021. <https://www.who.int/en/news-room/fact-sheets/detail/noncommunicable-diseases>.

¹¹⁰ WHO. Urban health. 2022. and <https://www.who.int/news-room/fact-sheets/detail/urban-health>.

¹¹¹ <https://www.who.int/publications/i/item/WHO-NMH-PND-2019-9>

encouraged to take a life course approach, adapting the intervention to one or more key life stage(s) critical for reducing lifelong NCD risk.

Proposals should address all of the following activities:

- Select one or more city/ies in which the research will be conducted. Applicants must justify why a particular context is considered a city.
- Select one or more evidence-based interventions known to reduce NCD risk factor(s) associated with city environments. Applicants should justify the choice of intervention(s) and provide evidence of the intervention's effectiveness, acceptability, feasibility, and potential for long-term health and other impacts. Applicants may also wish to consider implementation research focusing on the WHO Best Buys, though this is not a requirement.
- Adapt these intervention(s) for selected study population(s) based in one or more city/ies, taking into account the unique social, political, economic, and cultural context(s). Applicants should justify why these adaptations will not compromise the known effectiveness of the selected intervention(s).
- Provide a research plan for investigating how to promote the uptake and/or scale-up of the intervention(s) in the selected study population(s), using validated implementation research frameworks.
- Specifically address issues of equitable implementation to ensure interventions reach the populations that need them the most.
- Have an appropriate strategy for measuring both implementation research outcomes and real-world effectiveness outcomes and indicators (related to NCD prevention and, if feasible, planetary health and/or non-health sectors).
- Demonstrate a commitment to stakeholder engagement.
- Demonstrate a commitment to planetary health in that the proposed intervention, implementation strategies and research practices minimise the consortium's ecological footprint.
- Provide a sustainability plan or describe a pathway to sustain the proposed intervention after the funding ends.

The proposed interventions of focus may fall under one or a combination of the following themes:

Theme 1: Behavioural change interventions

These interventions comprise of innovative approaches to helping people live in cities maintain good physical and mental health despite infrastructural, environmental, climate, and social challenges. Behavioural interventions might include, but are not limited to,

programmes and policies that target alcohol and tobacco use, sleep, exercise promotion, healthful nutrition (e.g. in school canteens), addressing the psychosocial impacts of climate change and climate change related disasters, and reducing exposure to environmental contaminants.

Theme 2: Interventions that focus on modifying the built environment¹¹²

These interventions focus on modifying the built environment to improve its health-promoting potential¹¹³. Proposals should aim to inform urban design such that it reduces NCD risks; for example, by improving a city's walk- or bike-ability, increasing green space to reduce the health impacts of air pollution or extreme heat, reducing environmental toxins, addressing homelessness or unsafe housing, improving accessibility of healthy foods, decreasing widespread advertising for tobacco and alcohol, or reducing noise and air pollution from road traffic. For proposals that focus on modifying the built environment, applicants should demonstrate that the intervention will be able to withstand expected impacts from climate and/or improve resilience to the health impacts of climate change in city environments.

Applicants should be able to show that the city government or community based organisation that they partner with has a dedicated budget for the construction, maintenance, and/or scale up of the proposed intervention(s), especially for large infrastructure projects. Applicants must also be able to show that the timelines of the research and construction of infrastructure projects will align such that it will be possible to answer the proposed implementation research questions over the proposed duration, and such that the research results will be available in time to inform stakeholder decisions about how the project is implemented, improved, and/or scaled up.

Proposals must include a plan on how to measure implementation research outcomes and the intervention's real world efficacy in preventing NCDs. In case health outcomes might not be apparent over the duration of the study period, and applicants may therefore instead include plans to measure the intervention's impact on upstream health indicators, such as those related to the social determinants of health, or to measure other proxy health outcomes. Where feasible and relevant, applicants should also describe a plan for evaluating the planetary health and/or climate impacts of an intervention's implementation. Applicants are also encouraged to develop a plan for measuring outcomes or indicators relevant to non-health or environmental impacts, especially when working on projects with multi-sectoral themes (for example, themes that cut across health and transportation, social services, waste management, etc.).

¹¹² The man-made components of the environment, such as building, traffic, sewage, parks, and other infrastructure.

¹¹³ Proposals are intended for research that helps guide the implementation and/or scale up of the proposed intervention. Therefore, the execution of infrastructural interventions (e.g., constructing bike lanes or housing, etc.) is not in the scope of this topic.

Projects should consider the structural and social determinants of health and discuss their potential impact on the effective implementation of the intervention(s) in city environments. Of interest is also the EU Mission on Climate-Neutral and Smart Cities¹¹⁴.

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. The aim should be to adapt and scale-up the implementation of these intervention(s) in accessible and equitable ways in order to prevent or delay the onset of chronic diseases in real-life settings. Poverty, racism, ethnic discrimination, physical and mental ableism, ageism, and other inequities are directly associated with reduced potential for health promotion and disease prevention. If there is a focus on a particular population in this context, then the reason for this should be justified.

This topic requires the effective contribution of social 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.

Proposals should present a strategy to include the relevant policy makers, local authorities, as well as other stakeholders such as community groups, or other individuals or organizations involved in the implementation of the intervention, from the development to the implementation knowledge translation phase.

Applicants are encouraged to propose activities to increase research capacity and capability in the field of implementation research among researchers, health professionals, and public health leaders through skill building, knowledge sharing, and networking. In this regard, they may propose plans for capacity building within their proposal, especially, but not exclusively, for early career researchers and for members from lower resourced environments, such as LMICs or indigenous communities.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-DISEASE-03-04: Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 7.00 and 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.

¹¹⁴ https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/climate-neutral-and-smart-cities_en

<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
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

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

- The scientific and clinical communities have an increased knowledge on viruses with epidemic potential and in particular a better understanding of different potential mechanisms of action for the development of broad-spectrum anti-viral therapeutics for these viruses.
- The scientific and clinical communities have access to novel approaches for the development of anti-viral therapies for emerging and re-emerging infections in the context of epidemic and pandemic preparedness.
- The scientific and clinical communities have access to experimental broad-spectrum anti-viral candidates against emerging or re-emerging viral infections for further clinical investigation.
- A diverse and robust pipeline of broad-spectrum anti-viral drug candidates is available for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is expected to accelerate due to among other, climate change, and thus a proactive approach to the development of anti-viral therapeutics in preparedness for future infectious disease outbreaks is needed. The availability of broad-spectrum anti-viral therapies would provide a critical preparedness measure against future health threats, due to infectious disease epidemics or pandemics.

Proposals should develop and advance broad-spectrum anti-viral compounds and develop novel approaches to the development of such compounds, which target viruses with high epidemic or pandemic potential for the EU, such as those included in the list of priority diseases of the World Health Organization (WHO)¹¹⁵, with particular attention to those identified by the Health Emergency Preparedness and Response Authority (HERA).

Proposals should cover viruses for which there are no currently available effective therapeutics or for which the therapeutics available are sub-optimal, and are expected to incorporate state-of-the-art screening technology and innovative approaches to identify new targets for antiviral compound development. Emphasis should be put on the research and development of broad-spectrum antivirals, which may include repurposing of previously approved or in-pipeline drugs. Proposals could also include elucidation of mode-of-action for candidate anti-viral therapeutics.

Proposals should aim to diversify and accelerate the global therapeutic research and development pipeline for emerging and re-emerging viral infections, and to strengthen the current leading role of the EU in therapeutic research and development.

Proposals should address several of the following areas:

- Preclinical work and proof-of-concept/first-in-human studies and early safety and efficacy trials for testing new or improved anti-viral therapeutic, with a clear regulatory and clinical pathway. Phase IIb/III phase trials will not be supported.
- Innovative delivery systems and suitable safety profiles for broad use should be considered when possible. Attention should be paid to critical social factors such as sex, gender, age, socio-economic factors, ethnicity/migration, and disability.
- Apply novel approaches and widely applicable workflows (e.g. artificial intelligence) for rapid and reliable identification of broad-spectrum anti-viral therapeutics.
- Timely engagement with the relevant regulatory bodies is expected to ensure adequacy of the actions from a regulatory point of view.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-DISEASE-03-05: Pandemic preparedness and response: Sustaining established coordination mechanisms for European adaptive platform trials and for cohort networks

Specific conditions	
<i>Expected EU</i>	The Commission estimates that an EU contribution of between EUR 1.00

¹¹⁵ <https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts>

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<i>contribution per project</i>	and 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 3.00 million.
<i>Type of Action</i>	Coordination and Support Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>Legal entities established in the United States of America may exceptionally participate in this Coordination and support action in a capacity other than Associated Partner.</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>Coordinators of projects must be legal entities established in an EU Member State or Associated Country.</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

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

- The research community sustains appropriate coordination mechanisms 1) among different EU-wide adaptive platform trials and 2) among established cohorts in Europe and beyond with a view for better pandemic preparedness and response,
- The adaptive platform trial and the cohort networks maximise coordination and harmonisation of their respective studies within their relevant network for maximum research efficiency and optimal evidence generation.
- The European adaptive platform trial and the cohort networks coordinate with the European Pandemic Preparedness Partnership, and are well connected to each other and to relevant other regional and global initiatives.

Scope: The COVID-19 pandemic research response has illustrated the importance of clinical research preparedness, as well as the benefit gained from the coordination between European clinical research initiatives. Two key pillars of such clinical research in pandemic

preparedness and response are the clinical (interventional) trials and the cohort (observational) studies.

The large-scale European COVID-19 clinical trials have been gathered under a network for COVID-19 therapeutic trials¹¹⁶ and a network for COVID-19 vaccine trials¹¹⁷ and strong common coordination mechanisms between the trials have been established. The recently launched Ecraid¹¹⁸ is a European clinical research network that has been in development since before the COVID-19 pandemic. The EU-funded projects conducting cohort research in Europe and globally have also come together to establish stronger coordination between them.

This topic aims at maintaining and strengthening existing strategic coordination mechanisms across adaptive platform trials and across cohort studies in Europe and beyond for avoiding redundancies, promoting complementarities and facilitating cooperation among EU-funded clinical research for infectious diseases. Proposals should strengthen the leading role of the EU in clinical research preparedness for future epidemics and pandemics, through ensuring coordination of the European adaptive platform trials and of the European cohort studies. The coordination mechanisms support the longer-term perspective of preparedness for future infectious disease epidemics and pandemics, where the networks enable the conduct of perpetual platform trials and of perpetual strategic cohorts with the in-built agility to pivot to emerging diseases when an epidemic strikes.

Proposals should describe a coordination mechanism for adaptive platform trials and/or for cohort research. The coordination mechanism builds on existing coordination efforts for these networks, providing strategic support and vision for the perpetual trials and cohort studies belonging to the networks in the context of pandemic preparedness. Within the adaptive platform trial network, the coordination mechanism supports reflections e.g. on the diversity of the trial target populations (e.g. primary care or hospitalised patients) or on different possible medical countermeasures (e.g. therapeutics, vaccines), etc. Within the cohort network, the coordination mechanism supports reflections e.g. on diversity in type of cohorts and research questions to be addressed, or on harmonised approaches to data collection and analysis, etc.

Proposals should address proper connections with relevant European initiatives and organisations, such as the European Pandemic Preparedness Partnership, the European Health Preparedness and Emergency Response Authority (HERA), as well as the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC). Synergies with successful proposals under the HORIZON-INFRA-2023-DEV-01-01 topic should be sought, and collaboration with relevant research infrastructures should be envisaged. Proposals should also be open to engage with global initiatives such as the Global

¹¹⁶ <https://covid19trials.eu/en>

¹¹⁷ <https://vaccelerate.eu/>

¹¹⁸ <https://www.ecraid.eu/>

Research Collaboration for Infectious Disease Preparedness (GloPID-R)¹¹⁹, the Global Health EDCTP3 Joint Undertaking¹²⁰, or the World Health Organization (WHO).

Proposals should address the following areas:

- Fostering a trusted and proactive environment within each coordination mechanism that supports the timely exchange of research results, allows for discussion on challenges encountered in their research and finding solutions together to ensure cooperation and synergy within each network;
- Developing a common approach for the European clinical research to enable pragmatic solutions to shared challenges across European clinical trials and/or cohorts for pandemic preparedness and response, guaranteeing the best interest of European trial or study patients or volunteers;
- Promoting an optimal use of resources, based on a sound scientific approach and maximising the value added for the generation of scientific evidence, through a common baseline approach towards protocol development, harmonised and FAIR¹²¹ data collection and analysis leveraging existing initiatives;
- Involving relevant European stakeholders, such as representatives from regulatory authorities, industry, policy makers, patient organisations, etc., as well as relevant non-European networks and stakeholders;
- Promoting the visibility and attractiveness of European adaptive platform trials and/or cohorts for clinical investigators in Europe and beyond ; as well as active communication with the science community, patient advocacy groups and other stakeholders, to develop trust, and also promote innovative approaches;
- Partners within the coordination mechanism should develop a plan to ensure its sustainability. Coordination with the European Pandemic Preparedness Partnership and the European Health Preparedness and Emergency Response Authority (HERA) is expected.

HORIZON-HLTH-2023-DISEASE-03-06: Towards structuring brain health research in Europe

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 1.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a

¹¹⁹ <https://www.glopid-r.org/>

¹²⁰ https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/edctp_en

¹²¹ FAIR data are data which meet principles of findability, accessibility, interoperability, and reusability

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	proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 1.00 million.
<i>Type of Action</i>	Coordination and Support Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>Legal entities established in the United States of America may exceptionally participate in this Coordination and support action in a capacity other than Associated Partner.</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>Coordinators of projects must be legal entities established in an EU Member State or Associated Country.</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

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

- Policy makers, funders and other relevant stakeholders ¹²² identify and agree on the governance structure and implementation modalities, allowing for an efficient establishment of a potential future partnership.
- Policy makers, funders and other relevant stakeholders build on the knowledge gathered in past studies performed at EU and national level.
- Policy makers, funders and other relevant stakeholders identify and agree on common research priorities and research needs, also taking into consideration developments at the international level where relevant.
- Policy makers, funders and other relevant stakeholders develop and align national and regional research strategy plans with long-term sustainability in mind.

¹²² Other relevant stakeholders include researchers, health care providers and practitioners, patients, citizens, regulators and industry.

- Policy makers and funders commit to providing financial support that will allow for a comprehensive, impact-driven structuring of the field of European brain health research.

Scope: Member States and Associated Countries have agreed to step up their coordination in the area of brain research, which could take the form of a European partnership on Brain Health¹²³ in the second Strategic Plan of Horizon Europe¹²⁴.

Proposals should address all of the following aspects:

- To structure brain health research in Europe and pave the way for a possible future partnership, this coordination action will develop a structured system of exchange of information between policy makers, funders, and other relevant bodies¹²⁵ in order to establish synergies and avoid duplication of efforts.
- It will further facilitate the development of a strategic research and innovation agenda, taking into account the efforts already undertaken by EU-supported actions¹²⁶. The strategic research and innovation agenda will identify a number of measurable, scientific-technological priorities and socio-economic objectives, supported by an appropriate analysis.
- The coordination action, under the leadership of an EU Member State or Associated Country, should develop plans for a governance structure of a future partnership, as well as implementation modalities with long-term sustainability in mind.
- It should ensure a broad geographical representation of European countries and plan for inclusion of all main related research initiatives, as well as key organisations and associations. In this way, the coordination action should reflect the ‘umbrella’ role of a future initiative that will structure brain health research in Europe, and make it more impactful.
- Consideration should be made for international initiatives by engaging with global organisations¹²⁷, as well as with global initiatives and research organisations¹²⁸ in the field.

¹²³ In the context of the partnership, ‘brain health’ should be interpreted as a concept that encompasses neural development, neuroplasticity, brain functioning, and recovery across the life course, including mental health and wellbeing elements.

¹²⁴ This topic does not pre-judge the content of the second Strategic Plan of Horizon Europe.

¹²⁵ Relevant bodies include EU-supported initiatives, scientific and clinical societies, patient organisations, regulators and the industry.

¹²⁶ This includes the common research agenda developed by the ‘European Brain Research Area’ (EBRA) project, as well as the strategic research agendas of the partnerships: ‘EU Joint Programme – Neurodegenerative Disease Research’ (JPND), ‘Network of European Funding for Neuroscience Research’ (NEURON), ‘Human Brain Project’ (HBP) and the ‘Innovative Medicines Initiative’ (IMI) and its successor the ‘Innovative Health Initiative’ (IHI).

¹²⁷ Global organisations include the World Health Organization (WHO), the Organisation for Economic Co-operation and Development (OECD) and the Global Alliance for Chronic Diseases (GACD).

¹²⁸ Entities include the global brain initiatives, the International Initiative for Traumatic Brain Injury Research (InTBIR) and the International Brain Research Organisation (IBRO).

- The action should elaborate on platforms and tools for use by the research community, including on how they best complement, integrate with each other. In this context, infrastructures already developed at the European¹²⁹ or national level that enable sharing of samples, quality data and advanced analytical tools should be included in the analysis. Reflections should also be made on how the future initiative can contribute to the development of the European Health Data Space.
- This coordination action implies the preparation and organisation of meetings, as well as support to information exchange with relevant stakeholder groups and with the public.

This topic requires the effective contribution of social 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.

HORIZON-HLTH-2023-DISEASE-03-07: Relationship between infections and non-communicable diseases

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 6.00 and 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 30.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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

¹²⁹ EU-supported infrastructures include, for example, the BBMRI-ERIC infrastructure for biobanking, the EBRAINS research infrastructure, and various platforms developed by the Innovative Medicines Initiative (IMI) and its successor the Innovative Health Initiative (IHI).

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

- All players along the health care value chain are provided with new knowledge for a better understanding of the links (e.g. causalities) between infectious diseases (IDs) and non-communicable diseases (NCDs) and comorbidities, including knowledge on host risk factors that impact the development of disease progression for NCDs and/or IDs.
- Researchers and clinicians are provided with a robust evidence base that will contribute to the development of new or improved tools to diagnose and prevent the development and aggravation of non-communicable disease(s) as well as early treatment and management of patients suffering from co-morbidities following an infectious disease.
- Healthcare practitioners have access to knowledge to guide them on preventive measures, on early identification of diseases onset and of those patients at risk of developing severe disease progression, and on the optimal treatment of patients.

When NCDs are related to infectious diseases with pandemic potential, healthcare practitioners will be provided with new evidence to help them make informed decision on the management of the diseases in the future. Public health authorities will be better prepared to issue targeted recommendations linked or not to the use of specific medical countermeasures in crisis times.

Scope: Increasing evidence suggests that several infections might influence the development of many non-communicable diseases (e.g. multiple sclerosis, Alzheimer, post-covid-19 condition¹³⁰), or that NCD may be influenced by concurrent presence in the same individual of one (or more) infections. On the other hand, NCDs might represent risk factors for IDs.

The proposals are expected to elucidate and provide a better understanding of causative links between infections and non-communicable diseases onsets, and/or the impact of infections on the exacerbation of existing NCDs or vice versa, in children and/or adults. The analysis of genetics, immune status, immune or inflammatory responses, microbiome, lifestyle and/or other relevant factors (e.g. differences in age, sex/gender, vaccination status, ethnicity) should be integrated to get information for prevention, early diagnosis, risk factors, and to better understand causative links as well as the progression of those non-communicable diseases.

In determining the connection between one or multiple concomitant infection(s) and the development of non-communicable disease(s), the proposals might address any infection including those with pandemic potential (viral, bacterial, or fungal) with non-communicable diseases of major importance. Research on cancer is excluded as it will be covered by the Mission on Cancer.

Special attention should be given to vulnerable individuals, such as those with known existing preconditions.

¹³⁰ https://www.who.int/publications/i/item/WHO-2019-nCoV-Post_COVID-19_condition-Clinical_case_definition-2021.1

Preclinical research, observational studies and/or clinical studies can be considered for this topic. Proposals could include patient follow-up to identify conditions that may appear only after a patient has recovered from the infectious disease. Those proposals including clinical evaluation 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.

The applicants are encouraged to incorporate artificial intelligence (AI) tools that enable advanced quality data analysis and for assessing and predicting the risk of developing a disease and/or the risk of disease progression/severity where relevant.

Projects funded under this topic that focus on COVID-19 and post COVID-19 condition (also known as long-COVID) are strongly encouraged to collaborate and build links with (one of) the relevant EU-funded projects, such as ORCHESTRA¹³¹. They should also pay special attention and link to the newly established European COVID-19 data sharing platform¹³².

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-DISEASE-03-17: Pandemic preparedness and response: Understanding vaccine induced-immunity

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 7.00 and 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 20.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may</p>

¹³¹ <https://orchestra-cohort.eu/>

¹³² <https://www.covid19dataportal.org/>

	additionally be used).
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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

- The scientific and clinical communities have an increased knowledge of vaccine-induced immunity and, in particular, a better understanding of factors that affect the magnitude, breadth, nature and duration of immunity to vaccine antigens.
- The scientific and clinical communities have an increased knowledge of the durability and breadth of vaccine-induced immunity in vulnerable populations and older age groups.
- The scientific and clinical communities have an increased knowledge of correlates of protection for pathogens with epidemic potential to allow the development of effective vaccines.
- The scientific and clinical communities have an increased knowledge of the characteristics that influence vaccine effectiveness to allow for novel approaches for the development of vaccines for emerging and re-emerging infections, including antigenic variants, in the context of epidemic and pandemic preparedness.

Scope: As shown by the COVID-19 pandemic, vaccines are a critical component needed to bring infectious disease pandemics under control. The availability of effective vaccines that are able to induce a strong and durable immune response are critical to respond to health threats caused by infectious disease epidemics or pandemics. A proactive approach to understanding the factors that affect vaccine durability and strength is necessary to ensure development of effective vaccines for future infectious disease outbreaks.

Proposals should study vaccine-induced immunity in the general population and vulnerable groups. Proposals should look both at the magnitude and breadth of initial immune responses and the duration of immunity after vaccination with different vaccine types (mRNA, vector, inactivated, subunit, attenuated,...). Proposals should assess how sex (e.g. male vs female, pre- vs postmenopausal), age (childhood vs adolescent vs elderly) and/or life style (e.g. obesity, drug addiction, diet, sport) affect the immune response. Proposals may also examine genetic and other molecular factors that may influence immune response in humans. Proposals should pursue a multi-omics approach in order to foster a deep understanding of vaccine induced immunity.

Proposals should identify correlates of protection that can be used to develop vaccines against viruses with a high epidemic or pandemic potential, such as those identified by HERA¹³³ or included in the list of priority diseases of the World Health Organization (WHO)¹³⁴.

Proposals should also assess how pre-existing conditions or chronic infections influence the immune response.

Proposals should aim to improve the global vaccine research and development pipeline for emerging and re-emerging viral infections, and to strengthen the current leading role of the EU in vaccine development, and therefore contributing to the work of the European Health Emergency Preparedness and Response Authority (HERA).

This topic requires the effective contribution of social 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.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-DISEASE-03-18: Pandemic preparedness and response: Immunogenicity of viral proteins of viruses with epidemic and pandemic potential

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 7.00 and 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 50.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply:

¹³³ Reference to be added once the list is available.

¹³⁴ <https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts>

	The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
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Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease burden*”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The scientific and clinical communities have an increased knowledge on viruses with epidemic and pandemic potential and in particular a better understanding of viral targets for vaccine development.
- The scientific and clinical communities have access to novel approaches for the prevention and treatment for emerging and re-emerging infections in the context of epidemic and pandemic preparedness.
- The scientific and clinical communities have access to experimental vaccine candidates against emerging or re-emerging viral infections for further clinical investigation.
- A diverse and robust pipeline of vaccine candidates is available for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is expected to accelerate due to among other factors, climate change, and thus a proactive approach to the development of vaccines and inhibitors for the cellular uptake of viruses in preparedness for future infectious disease outbreaks is needed. The availability of vaccines would provide a critical preparedness measure against future health threats, due to infectious disease epidemics or pandemics.

Proposals should identify targets for optimal vaccine design for those pathogens where information on host-pathogen interaction and viral surface structures is already available. These surface structures may require further characterisation. It is necessary to determine the extent of genetic variation with a view to develop vaccines with variant efficacy. In addition, it is necessary to develop animal and alternative models for the testing of vaccine candidates and for the kinetics, strength, breadth and persistence of the immune response. Proposals should focus on viruses identified by HERA¹³⁵ and those causing diseases that are in the list of priority diseases of the World Health Organization (WHO)¹³⁶, with particular attention given to: Hendra and Nipah Virus, Lassa virus, Crimean Congo hemorrhagic fever virus, Rift Valley fever virus, Ebola virus, Dengue virus, Yellow Fever virus, Zika virus, West Nile fever virus and Chikungunya virus. In order to ensure complementarity to ongoing research and

¹³⁵ Reference to be added once the list is available.

¹³⁶ <https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts>

development projects, proposals addressing influenza and coronaviruses are not in scope of this topic.

Proposals should provide innovative approaches with the aim to diversify and accelerate the global pandemic preparedness research and development pipeline for emerging and re-emerging viral infections, and to strengthen the role of the EU in therapeutic research and development, and therefore contributing to the work of the European Health Emergency Preparedness and Response Authority (HERA).

Proposals should address the following areas:

- Identification of key antigenic targets for the priority pathogens as mentioned above.
- Improvement or, if necessary, establishment of animal models for the testing of vaccine candidates where alternative models are not available.
- Characterisation of the immunogenicity of antigenic targets in appropriate animal or alternative models and in pre-clinical tests.
- Inclusion, if possible, of proof-of-concept studies in humans of the vaccine candidate.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

Call - Partnerships in Health (2023)

HORIZON-HLTH-2023-DISEASE-07

Conditions for the Call

Indicative budget(s)¹³⁷

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹³⁸	Indicative number of projects expected to be funded
		2023		

¹³⁷ 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 2023 and 2024.

¹³⁸ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

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Health**

Opening: 12 Jan 2023 Deadline(s): 19 Sep 2023				
HORIZON-HLTH-2023-DISEASE-07-01	COFUND	50.00	Around 50.00	1
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-2023-DISEASE-07-01: European Partnership on Rare Diseases

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 50.00 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>	Programme Co-fund Action
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply:

	<p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic, under the condition that the concerned consortium of eligible EU Members States and Associated Countries’ research funders provides agreement to this participation. The US contribution will be considered for the calculation of the EU contribution to the partnership.</p> <p>The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.</p>
<p><i>Award criteria</i></p>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>
<p><i>Legal and financial set-up of the Grant Agreements</i></p>	<p>The rules are described in General Annex G. The following exceptions apply:</p> <p>Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. Financial support provided by the participants to third parties is one of the primary activities of the action in order to be able to achieve its objectives. The maximum amount to be granted to each third party is EUR 10.00 million.</p> <p>Funding rate will be 50%. This is justified by the pooling of proposers' in-kind contributions and in-house activities and by the nature of activities to be performed: in addition of joint calls, highly integrative activities (EU clinical trial preparedness, training, patients’ empowerment activities etc.) contributing to enhance the rare disease research and innovation ecosystem in Europe and beyond.</p>

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “Tackling diseases and reducing disease burden” and 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:

- The EU is reinforced as an internationally recognised driver of research and innovation in rare diseases (RD) and thereby substantially contributing to the achievement of the Sustainable Development Goals related to rare diseases;
- Research funders align, adopt and implement their RD research policies allowing for the optimal generation and translation of knowledge into meaningful health products and

interventions responding to the needs of people living with a rare disease across Europe and globally.

- The RD research community at large benefit from and use an improved comprehensive knowledge framework integrating the EU, national/regional data and information infrastructures to improve translational research.
- People living with a rare disease benefit from a more timely, equitable access to innovative, sustainable and high-quality healthcare, taking stock of highly integrated research and healthcare systems.
- Researchers, innovators - as well as people living with a rare disease and their advocates (as co-creators) - effectively constitute and operate into an integrated research and innovation ecosystem to deliver cost-effective diagnosis and treatments.
- Public and private actors, including civil society (e.g. NGOs, charities), establish coordinated and efficient multi-stakeholder collaborations at EU and national (including regional) levels, allowing for more effective clinical research, for example aiming at improved success rates of therapeutic development.

Scope: The Partnership should 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 new EU4Health Programme (COM(2020) 405 final, [Regulation \(EU\) 2021/522](#)).

This partnership should also contribute to achieving the objectives of the Pharmaceutical Strategy for Europe¹³⁹, in terms of fulfilling unmet medical needs (e.g. for rare diseases with so called “orphan medicinal products”¹⁴⁰) and ensuring that the benefits of innovation reach patients in the EU.

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

The co-funded European Partnership on rare diseases should be implemented based on the priorities identified in the SRIA and through a joint programme of activities ranging from coordinating and funding transnational research to highly integrative and community-driven ‘in-house’ activities such as innovation strategies for the efficient exploitation of research results, EU clinical trial preparedness activities, optimisation of research infrastructures and

¹³⁹ COM(2020) 761 final, https://ec.europa.eu/health/medicinal-products/pharmaceutical-strategy-europe_en

¹⁴⁰ https://ec.europa.eu/health/medicinal-products/orphan-medicinal-products_en

resources, including networking, training and dissemination activities. It should be structured along the following main objectives:

- Launch joint transnational calls for RD research and innovation priorities as defined in the SRIA, resulting in financial support to third parties, based on the annual work plans;
- Develop a European Clinical Research Network to accelerate the clinical trial readiness of the RD research community in Europe, to improve the research and innovation potential of RD stakeholders and facilitate the cost-effective clinical development of new therapies;
- Develop and consolidate the capacity building of the RD data ecosystem by supporting the federated access/sharing of FAIR research data, information resources to ensure the effective and fast translation of the research results to safe and effective health innovations;
- Integrate basic, pre-clinical and clinical research to reduce the burden for people living with a rare disease.
- Support research in relevant medical fields and intervention areas (prevention, diagnosis, treatment), while improving the utilisation of existing health technologies in clinical practice;
- Support the scientific work of the International Rare Disease Research Consortium.

The Partnership is open to all EU Member States, as well as to countries associated to Horizon Europe and will remain open to those countries wishing to join. The Partnership should include or engage with 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 healthcare authorities, organisations and providers (including providers members of the European Reference Networks);
- Research infrastructures;
- Patients organisations;
- Industry;
- Charities.

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

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

To ensure coherence and complementarity of activities and leverage knowledge and investment possibilities, the Partnership is expected to establish relevant collaborations with other Horizon Europe partnerships (institutionalized and co-funded) and missions as set out in the working document on 'Coherence and Synergies of candidate European partnerships under Horizon Europe' as well as to explore collaborations with other relevant activities at EU and international level. The proposal should also consider synergies with EU programmes, including but not limited to EU4Health, the Digital Europe Programme (DIGITAL), the European Social Fund Plus (ESF+), the European Regional Development Fund (ERDF), InvestEU, the Recovery and Resilience Facility (RRF) and the Technical Support Instrument (TSI).

Cooperation with international organisations, and non-European institutions and experts may be considered. Participation of third countries is encouraged. Their commitments to the Partnership would not be eligible for the calculation of EU funding. Applicants should describe in their proposal the methodology for their collaboration and the aims they want to achieve with this kind of collaboration.

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

Depending on their individual legal and operational frameworks and in agreement with the relevant services of the European Commission (partner DGs), EU Agencies involved in authorising orphan medicinal products and/or producing knowledge on orphan medicinal products and rare diseases may also join the Partnership, e.g. as beneficiaries.

When defining calls for proposals, this Partnership needs to consider if to require the effective contribution of social 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.

Collaboration with the European Commission's Joint Research Centre (JRC) must be considered to materialise the sharing of (meta)data regarding registries for rare diseases, exchanging data for clinical studies and research based on a unified pseudonymisation tool provided by the European Platform on Rare Disease Registration (EU RD Platform) and related tools and services, as well as in other areas of mutual interest, such as training and capacity building.

The expected duration of the partnership is seven to ten years.

Call - Tackling diseases (Two stage - 2024)

HORIZON-HLTH-2024-DISEASE-03-two-stage

Conditions for the Call

Indicative budget(s)¹⁴¹

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁴²	Indicative number of projects expected to be funded
		2024		
Opening: 30 Mar 2023 Deadline(s): 19 Sep 2023 (First Stage), 11 Apr 2024 (Second Stage)				
HORIZON-HLTH-2024-DISEASE-03-08-two-stage	RIA	45.00	6.00 to 7.00	7
HORIZON-HLTH-2024-DISEASE-03-11-two-stage	RIA	30.00	8.00 to 10.00	3
HORIZON-HLTH-2024-DISEASE-03-13-two-stage	RIA	25.00	6.00 to 8.00	3
HORIZON-HLTH-2024-DISEASE-03-14-two-stage	RIA	25.00	6.00 to 7.00	4
Overall indicative budget		125.00		

General conditions relating to this call	
<i>Admissibility conditions</i>	The conditions are described in General Annex A.

¹⁴¹ 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 2023 and 2024.

¹⁴² Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

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<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-2024-DISEASE-03-08-two-stage: Comparative effectiveness research for healthcare interventions in areas of high public health need

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 6.00 and 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 45.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Admissibility conditions</i>	The conditions are described in General Annex A. The following exceptions apply: Applicants submitting a proposal under the blind evaluation pilot (see General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in Part B of their first stage application (see General Annex E).
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.

<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>
<i>Procedure</i>	<p>The procedure is described in General Annex F. The following exceptions apply:</p> <p>This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.</p>
<i>Legal and financial set-up of the Grant Agreements</i>	<p>The rules are described in General Annex G. The following exceptions apply:</p> <p>Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025).¹⁴³.</p>

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

- Health policy makers are aware of the healthcare interventions (pharmacological, non-pharmacological or technological interventions; including preventive and rehabilitative actions) that are identified as working best for the specific population groups from the point of view of safety, efficacy, patient outcomes, adherence, quality of life, accessibility, and (cost-) effectiveness.
- Health professionals have access to and use the improved clinical guidelines on the optimal treatment of patients and prevention of diseases e.g. through vaccines. Considerations made in the guidelines include the harmonisation and standardisation of care for high burden diseases or conditions throughout Europe, as well as possible individualised needs of patients.
- The scientific and clinical communities make effective use of state-of-the-art information, data, technologies, tools and best practices to develop interventions that are sustainable.

¹⁴³ This [decision](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf) is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under ‘Simplified costs decisions’ or through this link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf

- Citizens, patients, prescribers, and payers receive more accurate information on available healthcare interventions via ad hoc communication platforms.
- The scientific and clinical communities make wide use of the newly established open access databases and/or integrate them with existing open access infrastructures for storage and sharing of collected data according to FAIR principles.

Scope: Effective, affordable and accessible healthcare for diverse population groups is challenging and complex. For example, specific needs underlie the delivery of effective preventive actions and therapeutic treatments to a rapidly growing elderly population, often presenting comorbidities and associated poly-pharmacy. The paediatric population, including children born preterm, has also its specific needs in specially adjusted therapeutics and early interventions to address emerging health and developmental problems. Similar to the elderly population, the paediatric population is often excluded from many clinical trials that generate the evidence base for healthcare interventions. Women, including pregnant women, are also often under-represented in clinical studies and access to quality healthcare is frequently inadequate. Other population groups with limited access to quality healthcare and/or under-representation in clinical studies include low-income groups, and refugees. Intersectionality within these groups also needs consideration.

Applicants should address most of the following:

- Compare the use of currently existing (pharmacological, non-pharmacological and technological) healthcare interventions in specific population groups (or selected subgroups). While there is no restriction on diseases or conditions, preference will be given to proposals focusing on interventions with high public health relevance¹⁴⁴.
- Ensure acceptability and sustainability of the healthcare intervention through early involvement of ‘end users’ (e.g. patients, care providers) in the design of the study (integrating patient valued outcomes) and, where possible, in the research process including implementation. Additionally, proposals should take into account the diversity of health systems in different regions of Europe to allow large-scale uptake.
- Consider involving HTA bodies in order to create synergies and accelerate the practical implementation of the results. Where relevant, existing work of EU-funded projects such as EUnetHTA¹⁴⁵ should be also taken into account.
- Consider issues of particular relevance for the target populations, for example, multimorbidity, complex chronic conditions, poly-pharmacy, substance misuse, vaccine efficacy, compliance, age, gender specificities and diseases with high societal burden (including but not limited to e.g. musculoskeletal diseases and mental health disorders). Special consideration should be given to fulfilling all ethical requirements.

¹⁴⁴ Interventions addressing diseases or conditions that are particularly frequent, have a high negative impact on the quality of life of the individual and/or are associated with significant costs where savings can be achieved.

¹⁴⁵ <https://www.eunetha.eu/>

- For the chosen population, assess clinical and safety parameters, as well as health and socio-economic outcomes (e.g. quality of life, patient mortality, (co)morbidity, costs, and performance of the health system). Agreed core outcome sets (COS) should be used as endpoints in conditions where they already exist, in other cases, efforts should be made to agree on such COS. Consider using new instruments and methods for determining the burden of disease and for evaluating the effects of the interventions. Low cost innovations should also be considered.
- Inclusion of patient organisations and associations of caregivers and other healthcare professionals is recommended.
- Clinical trials, including pragmatic clinical trials, observational studies, use of existing health data in different study designs, creation of large-scale databases and performing meta-analyses may be considered for this topic. Use of existing data should always be considered to add value, increase quality and increase implementation speed of the study. Regarding databases, sustainability after the proposed action's end also needs to be considered.
- The proposed research needs to take into account sex and gender aspects.

This topic requires the effective contribution of social 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.

Applicants of second stage envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2024-DISEASE-03-11-two-stage: Pandemic preparedness and response: Adaptive platform trials for pandemic preparedness

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 8.00 and 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.

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<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
<i>Admissibility conditions</i>	<p>The conditions are described in General Annex A. The following exceptions apply:</p> <p>Applicants submitting a proposal under the blind evaluation pilot (see General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in Part B of their first stage application (see General Annex E).</p>
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>
<i>Procedure</i>	<p>The procedure is described in General Annex F. The following exceptions apply:</p> <p>This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.</p>
<i>Legal and financial set-up of the Grant Agreements</i>	<p>The rules are described in General Annex G. The following exceptions apply:</p> <p>Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025).¹⁴⁶.</p>

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “*Tackling diseases and reducing disease*”

¹⁴⁶ This [decision](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf) is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under ‘Simplified costs decisions’ or through this link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf

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:

- A diverse and comprehensive EU landscape of multi-country adaptive platform trials (i.e. able to study multiple interventions in a disease or condition in a perpetual manner, thus allowing modification to the trial after its initiation without undermining its validity and integrity) that assess vaccines and therapeutics for infectious diseases, and have the capacity to pivot rapidly in the case of epidemic or pandemic health threats.
- Innovative and improved design of clinical studies, suited for pandemic preparedness, is available for the clinical research community, taking into account the high safety standards in the European regulatory environment.
- Trial sites across multiple countries have the capacity to deliver robust clinical evidence in a diverse European population, using harmonised research methods, data collection and analysis.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally. Health threats are expected to arise due to among others, climate change, and thus a need for proactive approaches to ensure timely availability of medical countermeasures during disease outbreaks is anticipated. The conduct of perpetual adaptive platform trials, with the in-built agility to pivot when an epidemic strikes, is key to be prepared for infectious disease epidemics or pandemics.

This topic aims to provide funding to adaptive clinical platform trials that may be implemented routinely outside of an epidemic or pandemic context, but that are designed to be ready for the timely assessment of novel diagnostics, therapeutics or vaccines in the face of an epidemic or pandemic.

Proposals should develop the wide range of elements needed to sustain multi-country adaptive platform trials, including the trial implementation capacity, laboratory analysis capacity, and a harmonised approach to the collection, storage, sharing and analysis of data.

Proposals should ensure timely engagement with regulatory authorities and bodies. Proposals should consider the European regulatory environment and take full use of the European capacity to deliver quality trials, including the possibility for registration of new medical products. Proposals should strengthen the leading role of the EU in clinical research preparedness for future epidemics and pandemics.

The proposals should address the following areas:

- Development of robust clinical evidence that contributes to the knowledge base for the diagnosis, treatment and prevention of infectious diseases. Sex, gender, age, ethnicity and socio-economic factors should be taken into account.

- Known hurdles related to ethical, administrative, regulatory, legal and logistical aspects should be anticipated and addressed to the extent possible, in order to avoid such barriers when the trial needs to pivot in response to an epidemic or pandemic.
- Engagement with clinical researchers and biostatisticians, to increase capacity for the design and implementation of adaptive platform trials across Europe.

Collaboration and coordination with existing adaptive platform trials in the EU is expected, where relevant, as well as with the coordination mechanisms established under topic HORIZON-HLTH-2023-DISEASE- 3.05 and with the European Medicines Agency (EMA). Collaboration and coordination with other organisations and other regional and global initiatives, such as Global Health EDCTP3 Joint Undertaking¹⁴⁷, the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)¹⁴⁸, the European Pandemic Preparedness Partnership and the European Health Preparedness and Emergency Response Authority (HERA) should be envisaged. International cooperation is encouraged.

This topic requires the effective contribution of social 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.

Applicants of second stage envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2024-DISEASE-03-13-two-stage: Validation of fluid-derived biomarkers for the prediction and prevention of brain disorders

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 6.00 and 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 25.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Admissibility conditions</i>	The conditions are described in General Annex A. The following exceptions apply: Applicants submitting a proposal under the blind evaluation pilot (see

¹⁴⁷ https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/edctp_en

¹⁴⁸ <https://www.glopid-r.org/>

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	General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in Part B of their first stage application (see General Annex E).
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
<i>Procedure</i>	The procedure is described in General Annex F. The following exceptions apply: This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). ¹⁴⁹ .

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 most of the following expected outcomes:

- The scientific and clinical communities make effective use of state-of-the-art information, data, technologies, tools and best practices to underpin the development of the diagnostics, and as such can also facilitate the development of effective therapeutics and/or preventive strategies.

¹⁴⁹ This [decision](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf) is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under ‘Simplified costs decisions’ or through this link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf

- The scientific and clinical communities advance the field through a better understanding of mechanisms underlying brain disorders at the molecular, cellular and systemic level.
- The scientific and clinical community make wide use of newly established and where relevant open access databases and/or integrate them with existing infrastructures for storage and sharing of collected data according to FAIR principles, thereby encouraging further use of the data.
- Policy makers, funders, scientific and clinical communities, patient organisations, regulators and other relevant bodies are informed of the research advances made, while health professional envisage use of the biomarker tests for early detection of the disorder and for guiding patients in the selection of personalised treatments.
- Patients and caregivers are sufficiently engaged with the research, which also caters for their needs.

Scope: Treatments for some high-burden brain disorders are potentially on the horizon¹⁵⁰. Consequently, many patients and citizens will want to know if they are eligible for these treatments. For some disorders, a definitive diagnosis is difficult, expensive and time-consuming. Simple blood or other fluid-derived (e.g. saliva, urine, sweat) tests for markers that may indicate early signs of the disorder, and which can be deployed for widespread clinical use are needed.

The brain disorders within the scope of this topic fall under two categories, namely those listed under chapters six and eight of the International Classification of Diseases¹⁵¹. Proposals in the area of mental disorders are encouraged.

Proposals should address all of the following aspects:

- Proposals should aim to validate biomarkers that can reliably confirm early stages of the human brain disorder and guide treatment/ intervention selection¹⁵².
- Proposals should aim to provide evidence supporting the regulatory acceptance of the biomarkers¹⁵³.
- Exploitation of existing data, biobanks, registries and cohorts is expected, together with the generation of new key data.
- Inclusion of patients or patient organisations in the research is strongly encouraged, as to ensure that their views are considered.

¹⁵⁰ For example, the Nature news feature (March, 2022): Could drugs prevent Alzheimer's? These trials aim to find out. doi: <https://doi.org/10.1038/d41586-022-00651-0>

¹⁵¹ International Classification of Diseases 11th Revision (ICD-11), developed by the World Health Organization (WHO); Chapter 6: 'Mental, behavioural or neurodevelopmental disorders'; Chapter 8: 'Diseases of the nervous system'.

¹⁵² The biomarker should link to a clinical meaningful endpoint.

¹⁵³ The European Medicines Agency (EMA) offers scientific advice to support the qualification of innovative development methods for a specific intended use in the context of research and development into pharmaceuticals.

- Sex and gender aspects, age, socio-economic, lifestyle and behavioural factors should be taken into consideration in the study.
- To enable sharing of samples, quality data and advanced analytical and digital tools, consideration should be made for using infrastructures already developed at the European¹⁵⁴ or national level.
- To enable the management of brain disorders, consideration should be made in demonstrating the gained cost efficiency.
- SME participation is encouraged.

Applicants of second stage envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2024-DISEASE-03-14-two-stage: Tackling high-burden for patients, under-researched medical conditions

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 6.00 and 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 25.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Admissibility conditions</i>	The conditions are described in General Annex A. The following exceptions apply: Applicants submitting a proposal under the blind evaluation pilot (see General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in Part B of their first stage application (see General Annex E).
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support

¹⁵⁴ EU-supported infrastructures include, for example, the BBMRI-ERIC infrastructure for biobanking, the EBRAINS research infrastructure, and various platforms developed by the Innovative Medicines Initiative (IMI) and its successor the Innovative Health Initiative (IHI).

	its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
<i>Procedure</i>	The procedure is described in General Annex F. The following exceptions apply: This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). ¹⁵⁵ .

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 most of the following expected outcomes:

- The scientific and clinical communities make effective use of state-of-the-art information, data, technologies, tools and best practices to better understand the condition, underpinning the development of diagnostics, therapeutics and/or preventive strategies.
- The scientific and clinical community exchange data, knowledge and best practices, thereby strengthening their collaboration and building a knowledge and care networks in Europe and beyond.
- The scientific and clinical community make wide use of newly established and where relevant open access databases and/or integrate them with existing infrastructures for storage and sharing of collected data according to FAIR principles, thereby encouraging further use of the data.

¹⁵⁵ This [decision](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf) is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under ‘Simplified costs decisions’ or through this link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf

- Policy makers and funders are informed of the research advances made and consider further support in light of the sustainability of the studies.
- Patients and caregivers are constructively engaged with the research, which also caters for their needs.
- Health professionals have access to and use improved clinical guidelines on diagnosis and/or treatment of the condition.

Scope: A number of medical conditions fail to be recognised and/or be correctly diagnosed in a significant proportion of patients. As a consequence they are inadequately treated and often can become a chronic burden for the patient. These medical conditions¹⁵⁶ may be insufficiently researched even though they manifest with high prevalence^{157 158}.

Proposals should address all of the following aspects:

- Proposals should aim at identifying the pathophysiological mechanism (e.g. genetic, cellular and molecular) and potential risk factors (e.g. psychological and environmental) of the medical condition(s) through basic, pre-clinical and/or clinical research. These efforts should underpin the development of diagnostics, therapeutics, and/or preventive strategies for the condition.
- Sex and gender aspects, age, ethnicity, socio-economic, lifestyle and behavioural factors should be taken into consideration. In addition, the emotional and societal long-term effects of these chronic disorders for the affected individuals should be addressed.
- Where applicable, the development of biomarkers and other technologies for diagnosis, monitoring in patients, and stratification of patient groups.
- Where applicable, the development of clinically relevant, (non-)human model systems that can complement clinical investigations.
- Exploitation of existing data, biobanks, registries and cohorts is expected, together with the generation of new (e.g. genomics, epigenomics, transcriptomics, proteomics) data.
- To enable sharing of samples, quality data and advanced analytical tools, it is encouraged to make use of existing infrastructures developed at the European¹⁵⁹ or national level.

¹⁵⁶ High-burden medical conditions could for instance include those that are either life-threatening or lead to chronic invalidity or a severely reduced quality of life.

¹⁵⁷ Examples of medical conditions include Lyme disease, Chronic Fatigue Syndrome and back pain. This topic excludes rare diseases.

¹⁵⁸ The European Commission is commissioning an independent scoping study to help identify under-researched high-burden medical conditions and define the type of research and/or research priorities to better address the different needs of patients with these conditions.

¹⁵⁹ A variety of infrastructures have been developed at European level and include, for example, the BBMRI-ERIC research infrastructure for biobanking, while others are being developed like the 'Federated European infrastructure for genomics data'.

- Inclusion of patients or patient organisations in the research is strongly encouraged, to ensure that their views are considered.
- SME participation is strongly encouraged.

This topic requires the effective contribution of social 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.

Applicants of second stage envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

Call - Tackling diseases (Single stage - 2024)

HORIZON-HLTH-2024-DISEASE-08

Conditions for the Call

Indicative budget(s)¹⁶⁰

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁶¹	Indicative number of projects expected to be funded
		2024		
Opening: 26 Oct 2023 Deadline(s): 11 Apr 2024				
HORIZON-HLTH-2024-DISEASE-03-12	CSA	2.00	Around 2.00	1
HORIZON-HLTH-2024-DISEASE-03-20	RIA	50.00	7.00 to 8.00	5
Overall indicative budget		52.00		

¹⁶⁰ 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 2023 and 2024.

¹⁶¹ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

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-2024-DISEASE-03-12: Pandemic preparedness and response: Maintaining the European partnership for pandemic preparedness

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 2.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 2.00 million.
<i>Type of Action</i>	Coordination and Support Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>Legal entities established in the United States of America may exceptionally participate in this Coordination and support action in a capacity other than Associated Partner.</p> <p>In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support</p>

	its participation in projects funded under this topic. Coordinators of projects must be legal entities established in an EU Member State or Associated Country.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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

- Research funders, policy-makers and the research community maintain a consolidated research and innovation framework for the European partnership for pandemic preparedness, including the Partnership’s objectives, governance and ways of working/operationalisation;
- Research funders, policy-makers and the research community are aligned towards common objectives and have a common understanding of the long-term Strategic Research and Innovation Agenda for the Partnership;
- European research funders are supported by a dynamic and efficient secretariat in their coordination efforts for pandemic preparedness research;
- Healthcare providers, European and international stakeholders engage with the appropriate partners through the research and innovation framework for the partnership.

Scope: The COVID-19 pandemic illustrated how unilateral research initiatives may lead to a fragmented research landscape, with substantial room for efficiency gains in the development of the highly needed evidence to guide policy actions when facing an emergency. The European partnership for pandemic preparedness is working to improve the EU’s preparedness to predict and respond to emerging infectious health threats by better coordinating funding for research and innovation at EU, national (and regional) level towards common objectives and an agreed Strategic Research and Innovation Agenda. Such a partnership contributes to building a coherent European Research Area (ERA), enabling Member States, Associated Countries and the European Commission to rapidly and jointly support research and innovation in pandemic preparedness.

The Partnership is expected to continue to build on existing pandemic preparedness networks, and work in synergy with the Health Emergency Preparedness and Response Authority (HERA).

Proposals should foresee administrative and technical support through a secretariat to maintain and support the European partnership on pandemic preparedness.

Proposals should include all of the following activities:

- Provide an efficient secretariat for the European partnership for pandemic preparedness
- Provide administrative and organisational support to the Members in the European partnership for pandemic preparedness;
- Provide strong scientific support on topics requested by the GloPID-R Chairs, scientific advisors or (working) groups;
- Actively engage with relevant stakeholders and initiatives in the area of pandemic preparedness, ensuring collaboration and coordination, and avoiding duplication; e.g. the Global Health EDCTP3 Joint Undertaking, GloPID-R, WHO R&D blueprint, ACT-Accelerator, etc.;
- Implement strong communication and dissemination activities at EU level and in Member States and Associated Countries, on the purpose, activities and outputs of the European partnership for pandemic preparedness, both outside and during epidemic/pandemic episodes;
- Establish coordination and collaboration with relevant initiatives related to pandemic preparedness such as HERA to ensure complementarity and avoid overlaps;
- As relevant, apply a cross-cutting, interdisciplinary One Health approach;

This topic requires the effective contribution of social 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.

HORIZON-HLTH-2024-DISEASE-03-20: Pandemic preparedness and response: Host-pathogen interactions of infectious diseases with epidemic potential

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 7.00 and 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 50.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility</i>	The conditions are described in General Annex B. The following

<i>conditions</i>	exceptions apply: In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic. The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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

- The scientific and clinical communities have an increased knowledge on viruses with epidemic potential and in particular a better understanding of pathogen–host interactions for the targeted development of vaccines and inhibitors for the prevention of viral infection and the viral transmission during pathogenesis.
- The scientific and clinical communities have access to novel approaches for the prevention and treatment for emerging and re-emerging infections in the context of epidemic and pandemic preparedness.
- The scientific and clinical communities have access to experimental vaccine candidates and candidates that inhibit cellular uptake of viruses against emerging or re-emerging viral infections for further clinical investigation.

A diverse and robust development pipeline of vaccine candidates and candidates that inhibit cellular uptake of viruses is available to fight emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is expected to accelerate due to among other factors, climate change, and thus a proactive approach to the development of vaccines and inhibitors for the cellular uptake of viruses in preparedness for future infectious disease outbreaks is needed. The availability of vaccines and candidates that inhibit cellular uptake of viruses would provide a critical preparedness measure against future health threats, due to infectious disease epidemics or pandemics.

Proposals should follow innovative approaches to characterize host-pathogen interactions with a view to inhibit viral replication, viral proteases, viral exit strategies and to develop

therapeutic antibodies and vaccines that target viruses with high epidemic or pandemic potential for the EU. Proposals should focus on viruses identified by HERA¹⁶² and those causing diseases that are in the list of priority diseases of the World Health Organization (WHO)¹⁶³, such as Hendra and Nipah virus, Lassa virus, Crimean Congo hemorrhagic fever virus, Rift Valley fever virus, Ebola virus, Dengue virus, Yellow Fever virus, Zika virus, West Nile fever virus and Chikungunya virus. In order to ensure complementarity to ongoing research, proposals addressing influenza and coronaviruses are not in scope. Proposal should take into account sex and gender aspects.

Proposals should aim to diversify and accelerate the global therapeutic research and development pipeline for emerging and re-emerging viral infections, and to strengthen the current leading role of the EU in therapeutic research and development, and therefore contributing to the work of the European Health Emergency Preparedness and Response Authority (HERA).

Proposals should address several of the following areas:

- Identification and characterisation of receptors on the host cell that enable the docking and internalisation of a virus with a particular emphasis on the diversity of cellular entry receptors and tissue specificity.
- Identification and characterisation of viral surface proteins that are capable of interacting with host target cells.
- Characterisation of the mechanism of viral uptake in the host cell with regard to the topology and the dynamics of the host receptor – virus ligand interaction.
- Identification of receptor and ligand (sub)units that could be targeted by preventive or therapeutic intervention.

Proposals could consider the inclusion of the European Commission's Joint Research Centre (JRC) research infrastructure (Nanobiotechnology laboratory) for biophysical characterization of recombinant proteins, antigens and therapeutic antibodies, and its expertise at the interface between the research activities and regulatory aspects. In that respect, the JRC will consider collaborating with any successful proposal and this collaboration, when relevant, should be established after the proposal's approval.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

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¹⁶² Reference to be added once the list is available.

¹⁶³ <https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts>

Conditions for the Call

Indicative budget(s)¹⁶⁴

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁶⁵	Indicative number of projects expected to be funded
		2024		
Opening: 26 Oct 2023 Deadline(s): 11 Apr 2024				
HORIZON-HLTH-2024-DISEASE-09-01	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.
<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.

¹⁶⁴ The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2023 and 2024.

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

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

HORIZON-HLTH-2024-DISEASE-09-01: European Partnership: One Health Anti-Microbial Resistance

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 100.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 100.00 million.
<i>Type of Action</i>	Programme Co-fund Action
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic, under the condition that the concerned consortium of eligible EU Members States and Associated Countries’ research funders provides agreement to this participation. The US contribution will be considered for the calculation of the EU contribution to the partnership.</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>
<i>Legal and financial set-up of the Grant Agreements</i>	<p>The rules are described in General Annex G. The following exceptions apply:</p> <p>Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. Financial support provided by the participants to third parties is one of the primary activities of the action in order to be able to achieve its objectives. The maximum amount to be granted to each third party is EUR 10.00 million.</p> <p>The funding rate is 30% of the eligible costs.</p>

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

- The EU’s response to fight the rise of AMR is improved and the EU is reinforced as an internationally recognised driver of research and innovation on antimicrobial resistance (AMR) thereby substantially contributing to the achievement of the Sustainable Development Goals related to AMR;
- EU and national agencies, the scientific communities, policy makers and funders enhance their collaboration and coordination for a strengthened ‘One Health (OH) approach to fight antimicrobial resistance (AMR)’ forming a strong and structured ecosystem with shared evidence, tools and methodologies cutting across sectors;
- Research funders, policy makers, relevant agencies and authorities, and the research community are in a position to close the current gaps and break existing silos on AMR in accordance with the European One Health Action Plan against AMR¹⁶⁶;
- Research funders align, adopt and implement their research policies and activities allowing for the optimal generation of novel solutions to prevent and treat infectious diseases affected by AMR, improved surveillance and diagnosis and control of the spread of resistant microorganisms, testing and validation of such solutions and facilitating their uptake or implementation responding to the needs to reduce the burden of AMR;
- The EU is strengthened as an internationally recognised environment for OH AMR substantially contributing to global cooperation and coordination by expanding beyond Europe;
- The research community at large benefit from and use an improved comprehensive knowledge framework integrating the EU, national/regional data and information infrastructures to improve translational research.

Scope: The partnership shall contribute to the priorities set in the European One Health Action plan to fight AMR that provides a European framework with actions focused on areas with the highest added value for Member States, including boosting research development and innovation.

In this, the European partnership on One Health AMR should allow coordinating, aligning of activities and funding among countries in the EU and beyond, as well as facilitating national coherence between different services/ministries with responsibility for the various aspects of AMR and sectors involved (e.g. human and animal health, agriculture, environment, innovation).

¹⁶⁶ https://ec.europa.eu/health/system/files/2020-01/amr_2017_action-plan_0.pdf

This partnership should also contribute to achieving the objectives of the Pharmaceutical Strategy for Europe¹⁶⁷, in terms of fulfilling unmet medical needs on AMR and ensuring that the benefits of innovation reach patients in the EU, and support the objectives of the new EU4Health Programme¹⁶⁸.

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

The co-funded European Partnership on One Health antimicrobial resistance should be implemented through a joint programme of activities ranging from coordinating transnational research efforts to other activities such as coordination and networking activities, capacity building programmes, brokerage and mobility programmes, work on research infrastructures and resources, including training and dissemination activities.

The implementation of the future European Partnership for OH AMR should contribute to build a European Research and Innovation Area (ERA) to rapidly and jointly support research and innovation in the fight against AMR.

It should be structured along the following 3 main objectives:

1. Collaboration and alignment of Research and Innovation agendas on OH AMR

The Partnership should mobilise and link key AMR stakeholders, encompassing the human, veterinary, agricultural and environmental disciplines and including a broad spectrum of pathogens, bacteria, fungi, parasites and viruses, through a cross-cutting, interdisciplinary one health approach. It should provide a framework to close the current knowledge gaps and break existing silos in the AMR research landscape, facilitating the integration of national and international scientific and policy communities with industry and the civil society.

For this, the partnership could support, although no limited to, the following activities:

- Joint strategic programming and global coordination of research and innovation through an agreed One Health AMR SRIA (covering the scientific areas Therapeutics, Surveillance, Diagnostics, Transmission, Prevention and Intervention, environment and social behavioural science).
- Target research and innovation efforts to actual needs (challenge-driven) of policymakers and stakeholders.
- Create a transnational system that supports collaboration between EU, MS and international initiatives.

2. Boost Research and Innovation

¹⁶⁷ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761>

¹⁶⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AAOJ.L.2021.107.01.0001.01.ENG>

The Partnership should strengthen the European Research Area by supporting excellence in innovative research, capacity building, programmes for development of talent, widening the engagement of countries and sectors not yet involved.

For this, the partnership could support, although no limited to, the following activities:

- Support excellent OH AMR research and development of new prevention methods, interventions, treatments and diagnostics through annual joint transnational research calls and research network calls.
- Develop new tools and instruments to support research and innovation.
- Support networking, training and mobility of researchers.
- Facilitate sharing and use of data and research infrastructure.

3. Develop solutions

- Facilitate translation of scientific knowledge into innovations solutions
- Connect, merge and align dissemination of outputs with other initiatives to support evidence-based policy in whole One Health domain
- Societal engagement by bridging science to society creating awareness of AMR challenges, value creation, support the wellbeing of citizens and sustainability of the environment

The partnership shall also:

Strengthen the OH AMR ecosystem with integrating activities engaging key actors for AMR encompassing the field of human, veterinary and environmental disciplines and the broad spectrum of pathogens, including fungi and viruses.

Implement collaborative activities with International Organisations such as the World Health Organization (WHO), the World Animal Health Organisation (OIE), the Food and Agriculture Organization (FAO), the G7 and G20 fora, and the global AMR R&D Hub, with the aim to avoid duplication of efforts. International cooperation is encouraged also with low- and middle-income countries where AMR is highly prevalent and prone to spread to Europe.

Establish robust communication and effective information exchange between diverse scientific disciplines and among multiple sectors of the society (as patients, clinicians, veterinarians, pharmacists, food producers, pharmaceutical industry, policy makers and researchers (including those working in the social sciences and humanities).

The Partnership's governance structure should engage upfront the relevant actors to coordinate, steer and frame the research and innovation activities, facilitate the use and uptake of the results and contribute to a science-based communication of the risk of spread of AMR. The Partnership's governance and operational structures should also foster a dialogue on sustainability, beyond funding from EU research and innovation framework programmes.

The governance should involve key stakeholders, including but not limited to the research and innovation community, patients and citizens, health and care professionals, and innovation owners.

The Partnership is open to all EU Member States, as well as to countries associated to Horizon Europe and will remain open to those countries wishing to join.

The Partnership should build on, be complementary to and go beyond the existing initiative JPIAMR¹⁶⁹.

To ensure coherence and complementarity of activities and leverage knowledge and investment possibilities, the Partnership is expected to establish relevant collaborations with other Horizon Europe partnerships (institutionalized and co-funded) and missions as set out in the working document on ‘Coherence and Synergies of candidate European partnerships under Horizon Europe’¹⁷⁰ as well as to explore collaborations with other relevant activities at EU and international level. The proposal should also consider synergies with EU programmes, including but not limited to EU4Health. The Partnership should align with EU-wide initiatives on open access and FAIR data¹⁷¹.

Cooperation with international organisations, private sector and non-European institutions and experts may be considered. Participation of third countries is encouraged. Their commitments to the Partnership would not be eligible for the calculation of EU funding. Applicants should describe in their proposal the methodology for their collaboration and the aims they want to achieve with this kind of collaboration.

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

When defining calls for proposals, this Partnership needs to consider if to require the effective contribution of social 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.

¹⁶⁹ <https://www.jpiamr.eu/>

¹⁷⁰ https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/ec_rtd_coherence-synergies-of-ep-under-he_annex.pdf

¹⁷¹ https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-dissemination_en.htm

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

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

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

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

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

- Accelerating the development of personalised medicine in the EU and Associated Countries, especially through a public-public cofunded partnership on personalised medicine
- Increasing access to health and care services for patients and citizens, and especially for people in vulnerable situations and at risk of discrimination
- Improving the resilience and mental wellbeing of the health and care workforce, including informal carers
- Enhancing development and uptake of research and innovation in health and care systems, including environmental transformation of the systems and contributions to the European Green Deal.

In view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic but also between other projects funded under another topic, cluster or pillar of Horizon Europe (but also with ongoing projects funded under Horizon 2020). In particular, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health and EIT-KIC Health (under pillar III of Horizon Europe), or in areas cutting across the health and other clusters (under pillar II of Horizon Europe). For instance, with cluster 2 “*Culture, Creativity and Inclusive Society*” such as on health economics and economic models, on cost-effectiveness, fiscal sustainability and accessibility of health care, or on adaptation of public health systems to societal challenges (climate change, environmental degradation, migration, demographic change, emerging epidemics and One Health AMR) thereby contributing to building resilience; with cluster 3 “*Civil Security for Society*” such as on security of health care infrastructures, incl. digital health infrastructures, health systems preparedness and response to disasters and other emergencies, and quality and safety of medicine (counterfeit and substandard medicine, illicit drugs, One Health AMR); with cluster 4 “*Digital, Industry and Space*” such as on cybersecurity of (public) health systems, products and infrastructures of digitalised health and care, or on health impact assessment (e.g. related to consumer products, working place innovation); with cluster 5 “*Climate, Energy and Mobility*”; and cluster 6 “*Food, Bioeconomy, Natural Resources, Agriculture and Environment*”.

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:

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- Health and social care services and systems have improved governance mechanisms and are more effective, efficient, accessible, resilient, trusted and sustainable, both fiscally and environmentally. Health promotion and disease prevention will be at their heart, by shifting from hospital-centred to community-based, people-centred and integrated health care structures and successfully embedding technological innovations that meet public health needs, while patient safety and quality of services are increased.
- Health care providers are trained and equipped with the skills and competences suited for the future needs of health care systems that are modernised, digitally transformed and equipped with innovative tools, technologies and digital solutions for health care. They save time and resources by integrating and applying innovative technologies, which better involve patients in their own care, by reorganising workflows and redistributing tasks and responsibilities throughout the health care system, and by monitoring and analysing corresponding health care activities.
- Citizens are supported to play a key role in managing their own health care, informal carers (including unpaid carers) are fully supported (e.g. by preventing overburdening and economic stress) and specific needs of more vulnerable groups are recognised and addressed. They benefit from improved access to health care services, including financial risk protection, timely access to quality essential health care services, including safe, effective, and affordable essential medicines and vaccines.
- Health policy and systems adopt a holistic approach (individuals, communities, organisations, society) for the evaluation of health outcomes and value of public health interventions, the organisation of health care, and decision-making.

The actions resulting from the calls under this destination will also create strong opportunities for synergies with the EU4Health programme and in particular to contribute to the goals under the general objective “protecting people in the Union from serious cross-border threats to health and specific objective 4 “to strengthen health systems, their resilience and resource efficiency”.

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

Call	Budgets (EUR million)		Deadline(s)
	2023	2024	
HORIZON-HLTH-2023-CARE-04	60.00		13 Apr 2023
HORIZON-HLTH-2023-CARE-08	100.00		13 Apr 2023
HORIZON-HLTH-2024-CARE-04-two-stage		30.00	19 Sep 2023 (First Stage) 11 Apr 2024

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			(Second Stage)
Overall indicative budget	160.00	30.00	

DRAFT

Call - Ensuring access to innovative, sustainable and high-quality health care (Single stage - 2023)

HORIZON-HLTH-2023-CARE-04

Conditions for the Call

Indicative budget(s)¹⁷²

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ¹⁷³	Indicative number of projects expected to be funded
		2023		
Opening: 12 Jan 2023 Deadline(s): 13 Apr 2023				
HORIZON-HLTH-2023-CARE-04-01	RIA	20.00 ¹⁷⁴	4.00 to 6.00	4
HORIZON-HLTH-2023-CARE-04-02	RIA	20.00 ¹⁷⁵	4.00 to 6.00	4
HORIZON-HLTH-2023-CARE-04-03	RIA	20.00 ¹⁷⁶	4.00 to 6.00	4
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.

¹⁷² 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 2023 and 2024.

¹⁷³ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹⁷⁴ Of which EUR 11.00 million from the 'NGEU' Fund Source.

¹⁷⁵ Of which EUR 11.00 million from the 'NGEU' Fund Source.

¹⁷⁶ Of which EUR 11.00 million from the 'NGEU' Fund Source.

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<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-2023-CARE-04-01: Maintaining access to regular health and care services in case of cross-border emergencies

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 4.00 and 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
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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 several of the following expected outcomes:

- Decision- and policy makers have access to modelling tools and foresight studies (including cost studies on the non-access to health and care services) on health and care systems¹⁷⁷ for anticipating regular¹⁷⁸ and unplanned health and care demand during large-scale cross-border emergencies¹⁷⁹.
- Decision- and policy makers and health and care providers can better facilitate and manage access to regular health and care delivery during cross-border emergencies.
- Decision- and policy makers and health and care providers avail of management frameworks including organisational models for handling unplanned health and care demand linked to cross-border emergencies, while maintaining necessary regular health and care provision.
- Health and care professionals have access to training on how to deliver regular health and care services (including by means such as telemedicine) during cross-border health emergencies.
- Health and care professionals, citizens and patients access advanced digital tools enabling managed access to regular health and care services, complemented by other modes of health and care delivery (e.g., telemedicine, self-care, prioritised care).
- Patients can be involved in the co-design and co-production of health and care delivery models during cross-border emergencies and can benefit from better access to regular health and care services during such periods.
- Health and care providers and health and care professionals have access to knowledge and data on, and innovative solutions to combat, decreasing demand for regular health and care services resulting from an ongoing emergency (e.g. patients are avoiding visits to hospitals because they are worried about additional infections or do not want to add extra burden on the health and care systems).

Scope: Since the outbreak of the Covid-19 pandemic in Europe, as well as globally, health and care systems have been facing unprecedented challenges. Many systems were overwhelmed and fell short on available supplies, staff, and critical infrastructure. Beyond the

¹⁷⁷ “Health and care systems” implies a broader notion than “health systems” or “healthcare systems” notably encompassing all parts of health systems and health related parts of social care systems.

¹⁷⁸ Regular care refers to the care that would be expected to be needed and delivered under normal circumstances. This includes all types of morbidities (chronic diseases, mental health disorders, trauma care etc.) and also all parts of the health and care systems (prevention, follow-up, long-term care, primary care, both in- and out hospital care etc.), as well as related support services such as laboratories.

¹⁷⁹ Cross-border emergency refers to an emergent situation that spreads or entails a significant risk of spreading across the national borders of Member States and Associated Countries, and which may necessitate coordination at Union level in order to ensure a high level of human health protection (Art. 2(1) Regulation on serious cross-border threats to health). In this topic, only emergency situations with a high impact on health systems are included.

initial challenges posed by the pandemic, its prolonged duration has strained health and care facilities and providers, and had a negative impact on regular health and care provision. Disruptions in routine and non-emergency medical care access and delivery have been observed. It is hence timely to take stock and identify lessons for maintaining care delivery.

Another recent emergency situation that has had a great impact on health and care systems is the war in Ukraine and the resulting migration to bordering countries. Also under these circumstances, it is important to have the right tools for maintaining access to regular health and care services, while also accommodating the more urgent needs of migrants, for example.

The goal is to be better prepared for the multiple challenges faced by health and care systems during emergencies, and ensure that necessary access to regular health and care services can be maintained.

Proposals for research and innovation should focus on health and care systems, and actions are expected to address several of the following:

- Analysis and evaluation of different epidemics or other emergencies response measures in Member States and Associated Countries aimed at maintaining access to regular health and care services. Cost studies on not maintaining access to health and care services during cross-border emergencies.
- Development of innovative tools and models that maintain access to regular health and care services during cross-border emergencies – for example developing modelling and foresight tools to assess and anticipate impact of cross-border emergencies on regular health and care delivery; developing novel technical solutions or organizational management models, including training, for regular care delivery in future cross-border emergencies; demonstrating applicability of novel modelling tools, management frameworks and organisational models in selected areas of regular health and care services (e.g. chronic diseases, mental health disorders, trauma care).
- Development and implementation of digital tools and of effective communication strategies based on digital health literacy studies – for example developing, implementing and generating evidence of benefit of novel digital systems connecting health and care professionals, citizens and patients at-scale, helping maintain access to health and care services during emergencies (including but not limited to smart appointment management, chronic disease self-management applications, primary care and/or referral caseload prioritisation and management incl. triage, increasing clinical practice efficiency, management of health care professionals' caseload, integrated telecare suites complemented by new computational methods such as AI/machine learning, etc.).

This topic requires the effective contribution of social 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. Interdisciplinary research is thus encouraged,

including the involvement of SSH disciplines considered essential for health and care planning and delivery in different social contexts and for the evaluation of health economical aspects.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. Therefore, proposals should include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase.

Synergies should be sought with potentially complementary research initiatives, data stewards, custodians and research infrastructures such as the European Observatory on Health Systems and Policies, the Population Health Information Research Infrastructure and the future European co-funded partnerships¹⁸⁰, such as the partnership on Transforming Health and Care Systems (THCS).

Successful projects need to adequately link and integrate with relevant EU health policy efforts towards a European Health Data Space (EHDS)¹⁸¹ and the nascent Health Emergency Response Authority (HERA)¹⁸².

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-CARE-04-02: Resilience and mental wellbeing of the health and care workforce

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 4.00 and 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
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the

¹⁸⁰ https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partnerships-horizon-europe/candidates-european-partnerships-health_en

¹⁸¹ https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en

¹⁸² COM(2021) 576 final

	United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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 several of the following expected outcomes:

- Health and care workers receive support (including mental health support), access to tools and guidance that enhances their wellbeing and ability to adapt to changing working conditions, as a result of new technologies, new work models or unexpected adverse events, including during public health emergencies and when under ethical stress.
- Decision- and policymakers, employers and social partners in the health and care sectors¹⁸³ have knowledge of the specific risks for the resilience, mental health and well-being of health and care professionals and informal carers. They have access to solutions (regulatory, organisational, technological, educational, HR, health services) to prevent and manage them, based on the integrated development of work processes and wellbeing at work and on the study of effects of clustered work stressors on work ability and recovery from work.
- Funders of health and care provision have access to evidence, novel approaches and cost-effective recommendations for interventions supporting the mental health and well-being of health and care workers at individual, organisation and sector levels.
- Policy makers cooperate with relevant stakeholders, including health and care professionals associations and social partners to foster specific solutions to improve resilience and well-being of health workers and carers including informal carers¹⁸⁴, and fight the accumulation of stressors.

Scope: A resilient workforce in the health and care sectors is essential for the sustainability and prosperity of our societies. However, careers in the health and care sector can be physically and mentally taxing by submitting health professionals and carers to psychosocial risks (for example heavy workload, stressful working conditions, risk of exposure to

¹⁸³ “Health and care systems” implies a broader notion than “health systems” or “healthcare systems” notably encompassing all parts of health systems and health related parts of social care systems.

¹⁸⁴ OECD definition: “Informal carers are defined as people providing any help to older family members, friends and people in their social network, living inside or outside of their household, who require help with everyday tasks.”

infectious agents, precariousness, ethical stress etc.). Many health professionals and carers also commute to work or have migrated to work in a new country. This adds to the struggle of health and care systems to attract new people to their workforce, but also to maintain the ones already working. A combination of factors such as changes in work organisation, budgetary and administrative pressures faced by health and care systems, systemic shortages of health professionals, precarious working conditions, structural inequalities and leaps in technological innovation may leave health and care workers with feelings of helplessness, physical or mental vulnerability or moral injury.

Technological innovations (including digitisation, big data and artificial intelligence applications) provide opportunities for a more efficient provision of health and care services, and for lightening the workload of health and care workers. However, they also create new risks, potentially affecting the mental wellbeing of the workforce. For example, new skills, requirements, new organisational models, performance monitoring by algorithms, lack of control or accountability in workplace decisions, ethical questions, are elements that can increase stress and hamper the ability of health and care workers to function in their jobs on a daily basis.

The COVID-19 pandemic has put a strain on health and care workers' resilience and exacerbated mental health issues that were already a problem pre-pandemic, ranging from anxiety due to increased workload to burnout and post-traumatic stress disorder. Informal carers suffer from similar stress, potentially caused by different factors, such as the need to provide care which keeps them away from employment and puts them at an increased risk of poverty. Lack of acknowledgement that one's mental health is deteriorating, barriers to seeking help or the stigma that still surrounds mental illness may impede people from addressing such problems early enough. Different socio-economic groups are affected to different extents: in emerging virus outbreaks prior to the COVID-19 pandemic lower educational level among other things was associated with higher risk for adverse psychological outcomes among health workers¹⁸⁵.

Successful applicants must address several of the following activities:

- Collect and analyse new evidence and data generation – on occupation-specific factors building the resilience, mental health well-being of health and care workers, or informal carers. Where appropriate, evidence should be gathered and analysed on the interplay of such factors with non-occupation specific factors (e.g. genetic, social etc.). Where relevant, such evidence should be target-group specific, considering variation of challenges for professionals working in various settings (primary care, hospitals, residential care institutions, disadvantaged geographic locations).
- Develop action-oriented recommendations to policymakers, employers, social partners and relevant civil society organisations at the appropriate levels (EU, national, regional, local) based on evidence generated by the proposed action. Such recommendations should suggest (cost-)effective policy interventions or elements for further research

¹⁸⁵ https://ec.europa.eu/health/system/files/2021-10/028_mental-health_workforce_en_0.pdf

aiming to promote the resilience, mental health and well-being of health and care workers. They should be based on cost-benefit studies and ex-ante evaluations of proposed interventions.

- Develop, or identify, innovative solutions (including digitally enabled ones), organisational models and management approaches to support health policymakers, employers and formal or informal health and care workers in promoting resilience, mental health and well-being in the workplace.
- Develop financing and resource allocation models to ensure access to support and mental health services for health and care workers and informal carers.
- Carry out testing and validation activities for new or improved solutions¹⁸⁶ improving conditions for health and care workers or informal carers according to specific factors influencing their mental well-being.

Applicants can select one or more worker groups or informal carers as target of R&I activities, based on credible scientific criteria.

This topic requires the effective contribution of social sciences and humanities (SSH) disciplines and the involvement of SSH experts, institutions as well as the inclusion of relevant SSH expertise, health and care professionals associations and (informal) carers associations, in order to produce meaningful and significant effects enhancing the societal impact of the related research activities.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. Therefore, proposals should include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase.

With women making up over 70% of EU health care professionals and employees in the care sector and a great part of informal carers, an appropriate gender approach is essential in research and policy interventions, to prevent or mitigate workplace inequalities and imbalances. Researchers and policymakers should also take into account the inclusion dimension, as a significant share of health professionals or care workers typically come from minority groups, whether through declared or undeclared work.

Applicants should consider potential synergies and avoid overlaps with ongoing calls or actions funded under EU or national programmes for example the future cofunded partnership on Transforming Health and Care Systems (THCS).

Proposals are encouraged to take into account, when relevant, the EU Strategic Framework on Health and Safety at Work (2021-2027)¹⁸⁷, the report on mental health¹⁸⁸ and most

¹⁸⁶ Practices can be shared via the Best Practice Portal ([pb-portal \(europa.eu\)](https://pb-portal.europa.eu)). Examples of interventions that were initiated to tackle the mental health impact of the pandemic are also available on the pages of the dedicated web space on that topic on the Health Policy Platform <https://webgate.ec.europa.eu/hpf/>

importantly, the recommendations and analysis presented in the Expert Panel on effective ways of investing in health (EXPH) opinion on supporting the mental health of the health workforce and of other essential workers.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-CARE-04-03: Environmentally sustainable and climate neutral health and care systems

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 4.00 and 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
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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

- Policy and decision makers, providers of health and care, health and care workers and citizens have increased knowledge on how today’s health and care systems¹⁸⁹ are not

¹⁸⁷ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0323&from=EN>
¹⁸⁸ https://ec.europa.eu/health/other-pages/basic-page/mental-health-and-pandemic-living-caring-acting_en.

¹⁸⁹ “Health and care systems” implies a broader notion than “health systems” or “healthcare systems” notably encompassing all parts of health systems and health related parts of social care systems.

environmentally sustainable, what the possible costs of that are (today and future) and where improvements are possible with maintained or improved quality of care (optimal patient safety not being jeopardised) and possible investments needed.

- Policy and decision makers and providers of health and care services have access to innovative solutions, organisational models (including financing models), and guidelines and recommendations that reduce the pollution and carbon emissions stemming from health and care systems, so that health and care provision can become more sustainable and cost-effective while maintaining or improving quality of care thanks to the reduction of energy and materials use, decreased carbon emissions, reduced waste and discharges, and efficient resource management.
- Monitoring and reporting of carbon emissions and pollution is mainstreamed through a life-cycle approach and with standard methods in the health and care systems.

Scope: The health care sector is responsible for 4-5% of global total carbon emissions¹⁹⁰, and generates significant demands for energy and materials, as well as dangerous waste streams that may cause air, soil and water pollution. At the same time, health and care provision generally experiences less pressure to decarbonise and improve its circularity than other sectors of the economy. With the European Green Deal, the EU commits to reducing net greenhouse gas emission by at least 55% by 2030, and to reach no net emissions by 2050, and the health and care systems are not exempt. Research and innovation can support by ensuring a smooth transformation while maintaining or improving quality of health and care services.

Health and care systems are undergoing structural changes, for example by strengthening primary care and community-based care, strengthening digitalisation and making sure patients are treated or cared for at the most efficient level. This offers the possibility to connect structural changes with an environmental transformation.

During COP26, 18 countries (including two EU Member States) have committed to cutting all carbon emissions from their health systems over the next 10 to 30 years and during the same period in total fifty countries (including six EU Member States) have committed to creating climate resilient, low carbon, sustainable health systems.

In February 2022, the WHO published a report on the waste that had been generated as a result of the COVID-19 pandemic, even more emphasising the need to improve waste management systems of the health and care systems¹⁹¹. The report states that 30% of healthcare facilities world-wide, and 60% in the least developed countries, are not fit to handle the waste generated even when not taking the extra waste generated by the pandemic into account. Not only does this pose environmental risks such as water and air pollution, but it also poses a risk to health workers' safety by increasing the risk of being exposed to stick injuries, burns and pathogenic microorganisms.

¹⁹⁰ <https://www.thelancet.com/action/showPdf?pii=S2542-5196%2820%2930271-0>

¹⁹¹ <https://www.who.int/news/item/01-02-2022-tonnes-of-covid-19-health-care-waste-expose-urgent-need-to-improve-waste-management-systems>

Research and innovation activities under this topic should be specific to health and care sectors. They should include cost studies when relevant (environmental impacts and benefits to be quantified through the life cycle thinking approach (e.g. LCA/SLCA), to be effectively implemented in line with the European Green Deal and the Zero Pollution Action Plan) and piloting research results onsite in hospitals or other care settings while generating accessible knowledge could be included. Apart from that, successful proposals should address several of the following:

- Research and innovative solutions for decarbonisation of hospitals and other care providers: improvements in new and existing building stock, decarbonisation of energy supply to premises, reduction in energy demand of hospital sites and other care facilities (for example heating and cooling, hot water, laundry, cooking, transport systems).
- Research and innovative solutions for increased circularity of hospitals or other care providers that integrate the zero-pollution ambition: such as solutions to reduce waste, improved waste management practices (with a possible focus on water effluents and Antimicrobial Resistance (AMR)), increased circularity (for example sustainable use of linen).
- Research and innovative solutions for decarbonisation and greening of supply chains and material inflows: reduction of single-use plastics, substitution of anaesthetic gases and inhalers with high global warming potentials (GWPs), substitution of conventional pharmaceuticals with green(er) alternatives, low-carbon supply chains of food, waste reduction, management models on for example prescription of pharmaceuticals.
- Development of a framework to measure and benchmark the environmental footprint of the health and care sectors or improving infrastructures for relevant collecting, sharing, accessing and processing of data.

Projects with interdisciplinary teams representing the health and care sectors, and the environmental sector or other relevant sectors are welcome.

This topic requires the effective contribution of social 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.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. Therefore, proposals should include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase.

Applicants are encouraged to consider how their proposals can contribute in the context of the European Green Deal¹⁹², and to take into account the principles of the Circular Economy

¹⁹² https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

Action Plan¹⁹³, the Zero Pollution Action Plan¹⁹⁴ as well as the Technical guidance on the climate proofing of infrastructure in the period 2021-2027.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

Call - Partnerships in Health (2023)

HORIZON-HLTH-2023-CARE-08

Conditions for the Call

Indicative budget(s)¹⁹⁵

Topics	Type of Action	Budgets (EUR million) 2023	Expected EU contribution per project (EUR million) ¹⁹⁶	Indicative number of projects expected to be funded
Opening: 12 Jan 2023 Deadline(s): 13 Apr 2023				
HORIZON-HLTH-2023-CARE-08-01	COFUND	100.00 ¹⁹⁷	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

¹⁹³ https://ec.europa.eu/environment/strategy/circular-economy-action-plan_en

¹⁹⁴ https://ec.europa.eu/environment/strategy/zero-pollution-action-plan_en

¹⁹⁵ The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.

The Director-General responsible may delay the deadline(s) by up to two months.

All deadlines are at 17.00.00 Brussels local time.

The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2023 and 2024.

¹⁹⁶ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

¹⁹⁷ Of which EUR 50.00 million from the 'NGEU' Fund Source.

Horizon Europe - Work Programme 2023-2024
Health

	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-2023-CARE-08-01: European Partnership on Personalised Medicine

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 100.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 100.00 million.
<i>Type of Action</i>	Programme Co-fund Action
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic, under the condition that the concerned consortium of eligible EU Members States and Associated Countries' research funders provides agreement to this participation. The US contribution will be considered for the calculation of the EU contribution to the partnership.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

<i>Legal and financial set-up of the Grant Agreements</i>	<p>The rules are described in General Annex G. The following exceptions apply:</p> <p>The funding rate is 30% of the eligible costs.</p> <p>Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. Financial support provided by the participants to third parties is one of the primary activities of the action in order to be able to achieve its objectives. The maximum amount to be granted to each third party is EUR 10.00 million.</p>
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Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4, notably “Ensuring access to innovative, sustainable and high-quality healthcare”. 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 countries and regions, along with international partners, are engaged in enhanced collaborative research efforts for the development of innovative personalised medicine approaches regarding prevention, diagnosis and treatment;
- Healthcare authorities, policymakers and other stakeholders develop evidence-based strategies and policies for the uptake of personalised medicine in national or regional healthcare systems;
- Health industries, policymakers and other stakeholders have access to efficient measures and investments to allow swift transfer of research and innovation into market;
- Health industries and other stakeholders can accelerate the uptake of personalised medicine through the adoption of innovative business models;
- Healthcare authorities, policymakers and other stakeholders use improved knowledge and understanding of the health and costs benefits of personalised medicine to optimize healthcare and make healthcare systems more sustainable
- Healthcare providers and professionals improve health outcomes, prevent diseases and maintain population health through the implementation of personalised medicine;
- Stronger and highly connected local/regional ecosystems of stakeholders, including innovators, are in place and facilitate the uptake of successful innovations in personalised medicine, thus improving healthcare outcomes and strengthening European competitiveness;
- Citizens, patients and healthcare professionals have a better knowledge of personalised medicine and are better involved in its implementation;

- Stakeholders cooperate better and establish a network of national and regional knowledge hubs for personalised medicine.

Scope: Personalised medicine is a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging and lifestyle data) for tailoring the right health strategy. Personalized medicine shows great promise and has already led to ground-breaking developments in treatment of many diseases. Through this approach, better health outcomes can be achieved by preventing disease and providing patient-centred care tailored to the needs of citizens. There have been important investments in personalised medicine over the last decades. However, producing knowledge, translating it into clinical applications and accelerating innovation uptake are complex, time-consuming and involve multiple stakeholders. There is a need to facilitate the uptake of health technology innovations and ensure a rapid and effective implementation of personalised medicine on a larger scale in Europe. To this end, the creation of a research and innovation (R&I) partnership with a focus on personalised medicine represents a unique strategic opportunity to bring together stakeholders, create synergies, coordinate R&I actions and leverage the efforts to accelerate the evolution of healthcare toward personalised medicine.

The partnership should build on knowledge gained from supportive initiatives like the International Consortium of Personalised Medicine (ICPerMed), the European Research Area Network for Personalised Medicine (ERA-PerMed), several Coordination and Support Actions (CSAs) funded by the EC under Horizon 2020, the one million genomes initiative as well as with an increasing number of associated and related initiatives, research infrastructures and capacities in Europe and beyond.

The partnership will facilitate exchange of information and good practices among countries, provide robust guidance and tools, will network institutional stakeholders and involve regional ecosystems. It should 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. The partnership should bring together a broad range of actors with a common vision of future personalised medicine. Through the objectives of Horizon Europe, the partnership should contribute to achieving the following European Commission priorities:

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

The partnership will also 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 the Europe's Beating Cancer Plan.

Thanks to its capacity to bring together different stakeholders (e.g. research funders, health authorities, healthcare 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:

- Putting Europe at the forefront of research and innovation through the support of multidisciplinary actions open to international cooperation;
- Establishing a European national and regional network of research and innovation systems dedicated to personalised medicine;
- Translating basic research into clinical applications that make a difference for patients, their families and healthcare professionals;
- Filling scientific knowledge gaps, producing evidence and developing guidance and tools in priority areas for the development and the deployment of personalised medicine;
- Integrating big data and digital health solutions in research and personalised healthcare;
- Strengthening the European healthcare industry and accelerating the uptake of personalised medicine solutions;
- Developing appropriate ecosystems for the implementation of successful personalised medicine approaches and a swift uptake of relevant innovations by healthcare systems;
- Providing socio-economic evidence of the feasibility of personalised medicine approaches for its uptake by sustainable healthcare systems;
- Improving health outcomes for citizen and patients and ensuring a wide access to advanced personalised medicine intervention approaches to all.

The European Partnership for Personalised Medicine¹⁹⁸ will be implemented through a joint programme of activities ranging from research to coordination and networking activities, including training, demonstration, piloting and dissemination activities, to be structured along the following main building blocks:

- Joint implementation of the SRIA;
- Joint annual calls for R&I activities, applied R&I, pilots;
- Capacity building activities;
- Activities to enhance the skills of the relevant personalised medicine workforce, and improve citizen relevant awareness and literacy;

¹⁹⁸ More information on the planned European Partnerships is available on the Horizon Europe Webpage:

- Deployment activities through pilots, innovation procurements and financial support mechanisms,
- Flanking measures.

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

- Ministries in charge of R&I policy, as well as national and regional R&I and technology funding agencies and foundations;
- Ministries in charge of health and care policy, as well as national and regional healthcare authorities, organisations and providers.

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

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

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

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

To ensure coherence and complementarity of activities and leverage knowledge and investment possibilities, the Partnership is expected to establish relevant collaborations with other European partnerships and missions as set out in the working document on 'Coherence and Synergies of existing and candidate European partnerships under Horizon Europe'¹⁹⁹ as well as to explore collaborations with other relevant activities at EU and international level. On top of this, the proposal should consider synergies with EU programmes, including but not limited to EU4Health, DEP, ESF+, ERDF, InvestEU, RRF and TSI.

The Partnership should align with EU-wide initiatives on open access and FAIR data²⁰⁰.

¹⁹⁹

²⁰⁰ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.

Cooperation with international organisations, and non-European institutions and experts should be considered. Applicants should describe in their proposal the methodology for their collaboration and the aims they want to achieve with this kind of collaboration.

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

Call - Ensuring access to innovative, sustainable and high-quality health care (Two stage - 2024)

HORIZON-HLTH-2024-CARE-04-two-stage

Conditions for the Call

Indicative budget(s)²⁰¹

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ²⁰²	Indicative number of projects expected to be funded
		2024		
Opening: 30 Mar 2023 Deadline(s): 19 Sep 2023 (First Stage), 11 Apr 2024 (Second Stage)				
HORIZON-HLTH-2024-CARE-04-04-two-stage	RIA	30.00	4.00 to 6.00	5
Overall indicative budget		30.00		

General conditions relating to this call

<i>Admissibility conditions</i>	The conditions are described in General Annex A.
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²⁰¹ 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 2023 and 2024.

²⁰² Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

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<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-2024-CARE-04-04-two-stage: Access to health and care services for people in vulnerable situations

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 4.00 and 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 30.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Admissibility conditions</i>	The conditions are described in General Annex A. The following exceptions apply: Applicants submitting a proposal under the blind evaluation pilot (see General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in Part B of their first stage application (see General Annex E).
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.

<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
<i>Procedure</i>	The procedure is described in General Annex F. The following exceptions apply: This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). ²⁰³ .

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 several of the following expected outcomes:

- Decision- and policy makers, service providers, and health and care workers have better availability to and make use of knowledge on barriers to access to health and care services²⁰⁴ experienced by people in vulnerable situations and at risk of stigma or discrimination (from now on referred to as people in vulnerable situations)²⁰⁵.
- Decision- and policy makers, providers and health and care workers have access to innovative solutions to promote and improve access to health and care services for people in vulnerable situations.

²⁰³ This [decision](#) is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under ‘Simplified costs decisions’ or through this link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf

²⁰⁴ “Health and care systems” implies a broader notion than “health systems” or “healthcare systems” notably encompassing all parts of health systems and health related parts of social care systems.

²⁰⁵ Groups of people and/or patients vulnerable from a social, financial, or health perspective, or at risk of discrimination, such as migrants, Roma people, trans and intersex people, specific age and gender groups (that intersects with other aspects of vulnerability, such as elderly women), indigenous people, homeless people, people in poverty or at risk of poverty, people with disabilities or patients with complex conditions.

- Decision- and policy makers and providers have access to reliable quantitative data on health inequalities in access to health and care services for people in vulnerable situations.
- People in vulnerable situations are better equipped in terms of health and digital literacy, knowledge about their rights etc. when it comes to access to health and care services.
- People in vulnerable situations are involved in the design and implementation of research and innovation activities concerning access to health and care services.

Scope: Equal and needs-based access to health and care services are important values of the EU, as well as central principles within the Member States (for example Art. 3 TFEU, 2006 Council Conclusions on Common values and principles in European Union Health Systems, European Pillar of social rights). At the same time, plenty of evidence indicates that there is unmet need for health and care services. Although financial barriers are an important part of the explanation²⁰⁶, it is also evident that even in countries where co-payment is low or even zero, access to health and care services differs between groups. Certain groups are more at risk of not accessing all the health and care services they need, depending among other factors, on their socio-economic and legal status, age, sex and gender identity, (dis)ability, ethnicity and geographical location.

For example, the life expectancy for the Roma people – the largest ethnic minority in the EU – is on average ten years shorter than the general population. This is because, due to poor socio-economic conditions and ethnic segregation, many Roma people live in enclaves where equal opportunities to services including infrastructure are lacking. Due to these inequalities that are also rooted in antigypsyism²⁰⁷, Roma are facing much greater difficulties accessing and receiving standard health and care services including prevention compared to other citizens²⁰⁸.

There are significant health inequalities between the LGBTIQ community and the population as a whole. One part of the explanation is reluctance to seek health and care services because they have experienced or fear hostile reactions. Trans- and intersex people still struggle to access quality and affordable medication and care, both related to general health services and specific health care relating to transition, such as a lack of relevant medication or surgical procedures²⁰⁹.

Compared to men, older women have a higher poverty risk also due to lower pay and lower pensions. They face a higher risk to live longer in poorer health, so their overall need for

²⁰⁶ See for example OECD Health at a glance 2021.

²⁰⁷ Antigypsyism (a form of racism against Roma) is a historically rooted structural phenomenon that appears at institutional, social and interpersonal levels.

²⁰⁸ The EU Roma strategic framework for equality, inclusion and participation sets up the ambitious goal to lessen the life expectancy gap and ensure that by 2030 Roma women and men live 5 years longer. https://ec.europa.eu/info/sites/default/files/eu_roma_strategic_framework_for_equality_inclusion_and_participation_for_2020_-_2030_0.pdf

²⁰⁹ stateofart_report_en.pdf (europa.eu) The Commission's Health4LGBTI project concluded that trans and intersex-focused research is needed that addresses health inequalities and healthcare.

health and especially care services is therefore higher²¹⁰. People living in difficult socio-economic situations, such as homeless people or people at the risk of poverty may experience similar issues. For migrants and refugees, uncertain legal status, fear of public authorities, or language difficulties may cause additional barriers to seeking adequate health and care services.

Whilst factors outside the health and care sector also have an impact on people's access to health and care services, health and care systems can influence and facilitate access through accessibility, costs, referrals and attitudes.

Another aspect concerns access to data regarding certain groups. Whereas data on access to health and care when it comes to factors related to socio-economic characteristics, geographical barriers, sex, and age is more accessible, data on people in vulnerable situations (often due to the problem of sensitivity of data) is often less accessible, contributing to making the situation of these groups less visible.

Activities under this call should focus on groups that are in vulnerable situations from a social, financial or health perspective, or at risk of discrimination, such as migrants, Roma people, trans and intersex people, specific age and gender groups (that intersects with other aspects of vulnerability, such as elderly women), indigenous people, homeless people, people in poverty or at risk of poverty, people with disabilities or patients with complex conditions. Where relevant, activities should use intersectional approaches to consider, inter alia, socioeconomic factors, geography, citizenship, age, sex and gender identity, and ethnicity.

Next to the above-mentioned, research and innovation activities under this topic should address several of the following:

- Different types of barriers - different barriers to study could be financial, geographic, social, marginalisation and discrimination. When relevant, health and digital literacy aspects should be analysed. The selection of factors should be context specific as groups suffering from access barriers vary a lot across EU countries and at subnational level. The principle of needs-based health and care should be taken into account.
- Access to what? – for example: what part of the health and care system (from prevention, primary care and long-term care to tertiary care, any specific services, e.g. mental care) do different groups have access to? Is integrated care provided for these groups taking into account their particular needs? How much health and care services do different groups access?
- Solutions - What measures are needed to counter inequalities in health and care access and make sure that vulnerable groups access health and care services and that access is based on needs (measures to educate, support and empower vulnerable groups can be included here)? What are the costs, at different levels, to develop these solutions? Piloting of measures could be included. Community-based and/or co-created initiatives

²¹⁰ To be inserted

and peer-support approaches: what works and how can these be supported, sustained and/or integrated in the wider service landscape.

- Better data – improving access and quality of data will contribute to identify people in vulnerable situations' health needs and implement targeted measures corresponding to the challenges that each group experiences. The data could for example explore effectiveness of provided care (metrics helping to assess if provided care addresses the root causes of inequalities) or new valid methodologies to identify the unmet health related needs of people in vulnerable situations. Quantitative and qualitative data on inequalities in prevention, prevalence and treatment of different morbidities.
- Cost analyses - The cost of inequalities in access to health and care services: Quantitatively and/or qualitatively measure the negative impact on not taking measures for helping people in vulnerable situations have access to health and care services including prevention.

Proposals are expected to involve the people/groups studied in the design and implementation of the research and innovation activities and where relevant service providers and other stakeholders.

This topic requires the effective contribution of social 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.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. Therefore, proposals should include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase.

When relevant, funded actions should build on the work done by the European Joint Action on Health Equity Europe (JAHEE) and the upcoming activities under the EU4Health Programme (Direct grants to international organisations (WHO): supporting Member States in improving access to healthcare and effectiveness of health coverage, taking into account vulnerabilities of specific groups and targeted intervention and access to mental health for people in vulnerable situations).

Also, when relevant, projects should build on, and are encouraged to consider how their proposals can contribute to, the Commission's LGBTIQ Equality Strategy 2020-2025, the EU Strategy for the rights of persons living with disabilities, EU strategy on the rights of the child the Child Guarantee, the Gender Equality Strategy, the EU Roma Strategic Framework and the EU Strategy for the Rights of Persons with Disabilities 2021-2030²¹¹.

²¹¹ (under the European Pillar of Social Rights) Delivering on the European Pillar of Social Rights - Employment, Social Affairs & Inclusion - European Commission (europa.eu) Union of equality:

Projects are encouraged to coordinate their activities with the planned European Partnership on Transforming Health and Care Systems, the Cancer Mission, the Cancer Inequalities Registry and the EU Non Communicable Diseases Initiative.

Projects may explore the Health Systems Performance Assessment (HSPA) Report on more effective ways of measuring access to healthcare, published in 2021. The report provides a collection of tools used on the ground to better understand needs of people in vulnerable situations and adapt the health coverage to ensure more effective care.

2021 Country Profiles published in the framework of the State of Health in the EU can be used as a source of basic comparable data on health inequalities.

Applicants of second stage envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

DRAFT

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

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

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

In this work programme destination 5 has a strong focus on the personalization of health technologies and will address the following issues:

Developing computational systems for point-of-care applications, developing and validating computational models of physiological systems and integrating health data from different sources, for better patient management and improved clinical outcomes;

Fostering translational biomedical research and advancing regenerative medicine approaches into clinical settings and manufacturing;

Preparing for potential cross-border health threats through the development of innovative in-vitro-diagnostics;

Supporting the establishment of the European Health Data Space by designing a data quality label.

In view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic but also between other projects funded under another topic, cluster or pillar of Horizon Europe (but also with ongoing projects funded under Horizon 2020). In particular, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health, the European Innovation Ecosystems (EIE) interregional networks on health and EIT-KIC Health (under pillar III of Horizon Europe) or in areas cutting across the health and other clusters (under pillar II of Horizon Europe), like, for instance, with cluster 4 “*Digital, Industry and Space*” on digitalisation of the health sector or key enabling technologies.

Expected Impacts

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

- Europe’s scientific and technological expertise and know-how, its capabilities for innovation in new tools, technologies and digital solutions, and its ability to take-up, scale-up and integrate innovation in health care is world-class.
- Citizens benefit from targeted and faster research resulting in safer, more sustainable, 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)²¹².
- The EU gains high visibility and leadership in terms of health technology development, including through international cooperation.

²¹² Commission Communication on the digital transformation of health and care; COM(2018) 233 final.

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- The burden of diseases in the EU and worldwide is reduced through the development and integration of innovative diagnostic and therapeutic approaches, personalised medicine approaches, digital and other people-centred solutions for health care.
- Both the productivity of health research and innovation, and the quality and outcome of health care is improved thanks to the use of health data and innovative analytical tools, such as artificial intelligence (AI) supported decision-making, in a secure and ethical manner, respecting individual integrity and underpinned with public acceptance and trust.
- Citizens trust and support the opportunities offered by innovative technologies for health care, based on expected health outcomes and potential risks involved.

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

Call	Budgets (EUR million)		Deadline(s)
	2023	2024	
HORIZON-HLTH-2023-TOOL-05	214.00		13 Apr 2023
HORIZON-HLTH-2024-TOOL-05-two-stage		25.00	19 Sep 2023 (First Stage) 11 Apr 2024 (Second Stage)
HORIZON-HLTH-2024-TOOL-11		25.00	11 Apr 2024
Overall indicative budget	214.00	50.00	

Call - Tools and technologies for a healthy society (Single stage - 2023)

HORIZON-HLTH-2023-TOOL-05

Conditions for the Call

Indicative budget(s)²¹³

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ²¹⁴	Indicative number of projects expected to be funded
		2023		
Opening: 12 Jan 2023 Deadline(s): 13 Apr 2023				
HORIZON-HLTH-2023-TOOL-05-01	RIA	50.00 ²¹⁵	8.00 to 10.00	5
HORIZON-HLTH-2023-TOOL-05-03	RIA	50.00 ²¹⁶	8.00 to 10.00	5
HORIZON-HLTH-2023-TOOL-05-04	RIA	35.00 ²¹⁷	8.00 to 10.00	4
HORIZON-HLTH-2023-TOOL-05-05	IA	35.00 ²¹⁸	8.00 to 10.00	4
HORIZON-HLTH-2023-TOOL-05-08	IA	40.00 ²¹⁹	5.00 to 7.00	6
HORIZON-HLTH-2023-TOOL-05-09	CSA	4.00 ²²⁰	Around 4.00	1
Overall indicative budget		214.00		

General conditions relating to this call

²¹³ 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 2023 and 2024.

²¹⁴ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

²¹⁵ Of which EUR 30.00 million from the 'NGEU' Fund Source.

²¹⁶ Of which EUR 30.00 million from the 'NGEU' Fund Source.

²¹⁷ Of which EUR 20.87 million from the 'NGEU' Fund Source.

²¹⁸ Of which EUR 20.00 million from the 'NGEU' Fund Source.

²¹⁹ Of which EUR 24.00 million from the 'NGEU' Fund Source.

²²⁰ Of which EUR 2.00 million from the 'NGEU' Fund Source.

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

Proposals are invited against the following topic(s):

HORIZON-HLTH-2023-TOOL-05-01: Clinical trials of combined Advanced Therapy Medicinal Products (ATMPs)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 8.00 and 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 50.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3

	(Implementation). The cumulative threshold will be 12.
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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 towards and contributing to several of the following Expected Outcomes:

- Healthcare providers increase their knowledge on the potential of combined ATMPs and get access to innovative treatment options with demonstrated health benefits for unmet medical needs;
- Developers and manufacturers of combined ATMPs obtain scientific evidence on the proposed therapeutic approach;
- Patients benefit from new advanced therapies delivered through the combined ATMPs;
- EU companies get a better market position in the field of combined ATMPs.

Scope: The subjects of this topic are combined ATMPs (Advanced Therapy Medicinal Products) according to the definition of the ATMP-regulation (EU 1394/2007, Article 2d). Such combined ATMPs are composed of an ATMP and one or more medical devices or one or more active implantable medical devices, and their cellular or tissue part must either contain viable cells or tissues, or non-viable cells or tissues liable for exerting the primary action on the human body.

The combined ATMPs should be more effective than current state-of-the-art solutions on the European market owing to improved features like personalization, accuracy, reliability and usability and contribute to long-term sustainability (faster and affordable) of European health systems.

Research should focus on advanced stages of clinical development with regulatory work on the Medical Device part completed and safety studies of the combination product in an advanced stage.

Proposals should address all of the following activities:

- Phase 2 clinical trials and above of combined ATMP focussing on:
 - technologies ready to undergo interventional clinical trials in patients/end users assessing the usability and clinical performance, and/or
 - technologies that have demonstrable safety/performance profiles and should undergo clinical validation in view of their inclusion into guidelines for specific clinical pathways.
- Delivery of safe and clinically validated combined ATMPs that are compliant with current European regulatory requirements. The related regulatory work should be

considered as an essential component and the proposed work should involve consultation/interaction with competent regulatory agencies such as the European Medicines Agency (EMA) or national regulatory agency. Applicants are encouraged to seek regulatory and/or Health Technology Assessment (HTA) advice as appropriate.

The topic invites proposals that include innovative treatments for any medical condition excluding rare diseases that are ready to be assessed for clinical efficacy (performance and clinical benefit) in a specific indication on a big number of patient cohorts; already existing market solutions are not in the scope of this topic.

Sex and gender aspects, age, socio-economic, lifestyle and behavioural factors and any other non-health related individual attributes should be taken into consideration. SME participation is strongly encouraged.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-TOOL-05-03: Integrated, multi-scale computational models of patient patho-physiology ('virtual twins') for personalised disease management

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 8.00 and 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 50.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3</p>

(Implementation). The cumulative threshold will be 12.
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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 towards and contributing to several of the following expected outcomes:

- Clinicians and other healthcare professionals have access to and/or use validated multi-scale computational models of individual patients for delivering optimised and cost-effective patient management strategies superior to the current standard of care.
- Healthcare professionals benefit from enhanced knowledge of complex disease onset and progression by recourse to validated, multi-scale and multi-organ models.
- Clinicians and patients benefit from new, improved personalised diagnostics, medicinal products, devices, and therapeutic strategies tailored to the individual patient pathophysiology.
- Citizens and patients have access to validated ‘virtual twin’ models enabling the integration of citizen-generated data with medical and other longitudinal health data, and benefit from early detection of disease onset, prediction of disease progression and treatment options, and effective disease management.

Scope: This topic will contribute to the consolidation of existing virtual twin models and support research to move towards a more integrated human virtual twin, with the aim to accelerate translational research towards cost-effective development of new health technologies. Furthermore, ‘virtual twin’ patient models hold the potential of transforming clinical processes and healthcare with longitudinal monitoring, making personalised medicine, disease prevention and individualised patient management a reality.

Proposals are expected to contribute to the virtual human twin roadmap and ecosystem supported under the Digital Europe Programme²²¹, with models aligned and interoperable with those linked to the repository developed thereunder.

The proposals should address all of the following activities:

- Develop multi-scale and multi-organ, dynamic, interoperable, modular computational models, capable of accurately simulating the individual patient patho-physiology, spanning different anatomical scales, from the molecular to cell, tissue, organ and systems level, as necessary. Proposals should be multidisciplinary and focus on groups of communicable and/or non-communicable diseases with commonalities within the same or across different medical domains, including co-morbidities. SME(s)

²²¹ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/digital-2021-deploy-01-twins-health;callCode=DIGITAL-2021-DEPLOY-01> DIGITAL-2021-DEPLOY-01-TWINS-HEALTH

participation is encouraged with the aim to strengthen the scientific and technological basis of SME(s) and valorise their innovations towards citizen and patient benefit.

- Advance the state of the art in multi-scale modelling by employing diverse modelling methodologies, including but not limited to: mechanistic modelling, artificial intelligence, agent-based and network physiology as a means for modelling the healthy state, disease onset, progression, treatment and recovery. Availability of the necessary diverse data types (e.g. data from lab tests, medical imaging, wearables, sensors, medical check-ups, mHealth devices, longitudinal health monitoring etc.) should be demonstrated and the sex/gender dimension should be investigated.
- Integrate standardised spatiotemporal multi-scale models as a basis for developing personalised ‘virtual twin’ models taking account of patient individual characteristics, medical and health status history for advancing personalised disease management. Proposals should ensure that the development of ‘virtual twin’ models is driven by the end-users/citizens/healthcare professionals needs and their active involvement throughout the development process. Furthermore, applicants should utilise appropriate IT solutions for model visualisation and demonstrate their accessibility and usability for clinical uptake.
- Validate multi-scale patient-specific models and generate evidence that results can deliver clinically meaningful, real-world observations for the human diseases under study. Applicants should implement proof-of-concept, feasibility studies in relevant end user environments and/or real-world settings, and collect evidence of utility vis-à-vis current clinical practice. Dynamic ‘virtual twin’ models and simulations as clinical decision support tools will need be shown to improve prognosis, medical diagnosis, treatments and health outcomes across the continuum of diseases evolution, including co-morbidities and long-term care as appropriate. An exploitation strategy and a business plan, including regulatory and industrial input, should be developed for accelerating clinical and/or market uptake.

The proposals should adhere to the FAIR data principles and adopt data quality standards, GDPR-compliant data sharing, access and data integration procedures based on good practices developed by the European research infrastructures. In relation to the use and interpretation of data, special attention should be paid to systematically assess for bias and/or discrimination (sex/gender, ethnic, minority and vulnerable groups aspects). Proposals are invited to consider adopting recommendations for in-silico models construction and validation.²²²

This topic requires the effective contribution of social sciences and humanities (SSH) disciplines and the involvement of SSH experts, institutions as well as the inclusion of

²²² ISO-paper under development “[Recommendations and requirements for predictive computational models in personalized medicine research — Part 1: Guidelines for constructing, verifying and validating models](#)”.

relevant SSH expertise, in order to produce meaningful and significant effects enhancing the societal impact of the related research activities.

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

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-TOOL-05-04: Better integration and use of health-related real-world and research data, including genomics, for improved clinical outcomes

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 8.00 and 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 35.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).</p>
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply:

	The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
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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 towards and contributing to most of the following expected outcomes:

- Researchers, innovators and healthcare professionals benefit from better linkage of health data from various sources, including genomics, based on harmonised approaches related to data structure, format and quality, applicable across certain disease areas and across national borders.
- Researchers, innovators, healthcare professionals and health policy-makers have access to advanced digital tools for the integration, management and analysis of various health data re-used in a secure, cost-effective and clinically meaningful way enabling the improvement of health outcomes.
- By linking and using effectively more data and new methods and tools, including artificial intelligence, researchers, innovators and healthcare professionals are able to advance our understanding of the risk factors, causes, development and optimal treatment in disease areas where genomics integrated with other health data, spanning from clinical to e.g. lifestyle, offer potential for novel and more comprehensive information.
- Healthcare professionals and health policy-makers benefit from data-driven solutions and reinforced evidence base for decisions addressing health and care challenges.
- Citizens can be offered data-driven patient-focused health interventions, resulting in improved disease prevention, diagnosis, treatment and monitoring towards better patient outcomes and well-being.
- Citizens’ trust in the sharing and re-use of health data for research and healthcare increases due to the application of advanced technologies and data governance preserving data privacy and security.

Scope: Health data bear vast information potential in many disease areas, to significantly improve the outcomes and efficiency of healthcare delivery, unlock new research and innovation avenues, and inform public health policy across Europe. There is a huge need of integration, use and deployment of health data from multiple sources for effectively addressing the challenges of medical research underpinning diagnostics, therapy guidance and implementation decisions on new therapies. Such integration requires linking data of different types, disease areas and provenance which are scattered in several repositories and databases across Europe.

This topic aims to support proposals focusing on the integration of health data from multiple sources (e.g. electronic health records, genomics, medical imaging, laboratory and diagnostic results, pathogen data, public health registries and other clinical research data) by linking real-world and clinical research data. The data integration should be exemplified in several use-cases, i.e. well-justified groups of diseases (excluding cancer), within and/or across medical domains, and pave the way towards improved health outcomes. At least one of those use cases should build on the use of whole genome sequence data.

The consortium should ensure wide European coverage, contributing significantly to health data standardisation, while catering for the diversity of health data sources.

To enhance synergies and avoid overlaps of activities, the proposals are expected to align with and complement the relevant European initiatives, in particular the European Health Data Space (EHDS), the 1+Million Genomes initiative (1+MG) and the European Open Science Cloud.

The applicants have to demonstrate that the necessary data sources are, or will be, effectively, timely and legally available for the proposed research activities.

The proposals should address all of the following activities:

- Identification of the barriers to health data integration and access as needed for the selected use cases, and of specific existing tools, technological solutions and coordination and standardisation agreements addressing those barriers. Issues to be covered include semantic ontologies, data standards and formats, data quality, data storage, management and access modalities, as well as enhanced findability of relevant datasets through improved metadata standards and data catalogues.
- New approaches to assemble large, easily findable and lawfully accessible high-quality datasets integrating multiple types of health data leading to improved clinical outcomes (e.g. new care solutions, personalised disease management, advanced diagnostic tools), taking into account data FAIRification and inter-operability needs.
- New techniques, support tools, mechanisms and modalities to enable GDPR compliant access to sensitive personal data, including genomics, allowing for their re-use across borders and integration of different types of data relevant to human health. Legal and ethical frameworks should duly consider the heterogeneity in national and sectorial rules and procedures for data access and re-use.
- Data management approaches for cross-border distributed data storage and processing, enabling remote collaboration, electronic consent management, data provenance tracking, and scalability of data management resources, ensuring data privacy and security, and resulting in robust support to advanced, innovative clinical workflows. Joint data governance is expected to be piloted among several clinical centres across Europe.

- Development of a data analytics platform applying distributed learning and artificial intelligence approaches to query and aggregate efficiently, effectively and securely data from multiple sources for multiple use cases (groups of diseases), to monitor patients' health status, analyse causal inference, support diagnosis and health policy-makers, and establish recommendations for patients and other stakeholders.

The proposals should adhere to the FAIR data principles and build on existing and justified tools and harmonisation efforts, such as widely used standards for encoding the different types of health data and inter-operability for cross-sector collaborations. Also the data collection, management and/or modelling should build on ongoing EU and international efforts to avoid possible duplication of efforts and fragmentation. In particular, projects are expected to take into account the forthcoming legislation on the EHDS, so as to align, where possible, project activities with pertinent EHDS infrastructure efforts that provide for the secondary use of health data as regards e.g. cross-border access to data, cross-border infrastructures, data quality and utility labelling. The achievements of the relevant past and ongoing EU-funded projects and initiatives, and good practices developed by the European research infrastructures, should be duly considered and used. Close involvement of patients and end-users is crucial to ensure that the project outcomes are relevant, widely accepted and feasible in real-world settings.

The tools developed by the projects are expected to be widely accessible and amenable to necessary updates after the project's end for further use by interested parties. Datasets generated during the project should be accessible to researchers and innovators. For example, genomic data and linked patient level data are expected to be made accessible for secondary use through the 1+MG data infrastructure.

This topic requires an effective contribution of social sciences and humanities (SSH) disciplines and the involvement of SSH experts, in order to produce meaningful and significant effects enhancing the societal impact of the related research activities.

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

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-TOOL-05-05: Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 8.00 and 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 35.00 million.
<i>Type of Action</i>	Innovation Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).</p>
<i>Technology Readiness Level</i>	Activities are expected to achieve TRL 7 by the end of the project – see General Annex B.
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

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 towards and contributing to all of the following expected outcomes:

- Healthcare professionals benefit from secure, highly performant Point-of-Care computing technologies and devices able to process and analyse vast amounts of real-time data at the point of care, combined with extended reality and visualisation techniques, to enable continuous monitoring and/or fast real-time health status checks in clinical settings and workflows.

- Patients and clinicians benefit from wider access to real-time diagnosis, screening, monitoring and treatments using novel imaging and/or robotics systems and/or Point-of-Care devices that are seamlessly integrated in care environments and workflows.
- Quicker reaction times and improved patient safety in care settings.
- Researchers and healthcare professionals have more opportunities to use, extract value from and contribute to the uptake of real-time health data and/or Point-of-Care computing; existing technologies and methods are expected to progress from their current technology readiness levels (TRL), from TRL 3-4 to at least TRL 7²²³.
- Health and care settings benefit from reduced energy consumption of Point-of-Care tools, devices and systems, and/or data analysis.

Scope: The proposals are expected to develop and test innovative tools, devices and systems for point-of-care applications, including but not limited to robotics, photonics, bio-sensing, artificial intelligence etc. These would provide clinicians with real-time imaging, data analysis and interactive visual presentation for understanding and diagnosing diseases, facilitating risk-assessment, prevention, and carrying out medical interventions with improved patient safety. The proposals should demonstrate advancement and integration of technologies from proof-of-concept to prototype demonstration in operational environment. Devices and systems should be designed, developed and tested vis-à-vis defined use cases, based on the appropriate involvement of clinicians and other stakeholders, ensuring they can be seamlessly integrated into existing digital infrastructures and clinical workflows. The use cases in care settings could include but are not limited to surgery workflows, Intensive Care Unit workflows and integration of remote patient monitoring into clinical workflows. Data quality, integration and interoperability, as well as issues of cybersecurity and data protection have to be addressed. Design should take gender specificities into account. Clinical studies should be an integral part of the work proposed, with developmental iteration steps and consultation of regulators included as appropriate. Establishing synergies with AI Testing and Experimentation Facilities, European Digital Innovation Hubs and other similar initiatives is encouraged. Proposals must include a short description of initial business plan as part of the exploitation activities.

The proposals should address all of the following activities:

- Development and clinical validation of compact, cost- and energy-efficient, extended reality-enabled and other Point-of-Care devices and systems, with fast/real-time response times as required, reliable and capable of integration into clinical settings and workflows.

²²³ From proof-of-concept/technology validated in lab to at least prototype demonstration in operational environment; the definitions used in H2020 for TRLs apply under this topic: https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-g-trl_en.pdf

- Development and validation of instruments, continuous monitoring systems and/or analysis algorithms, including artificial intelligence approaches, for the analysis of biological samples, enabling detection of biomarkers in body fluids and tissues in clinical settings.
- Development and validation of imaging systems with a high spatial resolution down to the cellular level allowing for immediate clinical interventions. Single imaging modalities or the combination of different imaging modalities should be made compatible with other imaging tools and with state-of-the-art and/or novel medical technologies and devices, for example those used to remove tissues in precision surgery (e.g. robotic surgery).
- Advancements in the use of Point-of-Care computing, data modelling, extended reality and/or machine learning/AI technologies applied to diagnosis and risk assessment in cases requiring very fast, near to real-time response times in clinical settings and workflows. In addition, projects should showcase how distributed systems bringing computation and storage physically close to where data is generated and used can most effectively deliver actionable outputs for person-centred health care, contributing to improved patient safety, in the areas of for example healthy living support, remote patient monitoring, surgery workflows or acute care.

This topic requires the effective contribution of social 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.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-TOOL-05-08: Pandemic preparedness and response: In vitro diagnostic devices to tackle cross-border health threats

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 5.00 and 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 40.00 million.
<i>Type of Action</i>	Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply:

	<p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.</p> <p>If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

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:

- The scientific and clinical communities, including health care providers and payers, as well as regulators, health systems and patients benefit from innovative diagnostic solutions that are better suited to tackle cross-border health threats.
- The scientific and clinical communities have access to novel and improved methodologies for detection of pathogens with pandemic potential in humans and for timely discovery of other health threats, such as chemical, radiological and nuclear threats, including considerations on detection in animals and environmental conditions (One Health approach).
- A diverse and robust pipeline of in vitro diagnostics²²⁴ is available, increasing options for clinical deployment in case of an epidemic or pandemic.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally, this is also the case for other health threats that can be linked for instance to terror attacks. New cross-border health threats are expected to emerge in the coming years and therefore it is essential to promote advanced research of medical countermeasures that can be used to detect, prevent and treat in case of a new health

²²⁴ As defined in Guidance on Classification Rules for in-vitro Diagnostic Medical Devices for Regulation (EU) 2017/746 MDCG 2020-16 rev.1:https://ec.europa.eu/health/system/files/2022-01/md_mdcg_2020_guidance_classification_ivd-md_en.pdf

emergency. One of the most important aspects in crisis preparedness times is to ensure the availability of diagnostics that can contribute to detecting and characterising health threats.

Proposals should develop and advance on new in vitro diagnostics relevant for detecting and characterising cross-border health threats and develop novel approaches to the development of medical countermeasures targeting threats identified by HERA²²⁵ or by the WHO²²⁶.

Proposals should cover pathogens with pandemic potential in humans or other health threats, such as chemical, radiological and nuclear threats for which there are no existing diagnostics or where clinical practice could benefit from innovation. Emphasis should be put on the development of new diagnostics, innovative catch-all methodologies, or on the improvement of existing health technologies advancing diagnostics and characterisation of health threats, applying the One Health approach when relevant.

Proposals should aim to diversify and accelerate the global diagnostic research and development pipeline to tackle cross-border health threats, and to strengthen the current leading role of the EU in research and development, and therefore contributing to the work of the European Health Emergency Preparedness and Response Authority (HERA).

Attention should be paid to critical social factors such as sex, gender, age, socio-economic factors, ethnicity/migration, and disability.

Proposals should include a clear regulatory path to market in order to ensure future compliance with the legal requirements. Proposals should address several of the following areas:

- Proof-of-concept/early studies linked e.g. to performance evaluation of new diagnostics that facilitate screening, detection of the presence or exposure to a cross-border health threat or determination of infectious/disease status through human samples, included but not limited to the list of high impact health threats identified by HERA, as well chemical, radiological and nuclear threats for which there is a lack of in vitro diagnostics or existing diagnostics have a sub-optimal performance.
- Data-driven diagnostic and prognostic platforms with AI and other advanced data analytics functionalities, adaptable to respond to new and multiple pathogens/threats, e.g. covering prototype viruses.
- Innovative systems linked to high sensitivity/specificity profiles adaptable for broader use should be considered, such as portable, faster, more compact or accurate devices and technologies, including the possibility to develop point of care or self-tests.
- Innovative diagnostics sampling methods or samples bringing a significant improvement, such as less invasive sampling methods.

²²⁵ Reference to be included

²²⁶ <https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts>

This topic requires the effective contribution of social 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.

Proposals should consider the involvement of the European Commission's Joint Research Centre (JRC) in regard to its experience on the performance evaluation of in vitro diagnostic devices, with respect to the value it could bring in providing an effective interface between research activities and regulatory aspects and/or to translating research results into validated test methods and strategies fit for regulatory purpose. In that respect, the JRC will consider collaborating with any successful proposal and this collaboration, when relevant, should be established after the proposal's approval.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-TOOL-05-09: Developing a Data Quality and Utility Label for the European Health Data Space

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 4.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 4.00 million.
<i>Type of Action</i>	Coordination and Support Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>Legal entities established in the United States of America may exceptionally participate in this Coordination and support action in a capacity other than Associated Partner.</p> <p>In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>Coordinators of projects must be legal entities established in an EU Member State or Associated Country.</p>
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply:

	The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
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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 to deliver results that are directed towards and contributing to all of the following expected outcomes:

- Data Users (researchers, innovators, regulators, policy-makers, clinicians) are able to identify the most relevant datasets that meet their specific needs through a label describing accurately and in a standard way the quality and utility dimensions of the datasets, as proposed in the legal provisions of the European Health Data Space (EHDS).
- Data holders have clear specifications for dataset quality and utility labelling to comply with the requirements proposed in the EHDS legal provisions. In addition to that, data holders have access to a maturity model with the requirements a dataset needs to fulfil to achieve higher levels of data quality and utility.
- European and National public funders ensure that the datasets, for which they provided funding for the creation and curation of, are more widely available, furthering their reuse for secondary uses as proposed in the EHDS legal provisions (research, innovation, regulatory work, policy-making, personalised medicine).
- The European Commission has access to a set of specifications for the data quality and utility label supporting the implementation of the EHDS legal provisions.

Scope: A vast quantity of health datasets exist across Europe, from multiple sources (individual care, medical registries, social, environmental behavioural, wellbeing, clinical trials, research, administrative, etc.), and of varying quality. This represents a tremendous opportunity for the reuse of this data for purposes other than for the one for which they were originally collected and spur the development of better prevention strategies, diagnoses, treatments and care plans.

The European Health Data Space (EHDS) will provide a common EU framework for secondary use of health data such as research, innovation, regulatory purposes, policy-making and personalised medicine. It will enable data users to have access to large amounts of health data through health data access bodies empowered with the EHDS legal provisions to overcome existing limitations regarding the processing of health data for secondary uses.

To support data users in the discovery and selection of datasets for their purposes, there is a growing need to develop a data quality and utility framework to articulate the characteristics and the potential usefulness of datasets. This framework will also support data holders in identifying and addressing areas of improvement which can, in turn, allow for wider and better use of these datasets.

Several initiatives have developed or are developing guidelines and recommendations for health data quality, however, these typically focus on specific data types (i.e. 1+ Million Genome Initiative²²⁷) or areas of applications (i.e. European Medicines Agency – EMA and Heads of Medicines Agencies’ Big Data Steering Group activities to support medicines regulation²²⁸). Similarly, previous studies and initiatives have addressed specific dimensions of ‘data quality’ for health data but none are offering a framework suitable for the breadth of data types and encompassing the quality and utility elements proposed in the EHDS legal provisions. The proposed framework should take into account the various needs of data users whilst at the same time avoid becoming an excessive burden on data holders which will need to produce the data quality and utility label.

Proposals should address all of the following activities:

- Perform a mapping of existing data quality and utility principles/initiatives/frameworks (i.e. EMA/HMA Big Data Stakeholders Group Data quality efforts, TEHDAS Data Quality Working Group²²⁹, EOSC-LIFE²³⁰ Health Data Research UK’s data quality and utility framework²³¹, and relevant data principles (FAIR²³²), resources and tools (FAIR Cookbook²³³, etc.);
- Conduct various stakeholder consultations, integrating all relevant data users and data holders of health data, EHDS Health Data Access Bodies (HDABs) and other relevant actors to validate data user needs and adequately take into account relevant initiatives when developing the proposed framework;
- Develop a framework (set of technical specifications) for the data quality and utility label that supports the implementation of the EHDS legal provisions and the roll out of the label by the data holders and EHDS Health Data Access Bodies;
- Pilot and evaluate the use of the proposed framework (as a label and as a maturity model) on a datasets sample representing the wide-ranging data types (such as electronic health records, genomics datasets, medical registries, administrative data, etc.) and taking into account the needs of all data users identified.
- Develop recommendations for the successful implementation and adoption of the data quality and utility label and maturity model across European Member States considering the maturity levels regarding secondary of health data.

The consortium should be composed of representatives from data users, data holders, health data access bodies, and other relevant stakeholders to the scope of secondary use of health

²²⁷ <https://blmg-project.eu/work-packages/wp3>

²²⁸ <https://www.ema.europa.eu/en/about-us/how-we-work/big-data>

²²⁹ <https://tehdas.eu/packages/>

²³⁰ <https://www.eosc-life.eu/>

²³¹ https://www.hdruk.ac.uk/wp-content/uploads/2021/08/Data-UtilitFramework_withlink_updatedDC100821.pdf

²³² <https://www.go-fair.org/fair-principles/>

²³³ <https://faircookbook.elixir-europe.org/content/home.html>

data, adequately covering the diversity of health data types and users' needs across European Member States.

Call - Tools and technologies for a healthy society (Two stage - 2024)

HORIZON-HLTH-2024-TOOL-05-two-stage

Conditions for the Call

Indicative budget(s)²³⁴

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ²³⁵	Indicative number of projects expected to be funded
		2024		
Opening: 30 Mar 2023 Deadline(s): 19 Sep 2023 (First Stage), 11 Apr 2024 (Second Stage)				
HORIZON-HLTH-2024-TOOL-05-06-two-stage	RIA	25.00	4.00 to 8.00	4
Overall indicative budget		25.00		

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.

²³⁴ 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 2023 and 2024.

²³⁵ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

**Horizon Europe - Work Programme 2023-2024
Health**

<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-2024-TOOL-05-06-two-stage: Innovative non-animal human-based tools and strategies for biomedical research

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 4.00 and 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 25.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Admissibility conditions</i>	The conditions are described in General Annex A. The following exceptions apply: Applicants submitting a proposal under the blind evaluation pilot (see General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in Part B of their first stage application (see General Annex E).
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic. The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative

	threshold will be 12.
<i>Procedure</i>	The procedure is described in General Annex F. The following exceptions apply: This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). ²³⁶ .

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 towards and contributing to several of the following Expected Outcomes:

- Researchers utilize tools and strategies that are more relevant to the human situation as compared to the currently used animal models.
- Fewer live animals are used in biomedical research.
- Health technology developers will get access to improved human-relevant tools or strategies allowing for a faster pace of innovation.
- Legislators and regulators will benefit from strengthened EU leadership in non-animal based biomedical research that is socially accepted and sustainable.
- Healthcare providers and patients will benefit from innovative tools or strategies opening up novel biomedical concepts enabling improved disease prediction, prevention and treatment.

Scope: The proposal(s) should develop and/or use tools and strategies that address critical areas of biomedical research where animal-models are currently used but are of limited translational value for investigation and development of prevention and treatment. Such advanced tools and strategies should aim at a better understanding of the pathogenesis of disorders that feature a high impact on public health and exhibit a high rate of animal use or

²³⁶ This [decision](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf) is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under ‘Simplified costs decisions’ or through this link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf

severe animal suffering, and enable to develop biomedical concepts with increased translational value, thereby ultimately leading to improved disease prediction, prevention and treatment.

The proposals should address all of the following aspects:

- The innovative tools and strategies should include a variety of technologies and methodological approaches such as –omics and other high-throughput procedures, human-derived cell-based material, organoids, micro-physiological systems, and in-silico models.
- The newly proposed tools and strategies should demonstrably advance the state-of-the-art in specific areas of biomedical research.
- Prospects and avenues for dissemination, knowledge sharing, uptake or translation into health policies of the proposed tools and strategies within the EU should be provided.
- Aspects such as harm and cost-benefit assessment as well as ease of production with respect to current practices should also be considered.
- Criteria for model qualification and standardization should be developed in well-justified use-case contexts to demonstrate their translational values.

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

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

This topic requires the effective contribution of social 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.

Applicants of second stage envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in

the submission system. See definition of clinical studies in the introduction to this work programme part.

Call - Tools and technologies for a healthy society (Single stage - 2024)

HORIZON-HLTH-2024-TOOL-11

Conditions for the Call

Indicative budget(s)²³⁷

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ²³⁸	Indicative number of projects expected to be funded
		2024		
Opening: 26 Oct 2023 Deadline(s): 11 Apr 2024				
HORIZON-HLTH-2024-TOOL-05-02	RIA	25.00	6.00 to 8.00	4
Overall indicative budget		25.00		

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.

²³⁷ 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 2023 and 2024.

²³⁸ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

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<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-2024-TOOL-05-02: Bio-printing of living cells for regenerative medicine

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 6.00 and 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 25.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

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 towards and contributing to several of the following expected Outcomes:

- Biomedical scientists will access entire bio-printing units for regenerating human tissue.
- Availability of larger-scale bio-printed tissues for biomedical research purposes to both industry and academia.

- Healthcare professionals acquire information on the safe and effective use of advanced therapies.
- Healthcare providers dispose of tools enabling them to treat conditions of unmet medical need.
- Individual patients will benefit from a personalised approach to their respective medical condition thanks to the bio-printed regenerative medicine solution.

Scope: Regenerative medicine is a branch of translational research in tissue engineering and molecular biology which deals with the "process of replacing, engineering or regenerating human cells, tissues or organs to restore or establish normal function". 3D-printing in general is considered an advanced manufacturing technique and 3D-printing of non-viable biomaterials to serve e.g. as scaffold for cell growth or as structure for medical devices is already broadly used.

However, bio-printing technology involving living cells is still in early stages of development, but has a huge potential for tissue engineering, drug testing and other biomedical applications. Tissue-specific functional 3D bio-printing is a new approach for transplantation applications in regenerative medicine, relying on the fabrication of tissues and organs with respect to the desired shape and function and their delivery and application in vivo. "In-situ bio-printing" known as printing cells and biomaterials directly onto or in a patient, or 4D bio-printing, which introduces a "time" variable that allows 3D printed materials to change shape or function when external stimulus is applied, are recent developments facing multiple additional challenges.

Despite some success of 3D bio-printing with thin tissue, thick tissue and complex organs remain a bottleneck because it is difficult to sufficiently mimic their metabolic needs, and the scientific knowledge about their intimate architecture and interplay with other tissues are not sufficiently elucidated. Next to these limitations are a lack of standardized manufacturing protocols and standardized bio-ink formulations with tuneable properties, unstable cellular behaviour, material biocompatibility and printability, etc. Taken together, 3D bio-printing is confronted with several challenges that currently hamper its large-scale deployment.

To overcome these challenges, researchers need to work in multidisciplinary teams with engineers, biomedical scientists, cell biologists and medical doctors and proposals should address most of the following activities:

- Design the best bio-printing strategy for at least one type of tissue thanks to a better understanding of the interconnections of the different cell types inside the chosen tissue or organ
- Develop or improve existing equipment able to print bio-constructs with higher resolution in a shorter time using various biomaterials and different cell types

- Cover all steps of the bio-printing suite, including cell collection, cell differentiation and expansion, imaging, modelling, bio-ink formulation, actual bio-printing, nutrient supply, process monitoring and cell-construct delivery at target site
- Scale-up the chosen bio-printing technology to a GMP-conform manufacturing process
- Combine different bio-printing technologies in order to obtain fully functional synthetic constructs of complex tissues or organs.

Proof of regulatory knowledge of the field is required in the proposal by documented contacts with relevant national or international European regulatory authorities.

The chosen medical area (tissue, organ, condition) should be duly justified. Sex differences at the cellular level should be taken into consideration.

Preclinical stage and early clinical development are eligible. The involvement of SMEs is encouraged.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

Destination 6. Maintaining an innovative, sustainable and globally competitive health industry

Calls for proposals under this destination are directed towards the Key Strategic Orientation KSO-A *'Promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains'* of Horizon Europe's Strategic Plan 2021-2024. Research and innovation supported under this destination should contribute to the impact area *'A competitive and secure data-economy'* and in particular to the following expected impact, set out in the Strategic Plan for the health cluster: *'EU health industry is innovative, sustainable and globally competitive thanks to improved up-take of breakthrough technologies and innovations, which makes the EU with its Member States more resilient and less dependent from imports with regard to the access to and supply of critical health technologies'*. In addition, research and innovation supported under this destination could also contribute to the following impact areas: *'Industrial leadership in key and emerging technologies that work for people'*, *'High quality digital services for all'*, and *'Good health and high-quality accessible health care'*.

The health industry is a key driver for growth and has the capacity to provide health technologies to the benefit of patients and providers of health care services. The relevant value chains involve a broad variety of key players from supply, demand and regulatory sides. In addition, the path of innovation in health is long and complex. The development of novel health technologies is generally associated with uncertainties and market barriers due to expensive and risky development (e.g. high 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:

- Facilitating the production of pharmaceuticals in compliance with the objectives of the European Green Deal.
- Developing 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.
- Supporting public authorities with better methodologies and interdisciplinary approaches to assess and value new health technologies and interventions.

In view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic but also between other projects funded under another topic, cluster or pillar of Horizon Europe (but also with ongoing projects funded under Horizon 2020). In particular, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health and EIT-KIC Health (under pillar III of Horizon Europe), or in areas cutting across the health and other clusters (under pillar II of Horizon Europe). For instance, with cluster 4 “Digital, Industry and Space” such as on industrial research and innovation infrastructures (pilot plants, testing and simulation facilities, open innovation hubs); additive manufacturing and other production technologies (incl. bio manufacturing); safe, smart and sustainable materials.

Expected Impacts:

Proposals for topics under this destination should set out a credible pathway to contributing to maintaining an innovative, sustainable and globally competitive health industry, and more specifically to one or several of the following expected impacts:

- Health industry in the EU is more competitive and sustainable, assuring European leadership in breakthrough health technologies and strategic autonomy in essential medical supplies and digital technologies, contributing to job creation and economic growth, in particular with small- and medium-sized enterprises (SMEs).
- Health industry is working more efficiently along the value chain from the identification of needs to the scale-up and take-up of solutions at national, regional or local level, including through early engagement with patients, health care providers, health authorities and regulators ensuring suitability and acceptance of solutions.
- European standards, including for operations involving health data, ensure patient safety and quality of healthcare services as well as effectiveness and interoperability of health innovation and productivity of innovators.
- Citizens, health care providers and health systems benefit from a swift uptake of innovative health technologies and services offering significant improvements in health outcomes, while health industry in the EU benefits from decreased time-to-market.
- Health security in the EU benefits from reliable access to key manufacturing capacity, including timely provision of essential medical supplies of particularly complex or critical supply and distribution chains, such as regards vaccines or medical radioisotopes.

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

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Call	Budgets (EUR million)		Deadline(s)
	2023	2024	
HORIZON-HLTH-2023-IND-06	56.00		13 Apr 2023
HORIZON-HLTH-2024-IND-06		12.00	11 Apr 2024
Overall indicative budget	56.00	12.00	

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Call - A competitive health-related industry (Single stage - 2023)

HORIZON-HLTH-2023-IND-06

Conditions for the Call

Indicative budget(s)²³⁹

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ²⁴⁰	Indicative number of projects expected to be funded
		2023		
Opening: 12 Jan 2023 Deadline(s): 13 Apr 2023				
HORIZON-HLTH-2023-IND-06-01	CSA	5.00 ²⁴¹	Around 5.00	1
HORIZON-HLTH-2023-IND-06-02	RIA	8.00 ²⁴²	3.00 to 5.00	2
HORIZON-HLTH-2023-IND-06-04	RIA	25.00 ²⁴³	4.00 to 6.00	5
HORIZON-HLTH-2023-IND-06-05	CSA	3.00 ²⁴⁴	Around 3.00	1
HORIZON-HLTH-2023-IND-06-07	RIA	15.00 ²⁴⁵	7.00 to 8.00	2
Overall indicative budget		56.00		

General conditions relating to this call

<i>Admissibility conditions</i>	The conditions are described in General Annex A.
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²³⁹ 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 2023 and 2024.

²⁴⁰ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

²⁴¹ Of which EUR 2.50 million from the 'NGEU' Fund Source.

²⁴² Of which EUR 4.00 million from the 'NGEU' Fund Source.

²⁴³ Of which EUR 14.00 million from the 'NGEU' Fund Source.

²⁴⁴ Of which EUR 1.50 million from the 'NGEU' Fund Source.

²⁴⁵ Of which EUR 8.00 million from the 'NGEU' Fund Source.

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<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-2023-IND-06-01: Supporting the uptake of innovative Health Technology Assessment (HTA) methodology and advancing HTA expertise across EU

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 5.00 million.
<i>Type of Action</i>	Coordination and Support Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>Legal entities established in the United States of America may exceptionally participate in this Coordination and support action in a capacity other than Associated Partner.</p> <p>In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>Coordinators of projects must be legal entities established in an EU Member State or Associated Country.</p>

<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
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Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “Maintaining an innovative, sustainable and globally competitive health industry”. To that end, proposals under this topic should aim to deliver results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Identification of the most innovative HTA methods developed by EU-funded projects, which respond to the needs of HTA bodies and are ready to be used in real-life settings. Endorsement by HTA bodies of such innovative methods would allow for advancing HTA methodology and improve evidence-based decision making, and patient access to novel health technologies
- Dissemination among EU HTA bodies of robust innovative HTA methods and tools developed by EU-funded projects.
- Harmonisation of HTA expertise across EU through the development of a training programme developed in collaboration with academia. The training should address HTA expertise in general, as well as expertise in joint HTA to be carried out at EU level in accordance with Regulation (EU) 2021/2282, based on the methodological guidelines elaborated by the Coordination Group on HTA.
- Contribution to a successful implementation of the HTA Regulation as well as to building an EU methodological HTA framework fit for purpose and fit for the future.

Scope: HTA bodies have the responsibility to assess the added-value of new health technologies and advise on its reimbursement and use within a healthcare system. Due to the rapid pace at which technology advances and in order to support decision making in an appropriate manner, HTA experts have to adapt/revise regularly their methodology. Whilst EU-funded projects in the field of HTA have addressed some of the research needs of the HTA bodies (e.g. methods of analysis, use of real world data, use of patient reported outcomes), translation of their results/recommendations into HTA work remains limited.

Advancing HTA methodology and expertise could benefit from a more systematic dialogue between HTA bodies and academia. Therefore, this action could represent an excellent opportunity for both those generating and those using the evidence to come together and discuss the key HTA methodological issues.

Under the newly adopted Regulation (EU) 2021/2282, the Coordination Group on HTA will have to adopt methodological guidelines for joint HTA work (e.g. joint clinical assessments, joint scientific consultation), to regularly review, and where necessary update them. The

project could provide input to issues identified by the Coordination Group as important for future updates/revisions of HTA methodology for joint HTA work.

The topic is divided into two strands of activities, with applicants tackling both in their proposals:

- **Implementation of innovative HTA methods:** EU-funded research projects (e.g. COMED, IMPACT-HTA, HTx, GetReal, EHDEN) developed innovative methods aiming at addressing HTA bodies' needs. Identifying which of these methods are ready to be used in real-life settings is a first crucial step towards broader uptake and dissemination. Successful implementation of innovative methods in actual HTA practices will contribute to provide a timely response to HTA challenges (e.g. use of real-world data in HTA) also providing a sound scientific resource for updates of methodological guidelines by the Coordination Group on HTA for joint activities as requested by the Regulation (EU) 2021/2282. HTA bodies/agencies participating in such activities will gain expertise in those methods that could be later transferred to other bodies/agencies using the training framework developed in the second strand of work.
- **Advancing HTA expertise across Europe should be carried out through** a training programme tailored to the needs of HTA bodies, which may include twinning activities between HTA bodies/agencies to develop expertise and facilitate knowledge sharing among HTA bodies/agencies in the EU. The training programme is expected to contribute to the harmonisation of HTA practices in the EU that will in turn contribute to a greater consistency of health technology assessments across Europe. Thus, the training programme should also support the engagement of HTA experts from Member States and EEA countries in carrying out joint HTA work starting January 2025 (i.e. implementation date of the Regulation on HTA), with the aim to produce high-quality and robust joint clinical assessments. The training programme should include all the necessary elements for carrying out robust assessments at national and EU level. Regarding the latter, the training programme should also promote the dissemination of the methodological guidelines to be adopted by the Coordination Group on HTA (based on the methodology developed and fine-tuned by EUnetHTA joint actions and EUnetHTA21 service contract).

The proposals should address all of the following activities:

- Identification of innovative methods and tools, in particular those developed in EU-funded projects able to address HTA bodies' needs (in different areas: relative effectiveness assessment, cost-effectiveness assessment, etc.)
- Identifications of barriers to the uptake of these methods (and potential associated tools, e.g. open source software to run cost-effectiveness analyses)
- Use cases (based on the needs identified by HTA bodies) to facilitate the endorsement by HTA bodies of innovative methods

- Development of an implementation plan including supporting tools and training modules (by researchers, alone or in collaboration with HTA bodies, to be delivered to HTA bodies/agencies)
- Recommendations for broader dissemination.

HORIZON-HLTH-2023-IND-06-02: Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 3.00 and 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 8.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

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 to deliver results that are directed, tailored towards and contributing to all of the following expected outcomes, and provide appropriate qualitative and quantitative indicators to measure their progress and specific impact:

- European Health Record (EHR) stakeholders (e.g. developers, suppliers, integrators, and operators) have at their disposal and use fit-for-purpose standards, guidelines, and toolsets for prioritised health information domains to address interoperability of EHRs in

line with the principles set in the EEHRxF Recommendation²⁴⁶, contributing also to security and privacy.

- Stakeholders dispose better quality and better integrated health datasets within the European Health Data Space,²⁴⁷ to foster innovations in the health sector and leverage the potential of new analytics solutions such as AI and big data, and to get new insights and detect trends from aggregated data, including for cross-border health threats.
- Citizens are provided with an expanded access to their health data, also across borders, and innovative digital services for high-quality health and care across the EU.

Scope: EHR interoperability has yet to become a reality in a number of use cases and health information domains. It is a complex, multi-dimensional challenge. EHRs across the Member States are diverse; so are languages, cultures, and practices in the health sector. Different technical specifications, technologies and clinical terminologies are used, involving a range of stakeholders, within and across care settings.

Proposals should address all of the following:

- Research, develop and validate harmonised interoperability formats for sharing data in some priority health information domains that should be selected with reference to the EU policies and priorities. The output formats should enable EHR interoperability across the Member States and address cross-border health data exchange by-design and in line with the principles set in the EEHRxF Recommendation.
- Leverage and scale up the potential of EHR through enhanced interoperability to improve the quality, safety, and efficiency of patient care, enforce patients right to data portability, enhance care coordination, guide crisis planning, reduce medical errors, and lower costs. For example, based on the lessons learnt from COVID-19, enable incorporating EHR data into the early stages of clinical crisis planning and leveraging it to identify potential cross-border health threats based on the analysis of patients' data trends.
- Address semantic interoperability for prioritised information domains so as the transmitted health record contains standardised coded data.
- Maximise synergies with relevant initiatives, activities and programmes, building upon previous and linking to on-going actions²⁴⁸.

²⁴⁶ Commission Recommendation on a European Electronic Health Record exchange Format (EEHRxF) (C(219)800)

²⁴⁷ https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en

²⁴⁸ Such as “Support for European eHealth Interoperability roadmap for deployment TOPIC ID: SC1-HCC-07-2020” <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-hcc-07-2020>; “Prototyping a European interoperable Electronic Health Record (EHR) exchange SC1-DTH-08-2018” <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-dth-08-2018>; “Setting up a European Electronic Health Record Exchange Format (EEHRxF) Ecosystem”

- Closely coordinate and collaborate with various stakeholders, from patients, and healthcare professionals to EHR providers, healthcare industry (including SMEs), policy makers and legislators to progress towards a more comprehensive EHR interoperability.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-IND-06-04: Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 4.00 and 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>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “Maintaining an innovative, sustainable and globally competitive health industry”. To that end, proposals under this topic should aim to deliver results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Developers and regulators have access to robust modelling and simulation tools to accelerate the effective development of orphan and/or paediatric medicinal products.

- Clinical researchers, developers and regulators use accurate computational models to improve the statistical robustness in clinical trials intended for small populations and guide cost-effective clinical trial designs.
- Clinical researchers and regulators have access to accurate in-silico tools for assessing the actionable use of real world data and for successfully estimating the risk-benefit effects in clinical trials for small populations.
- Regulators develop guidance for the use of validated computational models to support a robust extrapolation framework and facilitate the safety and efficacy assessment in the process of regulatory appraisal of orphan and/or paediatric medicinal products.

Scope: In its "Regulatory Science Strategy to 2025", the European Medicines Agency included specific recommendations to optimise the capabilities of modelling and simulation in the medicines development process and in particular to benefit special populations and neglected patient populations.

Orphan drug development faces numerous challenges, including low disease prevalence, patient population heterogeneity and strong presence of paediatric patient populations. Consequently, clinical trials for orphan and/or paediatric medicines are often smaller than traditional large-scale randomised ones and they require the development of efficient trial designs relevant to small.

Model-based approaches are significantly advantageous in small populations, as extrapolation tools for rationalising and increasing the statistical robustness in clinical trial designs and pharmacometric studies.

The topic will support research and innovation activities focusing on the development of diverse modelling and simulation methods, as tools for addressing some of the regulatory needs in the clinical development cycle of new orphan and paediatric medicinal products. The topic is not intended to support new preclinical/clinical studies but to use the existing knowledge/data for assessing and optimising the performance of mature in-silico models in the regulatory context with the goal of improving the clinical trial designs for small populations. Availability of the relevant data to address the requirements of the topic is an indispensable condition that must be demonstrated at the proposal submission.

Proposals should involve national healthcare product regulatory bodies and the European Medicines Agency (EMA) in order to catalyse an effective collaboration between the researchers and the regulators. The active involvement of patient representatives is required in all phases of the research and innovation activities. Furthermore, SME(s) participation is encouraged with the aim to strengthen their scientific and technological basis.

The proposals should address all of the following activities:

- Establish a multidisciplinary approach for assessing the utility of mature computational models, as tools for supporting the optimal design of innovative clinical trials for small populations and as fit-for-purpose solutions for enabling the regulatory scientific advice

and marketing authorisation assessment of orphan and/or paediatric medicines, including their pharmacovigilance follow-up.

- Calibrate and optimise mature computational models for enhancing their clinical performance, by using relevant sources of patient data (e.g. natural history and observational clinical studies, medical records, registries, pharmacovigilance and longitudinal studies etc.). The models should include a variety of modelling methods and in particular hybrid solutions linking quantitative mechanistic modelling with advanced statistical modelling (e.g. quantitative systems pharmacology, disease mechanistic models, physiology-based pharmacodynamic/pharmacokinetic models, Bayesian modelling, artificial intelligence algorithms etc.).
- Assess validated in-silico models for their capability to increase the statistical robustness, improve the risk/benefit assessment in small population clinical trials, and for their accuracy to predict and extrapolate the therapeutic and dose effects, taking into account the patient's genotypes/phenotypes, disease characteristics/stage variables and/or clinical/surrogate endpoints for delivering robust evidence of safety and efficacy of the orphan and paediatric medicines under study. The assessment of the in-silico models should be demonstrated in use cases representing well-justified group(s) of rare and/or paediatric diseases with commonalities, such as shared molecular denominators/disease pathways within the same and/or across different medical areas, excluding cancer and infectious diseases.
- Benchmark of diverse computational models by showcasing their simulation performance in virtual patient cohorts and by demonstrating that the models' synthetic data estimates match to actual clinical trial data. This should lead to an assessment of the performance and credibility of a model simulation in the context of their specific use for regulatory purposes. Benchmark studies should be performed in the use cases mentioned above. Availability of clinical trials data and other relevant data is an indispensable requirement that must be demonstrated at the proposal submission.
- Set-up the criteria for the performance and credibility assessment of any relevant computational models for small population clinical trials to progress on their regulatory qualification and acceptability. Further develop and disseminate standards for the design, performance assessment and reporting of modelling and simulation tools with an emphasis on those of high regulatory value for accelerating the clinical development of orphan and paediatric medicinal products.

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, where relevant. Proposals are invited to consider adopting recommendations for in-silico models construction and validation²⁴⁹. Data-

²⁴⁹ ISO-paper under development "[Recommendations and requirements for predictive computational models in personalized medicine research — Part 1: Guidelines for constructing, verifying and validating models](#)".

intensive proposals, particularly those using data from patient registries, should take stock of the tools and services provided by the European Platform on Rare Disease Registration (EU RD Platform). For example, retrospective registry data are expected to be made accessible via EU RD platform, if reasonably feasible.

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

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-IND-06-05: Mapping the hurdles for the clinical applications of Advanced Therapy Medicinal Products (ATMPs)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 3.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 3.00 million.
<i>Type of Action</i>	Coordination and Support Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>Legal entities established in the United States of America may exceptionally participate in this Coordination and support action in a capacity other than Associated Partner.</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>Coordinators of projects must be legal entities established in an EU</p>

	Member State or Associated Country.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “Maintaining an innovative, sustainable and globally competitive health industry”. To that end, proposals under this topic should aim to deliver results that are directed towards and contributing to all of the following expected outcomes:

- Challenging aspects of regulation, policy, safety, efficacy, manufacturing, organisation, infrastructure, decision-making, and commercialisation are identified for speeding up the equitable clinical applications of ATMPs.
- European regulatory frameworks are adapted to novel scientific progress, especially those related to platform approaches, genome editing, interface with medical devices, artificial intelligence.
- Competent authorities in the Member States can propose adapted pricing and reimbursement schemes that allow European citizens to benefit from novel ATMPs.
- Academic and SME developers and manufacturers of ATMPs have an increased knowledge of the regulatory aspects.
- The decentralised manufacturing of ATMPs is consistent across health care centres.

Scope: New pioneering treatments called Advanced Therapy Medicinal Products (ATMPs), including cell and gene therapies, have the potential to bring new cures to patients affected by diseases with limited or no available treatments. However, several hurdles impede or slow down the access of ATMPs to patients in Europe. These include e.g. regulatory challenges, underlying scientific uncertainties, differences in assessing the values of ATMPs by the various Health Technology Agencies (HTA), difficulties to perform randomized-controlled clinical trials or to obtain long-term safety and effectiveness data, the lack of harmonised approaches to the reimbursement of the high upfront costs by health systems, manufacturing processes, etc.

The proposals should address all of the following activities:

- Map the regulatory, safety and efficacy assessment, manufacturing, organisational and infrastructural needs to improve the translation of ATMPs from preclinical development to clinical use.

- Address the gaps and uncertainties in regulatory and policy aspects pertinent to complex innovative ATMPs.
- Address predictivity of preclinical data for safety and efficacy testing of ATMPs. Improved novel models could be proposed.
- Tackle decision-making processes relating to ATMPs, such as for instance the assessment of their values, the demonstration of the long-term safety and effectiveness, or new pricing and reimbursement frameworks.
- Propose opportunities for an improved knowledge of the regulatory processes among academic ATMP developers.
- Involve regulatory authorities, Health Technology Agencies (HTA), clinicians, ethics committees, and patients, with the aim to ensure higher clinical use of ATMPs. The findings of the project will be available to competent authorities, ATMP developers and manufacturers as well as to national/regional funding agencies.

HORIZON-HLTH-2023-IND-06-07: Development and harmonisation of methodologies for assessing digital health technologies in Europe

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 7.00 and 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 15.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	<p>The conditions are described in General Annex B. The following exceptions apply:</p> <p>In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

Expected Outcome: This topic aims at addressing digital transition challenges through 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 to deliver results that are directed towards and contributing to all of the following expected outcomes:

- Policy-makers in the EU have at their disposal a methodological framework and standardised approaches for assessing digital health technologies, that helps them make evidence-based decisions regarding the introduction of digital health technologies in their health and care systems with added value for patients and society.
- Regulators have access to robust, scientifically underpinned evaluation methodologies.
- EU citizens gain faster access to safe and well-performing person-centred digital technologies and are empowered through these tools.
- Health technology developers are better informed and dispose of more guidance on the evidence needed to demonstrate the added value of digital health technologies and have better insights on market predictability.
- (Digital) Health Industry/digital health technology developers and HTA bodies can contribute to the development of EU harmonised Health Technology Assessment (HTA) rules based on common principles.
- Improved cross-border use and interoperability of digital health tools and services throughout Europe.
- Increased trust in digital health technologies and better integration of digital health tools and services in health and care systems.

Scope: Digital health technologies have been driving a revolution in health and care ranging from general use of computers to algorithms designed to assist radiologists and radiotherapists in detecting and treating diseases, from robotic surgery to artificial intelligence, machine learning, computer aided decision models, and from mobile apps helping patients to self-manage their disease to electronic health records.

Digital health technologies are expected to further contribute to better people-centred health and care systems and have the vast potential to improve our ability to accurately prevent, diagnose and treat diseases.

However, assessing the added value and health benefits for patients and society pose a number of challenges in particular of methodological and technical nature. Best practice for common approaches in methodology for digital health are lacking, especially in the digital health tools that include artificial intelligence algorithms. A framework for the assessment of the digital transformation of health services and its impact is vital to generate the evidence

required for decision-making on stimulating, using and/or funding digital health strategies at various levels in the health and care systems.

The Expert Panel on effective ways of investing in Health (EXPH) recommended in its report ‘Assessing the impact of digital transformation of health services²⁵⁰’, further investment in the development of assessment methodologies and in a European repository for evaluation methods and evidence of digital health services.

To date, such assessment frameworks are relatively scarce, especially those addressing the transformative aspects of healthcare delivery on the organisational and operational level.

The proposals are expected to develop and harmonise methodologies for assessing digital health technologies (including mhealth apps and telehealth, as well as Artificial Intelligence powered health technologies) in order to facilitate assessment of their added value at individual, health system and society levels and facilitate the cross-border deployment of digital health services within the EU. Existing Health Technology Assessment (HTA) methodology is well developed for health technologies such as medicinal products, but also for some categories of medical devices; however digitalisation raises new methodological challenges to the standardisation of assessment criteria such as privacy, cybersecurity, data storage and handling, interoperability, usability etc. Also including aspects like learning curves, iterative development of innovations, variability between settings, determining optimal timing of evaluations in the development process (maturity) are not yet solved.

Proposals are expected to build on existing frameworks such as (but not restricted to) ‘Model for Assessment of Telemedicine’ (MAST framework – Kidholm et al., 2012) and the results of previous EU-funded projects in particular (but not restricted to) COMED, project that already identified HTA challenges of telehealth and mhealth, and mHealth hub²⁵¹.

Proposals should consider involving the JRC to take advantage of its expertise on assessment frameworks of innovative health technologies and its activities at the interface between research and regulatory aspects and/or in translating assessment results into best practice recommendations anchored in EU policies. In that respect, the JRC is open to collaborate with any successful proposal after its approval.

The proposals should address all of the following activities:

- Develop and/or expand a general methodological framework and standardised approaches to assess digital health technologies with a particular focus on criteria such as privacy, cybersecurity, data quality, data storage and handling, interoperability etc.;
- Comply with the relevant requirements proposed in the European Health Data Space (EHDS) legal provisions;

²⁵⁰ ASSESSING THE IMPACT OF DIGITAL TRANSFORMATION OF HEALTH SERVICES, Report of the Expert Panel on effective ways of investing in Health (EXPH) - https://ec.europa.eu/health/system/files/2019-11/022_digitaltransformation_en_0.pdf

²⁵¹ <https://mhealth-hub.org/>

- Test the robustness of the developed methodologies on minimum 3 different digital health technology use cases;
- Pilot the development of common specifications to the harmonisation of assessment frameworks (pre-market and post-market phases) throughout Europe;
- Include end-users of digital health technologies (be it professionals, care users or citizens), developers of digital health technologies, producers of health services, regulators and governments;
- Collect best practice for common approaches in methodology for digital health technology assessment and develop an open access European repository for evaluation methods, studies, results and evidence of digital health technologies and services;
- Contribute to a framework to evaluate and monitor whether the uptake and use of digital health services contribute to the overall goals of the health and care system;

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

Call - A competitive health-related industry (Single stage - 2024)

HORIZON-HLTH-2024-IND-06

Conditions for the Call

Indicative budget(s)²⁵²

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million) ²⁵³	Indicative number of projects expected to be funded
		2024		
Opening: 26 Oct 2023 Deadline(s): 11 Apr 2024				

²⁵² 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 2023 and 2024.

²⁵³ Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

**Horizon Europe - Work Programme 2023-2024
Health**

HORIZON-HLTH-2024-IND-06-08	RIA	10.00	8.00 to 10.00	1
HORIZON-HLTH-2024-IND-06-09	CSA	2.00	Around 2.00	1
Overall indicative budget		12.00		

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-2024-IND-06-08: Developing EU methodological frameworks for clinical/performance evaluation and post-market clinical/performance follow-up of medical devices and in vitro diagnostic medical devices (IVDs)

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of between EUR 8.00 and 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 10.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Eligibility conditions</i>	The conditions are described in General Annex B. The following exceptions apply:

	In recognition of the opening of the US National Institutes of Health’s programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.
<i>Award criteria</i>	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 “Maintaining an innovative, sustainable and globally competitive health industry”. To that end, proposals under this topic should aim to deliver results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Patients gain faster access to innovative, safe and well-performing medical devices;
- Regulators have access to sound scientific resources for clinical/performance evaluation guidance and development of common specifications as foreseen in Article 9 of the Medical Device Regulation (MDR);
- Notified bodies, by their direct participation to the production of documents, will have a harmonised way of assessing the clinical evidence in the pre-market and post-market phases; furthermore their network²⁵⁴, will be enhanced;
- Health technology developers gain insight on the evidence needed to demonstrate that their devices meet MDR clinical requirements throughout their lifetime. They will also have more guidance on the use of real-world data for their clinical development strategies.

Scope: The Medical Device Regulation (MDR) and *in vitro* diagnostic medical device Regulation (IVDR) provides a new regulatory framework where reinforcement of clinical/performance evaluation of medical devices and IVDs, and in particular high-risk medical devices, is a key element. The confirmation of conformity with the relevant general safety and performance requirements set out in the MDR and IVDR²⁵⁵ is based on clinical data and its assessment (clinical/performance evaluation), including the evaluation of the acceptability of the benefit-risk- ratio. Within this new framework, the clinical/performance evaluation should follow a defined and methodologically sound procedure based on the critical evaluation of the relevant scientific literature, a critical evaluation of the results of all available clinical investigations/performance studies, as well as consideration of currently available alternative treatment options for the device under evaluation. Clinical/performance evaluation has to be updated throughout the life cycle of the device. Hence,

²⁵⁴ Article 49 – Coordination Group of notified bodies

²⁵⁵ Annex I General safety and performance

clinical/performance evaluation can draw on multiple types of data including data from initial clinical investigations/performance studies and data gathered by the manufacturer's post-market surveillance system. To operationalise this new requirement, research is needed to help regulators develop common methodological frameworks (including common specifications²⁵⁶) on the clinical evidence needed to demonstrate safety, performance and clinical benefit all along the life cycle of devices taking into account the type of device and clinical intended purpose.

Such methodological frameworks and standardised approaches are particularly needed for high-risk medical devices, e.g. implantable and class III medical devices, class C and D IVDs, medical device software (including AI enabled devices and next generation sequencing) and other highly innovative devices.

In order to address the differences between evidence generation for medical devices and IVDs, the project should be tackled taking into account those differences.

Proposals should address all of the following activities:

- Development of a framework for a life-cycle approach to evidence generation and evaluation of high-risk and innovative medical devices and IVDs. This framework will provide a description of the types of evidence i) that meet safety and performance for market access, and ii) that have to be generated to fulfil post-market responsibilities. When appropriate it would be beneficial to consider to what extent the framework could be relevant to demonstrate relative effectiveness as needed for Health Technology Assessment. As regards highly innovative devices, particular attention may be paid to defining acceptable levels of uncertainty in terms of benefit-risk ratio at market entry as well as the type of post-market follow-up to be implemented to generate additional clinical evidence able to reduce this uncertainty. This could be particularly relevant for devices e.g. having no or little similarities with existing devices in terms of intended purpose, mode of action, materials or, for IVDs, with no existing reference materials.;
- For medical devices, a pilot to support development of common specifications which would set the stage for a common specification ecosystem for medical devices in Europe²⁵⁷, including the development of standardised/common endpoints and associated health outcomes measures by technology type and where relevant by clinical intended purpose;
- Development of a general methodological approach to define, determine and update the state of the art for different device technologies. The robustness of the developed approach should be evaluated on 3 different medical devices types and 3 different IVD types;

²⁵⁶ Mandatory applicable “technical standards” providing to the manufacturers means of proving conformity with the safety and performance legal requirements, issued by Commission as Implementing Acts.

²⁵⁷ building on previous initiatives such as PARENT, CORE-MD, JAMS

- Possible use of registries and other sources of real-world data for demonstration of regulatory compliance both pre- and post-market: minimum requirements for data quality, completeness and data reliability, statistical methods for data analysis, methods for limiting biases, methods for data linkage, determination of what acceptable evidence can be drawn from registries;
- Methodology for bridging studies for devices and IVDs with iterative development: assessment of data coming from previous versions of the device and where relevant integration of that data into the device’s clinical investigation/performance study and gap assessment between the different versions of the device;
- Identification of relevant quantitative and qualitative methodologies for integrating evidence derived from various data sources in the clinical evaluation/performance evaluation;

Proposals should build on relevant completed and ongoing initiatives in the field, in particular (but not restricted to) EU-funded initiatives.²⁵⁸ Proposals should involve researchers who are specialised in the clinical/performance evaluation of medical devices/IVDs and in the use of real-world data to evaluate medical products. Proposals should involve national competent authorities, notified bodies, IVD laboratories as well as Health Technology Assessment bodies and could involve patients’ representatives where relevant.

Applicants envisaging including clinical studies are strongly encouraged to provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2024-IND-06-09: Gaining experience and confidence in New Approach Methodologies (NAM) for regulatory safety and efficacy testing – coordinated training and experience exchange for EU regulators

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

²⁵⁸ e.g. PARENT (PATient REgistries iNiTiative) Joint Action, [CORE-MD](#) (Coordinating Research and Evidence for Medical Devices) H2020 research project, [JAMS](#) (Joint Action on Market Surveillance of Medical Devices) initiative

	<p>Legal entities established in the United States of America may exceptionally participate in this Coordination and support action in a capacity other than Associated Partner.</p> <p>In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding to support its participation in projects funded under this topic.</p> <p>Coordinators of projects must be legal entities established in an EU Member State or Associated Country.</p> <p>The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.</p>
<i>Award criteria</i>	<p>The criteria are described in General Annex D. The following exceptions apply:</p> <p>The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.</p>

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 "Maintaining an innovative, sustainable and globally competitive health industry". To that end, proposals under this topic should aim to deliver results that are directed, tailored towards and contributing to all of the following expected outcomes:

- European regulators gain state-of-the-art knowledge on different NAMs that are being proposed for the assessment of the safety and efficacy of chemicals and pharmaceuticals;
- European regulators understand better the shortcomings of the current tools based on animal procedures for the assessment of chemicals and pharmaceuticals;
- European regulators collaborate on a framework on how to assess the safety of chemicals and pharmaceuticals based on NAM-data and how to classify the hazardous properties based on such data;
- Citizens benefit from the supply and use of chemicals and pharmaceuticals that have been assessed through NAMs that are better predicting potential effects in humans than the current assessment methods;
- Industry has an improved competitive position with the availability of harmonized and standardized NAM-based assessment tools that are faster and more flexible;
- European Commission and Member States regulators are responding to the societal demand to move away from animal testing.

Scope: There is increasing scientific evidence pointing to the limitations of animal testing for safety and efficacy assessment of chemicals and pharmaceuticals. Europe is also experiencing

a strong societal demand to move away from animal testing. Scientific progress of the past two decades has produced a number of animal-free New Approach Methodologies (NAMs) that have the potential to be used instead of the animal models that are currently employed for such testing. However, knowledge, experience and confidence on how results from the NAM assays could be used is still lacking among regulators, which could limit the industry's use of NAMs because of lack of legal certainty when generating safety and health data requested by EU legislation.

The proposals should focus on alternatives to the use of animals for regulatory safety and efficacy testing. Applicants should propose activities that bring together NAM developers and NAM users with European regulators responsible for the safe use of chemicals (e.g. industrial chemicals, pesticides, biocides and cosmetics) and pharmaceuticals in order to inform on NAM solutions available and to encourage the building of a framework on how these NAMs could be most effectively used in the different decision-making contexts.

To build such a framework the proposals should address all of the following:

- develop technical and regulatory readiness criteria
- reflect on how to provide mechanisms to support technology transfer, i.e. bringing promising NAMs to the market (including optimisation and transferability assessment)
- discuss how to standardise NAMs and NAM-based strategies via OECD, CEN, ISO and other international organisations
- provision of technical training for Contract Research Organisations (CROs) applying NAMs for the (REACH) registrants
- promoting dialogue (involving companies, regulatory bodies on EU level and Member States authorities) on how to integrate and interpret data from NAMs and facilitate their uptake for safety and efficacy testing of chemicals and pharmaceuticals, while addressing the lack of reliability and shortcomings of the current tools based on animal procedures
- Identify obstacles in EU legislation for the regulatory use of NAMs and propose options/changes in the EU regulatory framework which address these obstacles and facilitate the uptake and use of NAM

Proposals should consider involving the JRC to take advantage of its expertise and relevant activities in bridging research and regulatory communities and facilitating uptake of NAMs for regulatory application. In that respect, the JRC is open to collaborate with any successful proposal after its approval.

Other Actions not subject to calls for proposals

Grants to identified beneficiaries

1. Contribution to the Coalition for Epidemics Preparedness Initiative (CEPI) - vaccine development for priority diseases

This is a topic for a grant awarded without a call for proposals (Article 195 (e) of the EU Financial Regulation). CEPI has been a key partner for implementing the common Union response to the COVID-19 epidemic. With this funding, CEPI will be able to award grants to third parties through competitive calls for proposals. The focus will be on development of new medical countermeasures to prevent and contain infectious diseases that have epidemic potential, before these diseases become global health emergencies. The call(s) will be issued by the Norwegian beneficiary, to fund advanced pre-clinical as well as clinical research on new vaccines for the prevention of emerging and re-emerging infectious diseases, with a view to preventing future epidemics. It will be aligned with activities of the European Health Emergency Preparedness and Response Authority (HERA) and a new Partnership for Pandemic Preparedness.

Expected Impact:

Proposals should set out a credible pathway to contributing to one or several expected impacts of destination: “Tackling diseases and reducing disease burden”.

Expected Outcome:

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

- Health care providers have access to newly developed medical countermeasures against prioritised pathogens with epidemic potential.
- Citizens benefit from improvements in prevention and containment of epidemics.
- Research funders, policy makers and the research community will have better tools and solutions to achieve the Sustainable Development Goal 3.3²⁵⁹, “to combat communicable diseases” and to implement 3.B “to support the research and development of vaccines for the communicable diseases that primarily affect developing countries, and provide access to affordable essential vaccines”.

Scope:

This grant will be awarded without a call for proposals according to Article 195 (e) of the EU Financial Regulation and the relevant provisions of the Horizon Europe Regulation to the

²⁵⁹

<https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals>

legal entities identified below as CEPI has been a key partner for implementing the common Union response to the COVID-19 epidemic.

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international non-profit association established under Norwegian Law. It was founded by the Governments of Norway, Germany, Japan, India, the Bill & Melinda Gates Foundation (BMGF) and the Wellcome Trust, and launched during the World Economic Forum in Davos 2017. Its objective is to finance and coordinate the development of new medical countermeasures to prevent and contain infectious diseases that have epidemic potential, before these diseases become global health emergencies. The Horizon Europe funding will be used to enhance and expand CEPI's activities. This action will also contribute to the implementation of the Union's strategy for international cooperation in research and innovation and the EU's development policy, in particular attention will be given to the constraints national health systems face in low and middle income countries.

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

- Vaccine research and development for emerging pathogens to stop future epidemics.
- Research to advance adaptable vaccine technologies that can be used for rapid vaccine and immunoprophylactic development against previously unknown pathogens.
- 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.

With the grant from the European Union, CEPI will be able to award one or several grants to third parties through competitive calls for proposals. The call(s) will be issued to fund advanced pre-clinical as well as clinical research on new vaccines for the prevention of emerging and re-emerging infectious diseases, with a view to preventing future epidemics. For this purpose this action is also expected to engage with HERA. The expected recipients of the grant(s) issued by CEPI include research institutes, universities, SMEs as well as large companies, all active in research and innovation on new and improved vaccines.

Award criteria:

The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Legal and financial set-up of the Grant Agreements:

The funding rate will be 70%.

Financial support provided by CEPI to third parties is one of the primary activities of this action in order to be able to achieve its objectives as CEPI does not have the capacity to

develop new medical countermeasures itself. The maximum amount to be granted to a third party is EUR 35 million. This is justified by the high cost of development for new vaccines, that reach tens of millions of Euros²⁶⁰.

Legal entities:

Coalition for Epidemic Preparedness Innovations, Marcus Thranes gate 2, 0473 Oslo, Norway

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 195(e) - Programme co-fund action

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes.

Indicative timetable: 4th Quarter 2023

Indicative budget: EUR 35.00 million from the 2023 budget

2. Presidency event - Sweden

A maximum of EUR 300,000 will be allocated to the Swedish Presidency for conference(s) organisation.

Award criteria:

The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Procedure:

The evaluation committee will be composed fully by representatives of EU institutions.

Legal and financial set-up of the Grant Agreements:

The funding rate will be 100%.

Form of Funding: Grants not subject to calls for proposals

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

²⁶⁰ Gouglas, D. et al.: Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimisation study. *Lancet Global Health* Vol. 6 (12) E1386-E1396. DOI: [https://doi.org/10.1016/S2214-109X\(18\)30346-2](https://doi.org/10.1016/S2214-109X(18)30346-2), [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(18\)30346-2/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30346-2/fulltext)

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes.

Indicative timetable: 2023 - Exact timing to be confirmed

Indicative budget: EUR 0.30 million from the 2023 budget

3. Presidency event - Spain

A maximum of EUR 300,000 will be allocated to the Spanish Presidency for conference(s) organisation.

Award criteria:

The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Procedure:

The evaluation committee will be composed fully by representatives of EU institutions.

Legal and financial set-up of the Grant Agreements:

The funding rate will be 100%.

Form of Funding: Grants not subject to calls for proposals

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

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes.

Indicative budget: EUR 0.30 million from the 2023 budget

4. Presidency event - Belgium

A maximum of EUR 300,000 will be allocated to the Belgian Presidency for conference(s) organisation.

Award criteria:

The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Procedure:

The evaluation committee will be composed fully by representatives of EU institutions.

Legal and financial set-up of the Grant Agreements:

The funding rate will be 100%.

Form of Funding: Grants not subject to calls for proposals

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

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes.

Indicative timetable: 2024 - Exact timing to be confirmed

Indicative budget: EUR 0.30 million from the 2024 budget

5. Presidency event - Hungary

A maximum of EUR 300,000 will be allocated to the Hungarian Presidency for conference(s) organisation.

Award criteria:

The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Procedure:

The evaluation committee will be composed fully by representatives of EU institutions.

Legal and financial set-up of the Grant Agreements:

The funding rate will be 100%.

Form of Funding: Grants not subject to calls for proposals

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

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes.

Indicative timetable: 2024 - Exact timing to be confirmed

Indicative budget: EUR 0.30 million from the 2024 budget

Other Instruments

1. External expertise

This action will support the use of appointed independent experts for the monitoring of running actions (grant agreement, grant decision, public procurement actions, financial instruments) funded under Horizon Europe and previous Framework Programmes for Research and Innovation, for ethics checks, for the evaluation of large actions annual work plans, as well as for compliance checks regarding the Gender Equality Plan eligibility criterion. A special allowance of EUR 450/day will be paid to the experts appointed in their personal capacity who act independently and in the public interest.

Form of Funding: Other budget implementation instruments

Type of Action: Expert contract action

Indicative budget: EUR 2.00 million from the 2023 budget and EUR 2.00 million from the 2024 budget

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

Expected Impact:

Proposals should set out a credible pathway to contributing to one or several expected impacts of destination: “Tackling diseases and reducing disease burden”.

Expected Outcome:

Project results are expected to contribute to the following expected outcome: Allow the Union to respond to Public Health Emergencies

Scope:

In case of a public health emergency²⁶¹ (such as a Public Health Emergency of International Concern (PHEIC) according to the World Health Organization, a public health emergency under Decision 1082/2013/EU or under applicable national frameworks and regulations), funding will be mobilised for:

- The award of grants without a call for proposals according to Article 195 (b) of the EU Financial Regulation²⁶² in exceptional and duly substantiated emergencies. At that time, the Funding & Tenders Portal will open a dedicated section where proposals can be

²⁶¹ Should there be no Public Health Emergency in 2023 or 2024, the indicative budget may be reallocated.

²⁶² 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;".

submitted. This will be communicated to the National Contact Points. The invitation to apply for funding will be open to all eligible entities or be limited to targeted entities, taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances; and/or

- The award of additional funding for ongoing grant agreements to cover additional activities specifically linked to the public health emergency, in exceptional and duly substantiated emergencies. Providing such additional funding to ongoing grants that can support pertinent short- and mid-term research efforts to confront the public health emergency will save valuable time and allow addressing the situation with the appropriate urgency. Restricted calls for expression of interest or proposals will develop such additional activities or add additional partners to existing actions.

It is expected that quality-controlled data are shared in accordance with the FAIR²⁶³ principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

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

The beneficiaries must comply with the public emergency related provisions listed in the General Annexes concerning the project implementation under - Intellectual Property Rights (IPR), background and results, access rights and rights of use (article 16 and Annex 5) for the duration of the Public Health Emergency; and under Communication, dissemination, open science and visibility (article 17 and Annex 5) during the entire duration of the action and for four years after the end of the action.

The following derogations to the evaluation procedure described in General Annexes D and F apply to open invitations to submit applications:

In order to ensure a balanced portfolio covering responses to different aspects of the public health emergency, grants will be awarded to applications not only in order of ranking, but also to those projects that enhance the quality of the project portfolio through synergies between projects and avoidance of overlaps, provided that the applications attain all thresholds.

The action may also include justified derogations from the standard limits to financial support to third parties. Where applicable, the relevant grant agreement options will be applied.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant awarded without call for proposals according to Financial Regulation Article 195 (b)

²⁶³ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability. <https://www.openaire.eu/how-to-make-your-data-fair>

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes.

Indicative timetable: Will depend on the Public Health Emergency

Indicative budget: EUR 1.00 million from the 2023 budget and EUR 1.00 million from the 2024 budget

3. Studies, conferences, events and outreach activities

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

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

Form of Funding: Procurement

Type of Action: Public procurement

Indicative budget: EUR 10.48 million from the 2023 budget and EUR 2.30 million from the 2024 budget

4. Subscription to the Human Frontier Science Program Organization

An annual subscription to the international Human Frontier Science Program Organization (HFSP)²⁶⁴ 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.

An amount of EUR 1 Million in 2023 and EUR 1 Million in 2024 is set aside in order to enable initiatives to help the affected scientific community in and from areas recently severely ravaged by conflict and/or war on European ground.

Type of Action: Subscription action

Indicative timetable: 2023 and 2024

²⁶⁴ The European Commission is a member of the HFSP Organization (HFSP) and has funded HFSP under previous Framework Programmes

Indicative budget: EUR 6.30 million from the 2023 budget and EUR 6.30 million from the 2024 budget

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Horizon Europe - Work Programme 2023-2024
Health

Budget²⁶⁵

	Budget line(s)	2023 Budget (EUR million)	2024 Budget (EUR million)
Calls			
HORIZON-HLTH-2023-STAYHLTH-01		40.00	
	<i>from</i> <i>01.020210</i>	16.00	
	<i>from</i> <i>01.020210 -</i> <i>NGEU</i>	24.00	
HORIZON-HLTH-2024-STAYHLTH-01-two-stage			80.00
	<i>from</i> <i>01.020210</i>		80.00
HORIZON-HLTH-2023-ENVHLTH-02		103.00	
	<i>from</i> <i>01.020210</i>	43.50	
	<i>from</i> <i>01.020210 -</i> <i>NGEU</i>	59.50	
HORIZON-HLTH-2024-ENVHLTH-02-two-stage			60.00
	<i>from</i> <i>01.020210</i>		60.00
HORIZON-HLTH-2023-DISEASE-03		224.00	
	<i>from</i> <i>01.020210</i>	93.00	
	<i>from</i> <i>01.020210 -</i> <i>NGEU</i>	131.00	

²⁶⁵ 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 2023 and 2024.

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HORIZON-HLTH-2023-DISEASE-07		50.00	
	<i>from</i> <i>01.020210</i>	<i>50.00</i>	
HORIZON-HLTH-2024-DISEASE-03- two-stage			125.00
	<i>from</i> <i>01.020210</i>		<i>125.00</i>
HORIZON-HLTH-2024-DISEASE-08			52.00
	<i>from</i> <i>01.020210</i>		<i>52.00</i>
HORIZON-HLTH-2024-DISEASE-09			100.00
	<i>from</i> <i>01.020210</i>		<i>100.00</i>
HORIZON-HLTH-2023-CARE-04		60.00	
	<i>from</i> <i>01.020210</i>	<i>27.00</i>	
	<i>from</i> <i>01.020210 -</i> <i>NGEU</i>	<i>33.00</i>	
HORIZON-HLTH-2023-CARE-08		100.00	
	<i>from</i> <i>01.020210</i>	<i>50.00</i>	
	<i>from</i> <i>01.020210 -</i> <i>NGEU</i>	<i>50.00</i>	
HORIZON-HLTH-2024-CARE-04-two- stage			30.00
	<i>from</i> <i>01.020210</i>		<i>30.00</i>
HORIZON-HLTH-2023-TOOL-05		214.00	
	<i>from</i> <i>01.020210</i>	<i>87.13</i>	
	<i>from</i> <i>01.020210 -</i>	<i>126.87</i>	

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	<i>NGEU</i>		
HORIZON-HLTH-2024-TOOL-05-two-stage			25.00
	<i>from 01.020210</i>		25.00
HORIZON-HLTH-2024-TOOL-11			25.00
	<i>from 01.020210</i>		25.00
HORIZON-HLTH-2023-IND-06		56.00	
	<i>from 01.020210</i>	26.00	
	<i>from 01.020210 - NGEU</i>	30.00	
HORIZON-HLTH-2024-IND-06			12.00
	<i>from 01.020210</i>		12.00
Contribution from this part to call HORIZON-MISS-2023-CANCER-01 under Part 12 of the work programme		116.47	
	<i>from 01.020210</i>	116.47	
Other actions			
Grant to identified beneficiary according to Financial Regulation Article 195(e)		35.60	0.60
	<i>from 01.020210</i>	35.60	0.60
Expert contract action		2.00	2.00
	<i>from 01.020210</i>	2.00	2.00
Grant awarded without a call for proposals according to Financial Regulation Article 195		1.00	1.00
	<i>from 01.020210</i>	1.00	1.00
Public procurement		10.48	2.30
	<i>from</i>	10.48	2.30

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	<i>01.020210</i>		
Subscription action		6.30	6.30
	<i>from 01.020210</i>	6.30	6.30
Contribution from this part to Expert contract action under Part 12 of the work programme		0.27	
	<i>from 01.020210</i>	0.27	
Estimated total budget		1019.13	521.20

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