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 costs[97]. 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 predictions[98].

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

[97] 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).

[98] 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 policymaking; 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). In addition, while focusing on civilian applications, there may be there may be synergies with actions conducted under the European Defence Fund, notably in the field of defence medical countermeasures.

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"[99] 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)[100]. 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)[101,102, 103].

- Health care systems benefit from strengthened research and innovation expertise, human capacities and know-how for combatting communicable and non-communicable

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

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

101 WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 (resolution WHA66.10), https://www.who.int/publications/i/item/9789241506236

102 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.

103 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.

diseases, including through international cooperation. In particular, they are better prepared to respond rapidly and effectively to health emergencies and are able to prevent and manage communicable diseases transmissions epidemics, including within healthcare settings.

- Citizens benefit from reduced (cross-border) health threat of epidemics and AMR pathogens, in the EU and worldwide[104, 105].
- 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	

104 WHO global action plan on antimicrobial resistance, 2015
105 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)[106]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[107]	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 [108]	6.00 to 7.00	8
HORIZON-HLTH-2023-DISEASE-03-03	RIA	20.00 [109]	3.00 to 4.00	5
HORIZON-HLTH-2023-DISEASE-03-04	RIA	50.00 [110]	7.00 to 8.00	7
HORIZON-HLTH-2023-DISEASE-03-05	CSA	3.00 [111]	1.00 to 2.00	2
HORIZON-HLTH-2023-DISEASE-03-06	CSA	1.00 [112]	Around 1.00	1
HORIZON-HLTH-2023-DISEASE-03-07	RIA	30.00 [113]	6.00 to 7.00	5
HORIZON-HLTH-2023-DISEASE-03-17	RIA	20.00 [114]	7.00 to 8.00	5
HORIZON-HLTH-2023-DISEASE-03-18	RIA	50.00 [115]	7.00 to 8.00	7

106 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.

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

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

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

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

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

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

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

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

Overall indicative budget		224.00		

General conditions relating to this call	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.
Legal and financial set-up of the Grant Agreements	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	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 50.00 million.
Type of Action	Research and Innovation Actions
Eligibility conditions	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

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

	United States of America is eligible to receive Union funding.
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.

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 policymakers 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. Palliative[116] 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.

Proposals should address all of the following activities:

116 https://www.who.int/cancer/palliative/definition/en/

- 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 diseases[117] (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 equity[118] 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.

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

[117] 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.

[118] https://www.who.int/topics/health_equity/en/

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 covering 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 to include clinical studies should 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	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 20.00 million.
Type of Action	Research and Innovation Actions
Eligibility conditions	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. 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).
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.

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 city[119] environments.
- Public health managers and authorities have access to improved insights and evidence 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.

Scope: The European Commission is a member of the Global Alliance for Chronic Diseases (GACD)[120]. 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,

119 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.

120 https://www.gacd.org/

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 HICs[121]. 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 environments[122]. 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 adaptation[123]. 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 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.

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

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

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

- 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 both 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 environment[124]

These interventions focus on modifying the built environment to improve its health-promoting potential[125]. 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 should 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 should 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.).

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 Cities[126].

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

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

[125] 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.

[126] 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

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 policymakers, local authorities, as well as other stakeholders such as community groups, or other individuals or organisations 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 to include clinical studies should 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	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 50.00 million.
Type of Action	Research and Innovation Actions
Eligibility conditions	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.

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.

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)[127], with particular attention to those meeting the criteria identified by the Health Emergency Preparedness and Response Authority (HERA)[128].

[127] https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts

[128] https://health.ec.europa.eu/system/files/2022-07/hera_factsheet_health-threat_mcm.pdf

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 all 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 therapeutics, 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.
- Application of novel approaches and widely applicable workflows (e.g. artificial intelligence) for rapid and reliable identification of broad-spectrum anti-viral therapeutics.

Applicants are expected to engage with regulatory bodies in a timely manner to ensure adequacy of the actions from a regulatory point of view.

Applicants envisaging to include clinical studies should 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/or for cohort networks

Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 1.00 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.
Indicative budget	The total indicative budget for the topic is EUR 3.00 million.
Type of Action	Coordination and Support Actions

Eligibility conditions	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, legal entities established in the United States of America may exceptionally participate as a beneficiary or affiliated entity, and are eligible to receive Union funding. Coordinators of projects must be legal entities established in an EU Member State or Associated Country.
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.

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/or 2) among established cohorts in Europe and beyond with a view for better pandemic preparedness and response,
- The adaptive platform trial and/or 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/or 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 trials[129] and a network for COVID-19 vaccine trials[130] and strong common coordination mechanisms between the trials have been established. The recently launched Ecraid[131] is a European clinical research network that has been in development since

129 https://covid19trials.eu/en
130 https://vaccelerate.eu/
131 https://www.ecraid.eu/

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 other relevant research infrastructures should be envisaged. Proposals should also be open to engage with global initiatives such as the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)[132], the Global Health EDCTP3 Joint Undertaking[133], or the World Health Organization (WHO).

Proposals should address the following areas:

- Fostering a trusted and proactive environment within the 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;

132 https://www.glopid-r.org/

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

- 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 FAIR data [134] collection and analysis leveraging existing initiatives;

- Involving relevant European stakeholders, such as representatives from regulatory authorities, industry, policymakers, 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	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 1.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 1.00 million.
Type of Action	Coordination and Support Actions
Eligibility conditions	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, legal entities established in the United States of America may exceptionally participate as a beneficiary or affiliated entity, and are eligible to receive Union funding.

[134] See definition of FAIR data in the introduction to this work programme part.

	Coordinators of projects must be legal entities established in an EU Member State or Associated Country.
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.

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:

- Policymakers, funders and other relevant stakeholders[135] identify and agree on the governance structure and implementation modalities, allowing for an efficient establishment of a potential future partnership.
- Policymakers, funders and other relevant stakeholders build on the knowledge gathered in past studies performed at EU and national level.
- Policymakers, 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.
- Policymakers, funders and other relevant stakeholders develop and align national and regional research strategy plans with long-term sustainability in mind.
- Policymakers 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 Health[136] in the second Strategic Plan of Horizon Europe[137].

Proposals should address all of the following aspects:

- Develop a structured system of exchange of information between policymakers, funders, and other relevant bodies[138] in order to establish synergies and avoid duplication of

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

136 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.

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

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

efforts. The aim is to structure brain health research in Europe and pave the way for a possible future partnership.

- Develop a strategic research and innovation agenda, taking into account the efforts already undertaken by EU-supported actions[139]. The strategic research and innovation agenda will identify a number of measurable, scientific-technological priorities and socio-economic objectives, supported by an appropriate analysis.

- Develop plans for a governance structure of a future partnership, as well as implementation modalities with long-term sustainability in mind, and under the leadership of an EU Member State or Associated Country.

- 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.

- Consider international initiatives by engaging with global organisations[140], as well as with global initiatives and research organisations[141] in the field.

- Elaborate on platforms and tools for use by the research community, including on how they can best complement, integrate with each other. In this context, infrastructures already developed at the European[142] 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.

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139 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).

140 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).

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

142 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).

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

Specific conditions	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 30.00 million.
Type of Action	Research and Innovation Actions
Eligibility conditions	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.
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.

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 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 condition[143]), 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.

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 ORCHESTRA[144]. They should also pay special attention and link to the newly established European COVID-19 data sharing platform[145].

143 https://www.who.int/publications/i/item/WHO-2019-nCoV-Post_COVID-19_condition-Clinical_case_definition-2021.1
144 https://orchestra-cohort.eu/
145 https://www.covid19dataportal.org/

Applicants envisaging to include clinical studies should 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	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 20.00 million.
Type of Action	Research and Innovation Actions
Eligibility conditions	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. 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).
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.

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 lifestyle (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 meeting the criteria for pathogens with high pandemic potential as identified by HERA[146].

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.

146 https://health.ec.europa.eu/system/files/2022-07/hera_factsheet_health-threat_mcm.pdf

Applicants envisaging to include clinical studies should 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	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 50.00 million.
Type of Action	Research and Innovation Actions
Eligibility conditions	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.
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.

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 against pathogens with high pandemic potential meeting the criteria identified by the Health Emergency Preparedness and Response Authority (HERA)[147] would provide a critical preparedness measure against future health threats.

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 the following viruses: Hendra and Nipah Virus, Lassa virus, Crimean Congo haemorrhagic fever virus, Rift Valley fever virus, Ebola and Marburg virus, Dengue virus, Yellow Fever virus, Zika virus, West Nile fever virus and Chikungunya virus.

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 several of 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 to include clinical studies should 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.

147 https://health.ec.europa.eu/system/files/2022-07/hera_factsheet_health-threat_mcm.pdf

Call - Partnerships in Health (2023)

HORIZON-HLTH-2023-DISEASE-07

Conditions for the Call

Indicative budget(s)[148]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[149]	Indicative number of projects expected to be funded
		2023		
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	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.

148 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.

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

Procedure	The procedure is described in General Annex F.
Legal and financial set-up of the Grant Agreements	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	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 50.00 million.
Type of Action	Programme Co-fund Action
Eligibility conditions	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. Because the US contribution will be considered for the calculation of the EU contribution to the partnership, the concerned consortium of research funders from eligible EU Members States and Associated Countries must expressly agree to this participation. The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.
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 rules are described in General Annex G. The following exceptions apply: Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. 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. Given the type of action and its level of ambition, the maximum amount

	to be granted to each third party is EUR 10.00 million. The funding rate is 50% of the eligible costs. 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.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to 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 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[150]).

This partnership should also contribute to achieving the objectives of the Pharmaceutical Strategy for Europe[151], in terms of fulfilling unmet medical needs (e.g. for rare diseases with so called "orphan medicinal products"[152]) 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, policymakers), 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 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[153] 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.

150 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.107.01.0001.01.ENG
151 COM(2020) 761 final, https://ec.europa.eu/health/medicinal-products/pharmaceutical-strategy-europe_en
152 https://ec.europa.eu/health/medicinal-products/orphan-medicinal-products_en
153 See definition of FAIR data in the introduction to this work programme part.

The Partnership is open to all EU Member States, as well as to countries associated to Horizon Europe and will remain open to third 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 should 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. Importantly, the EU Member States, as public funders should have a leading role in the governance and strategic steering of the whole Partnership, including in the co-design and the strategic orientations of the 'in-house' activities, such as consolidating the research & innovation ecosystem, clinical trial preparedness for the community, contribution to ERA, training activities etc.). Moreover, the management structure should allow the coordinated input of 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 (institutionalised and co-funded) and missions as set out in the working document on 'Coherence and Synergies of candidate European Partnerships under Horizon Europe'[154] 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

[154] Directorate-General for Research and Innovation, A4 Partnership Sector, October 2020: https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/ec_rtd_coherence-synergies-of-ep-under-he_annex.pdf

Fund (ERDF)[155], 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.

Collaboration with the EU agency involved in authorising orphan medicinal products, the European Medicines Agency (EMA), should be considered to enhance the sharing of knowledge and data regarding orphan medicinal products and rare diseases, while national agencies 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 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 total indicative budget for the partnership is up to EUR 150 million and subject to the effective implementation of the commitments made by the members of the consortium. The Commission envisages to include new actions in its future work programmes to provide continued support to the partnership for the duration of Horizon Europe.

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

Call - Tackling diseases (Two stage - 2024)

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

[155] "Synergies between Horizon Europe and ERDF programmes (Draft Commission Notice)" https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/synergies-guidance-out-2022-07-06_en

Conditions for the Call

Indicative budget(s)[156]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[157]	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	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.

156 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.

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

Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.
Legal and financial set-up of the Grant Agreements	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	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 45.00 million.
Type of Action	Research and Innovation Actions
Admissibility conditions	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).
Eligibility conditions	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.
Award criteria	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.

Procedure	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.
Legal and financial set-up of the Grant Agreements	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). [158].

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 policymakers 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.

- Citizens, patients, prescribers, and payers receive more accurate information on available healthcare interventions via ad hoc communication platforms.

[158] 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

- 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[159] 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 polypharmacy. 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.

Proposals 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 relevance[160].

- 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 EUnetHTA[161] should be also taken into account.

- Consider issues of particular relevance for the target populations, for example, multimorbidity, complex chronic conditions, polypharmacy, 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.

- 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,

159 See definition of FAIR data in the introduction to this work programme part.

160 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.

161 https://www.eunethta.eu/

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 invited to the second stage and envisaging to include clinical studies should 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	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 30.00 million.

Type of Action	Research and Innovation Actions
Admissibility conditions	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).
Eligibility conditions	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.
Award criteria	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.
Procedure	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.
Legal and financial set-up of the Grant Agreements	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). [162].

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:

[162] 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

- 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 FAIR[163] 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.

163 See definition of FAIR data in the introduction to this work programme part.

- 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 Undertaking[164], the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)[165], 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 invited to the second stage and envisaging to include clinical studies should 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	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 25.00 million.
Type of Action	Research and Innovation Actions
Admissibility conditions	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).

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

165 https://www.glopid-r.org/

Eligibility conditions	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.
Award criteria	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.
Procedure	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.
Legal and financial set-up of the Grant Agreements	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). [166].

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.
- 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

[166] 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

storage and sharing of collected data according to FAIR [167] principles, thereby encouraging further use of the data.

- Policymakers, funders, scientific and clinical communities, patient organisations, regulators and other relevant bodies are informed of the research advances made, while health professionals envisage use of the biomarker tests for early detection of the disorder and for guiding patients in the selection of personalised treatments/interventions.

- 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 horizon[168]. 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 Diseases[169]. 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 selection[170].

- Proposals should aim to provide evidence supporting the regulatory acceptance of the biomarkers[171].

- 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.

- Sex and gender aspects, age, socio-economic, lifestyle and behavioural factors should be taken into consideration in the study.

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167 See definition of FAIR data in the introduction to this work programme part.

168 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

169 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'.

170 The biomarker should link to a clinical meaningful endpoint.

171 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.

- To enable sharing of samples, quality data and advanced analytical and digital tools, consideration should be made for using infrastructures already developed at the European[172] 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 invited to the second stage and envisaging to include clinical studies should 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	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 25.00 million.
Type of Action	Research and Innovation Actions
Admissibility conditions	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).
Eligibility conditions	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.
Award criteria	The criteria are described in General Annex D. The following exceptions apply:

[172] 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).

	For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
Procedure	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.
Legal and financial set-up of the Grant Agreements	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). [173].

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 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 [174] principles, thereby encouraging further use of the data.
- Policymakers and funders are informed of the research advances made and consider further support in light of the sustainability of the studies.

[173] 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

[174] See definition of FAIR data in the introduction to this work programme part.

- 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 conditions [175] may be insufficiently researched even though they manifest with high prevalence[176, 177]. This topic excludes rare diseases.

Proposals should address all of the following aspects:

- Proposals should address the gaps in robust, scientific evidence for improved policies and practices to tackle such medical condition(s), and aim at identifying the pathophysiological mechanism(s) (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.

- Proposals should demonstrate that the medical condition(s) under study is/are insufficiently understood, inaccurately diagnosed or inadequately treated in a significant proportion of patients, and as such represent a high burden for patients and society. This could be through referencing key literature.

- 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 should be considered.

- Where applicable, the development of clinically relevant, (non-)human model systems that can complement clinical investigations should be considered.

- Exploitation of existing data, biobanks, registries and cohorts is expected, together with the generation of new (e.g. genomics, epigenomics, transcriptomics, proteomics) data.

175 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.

176 Examples of medical conditions include Lyme disease, Chronic Fatigue Syndrome and back pain.

177 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.

- To enable sharing of samples, quality data and advanced analytical tools, it is encouraged to make use of existing infrastructures developed at the European[178] or national level.

- 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 invited to the second stage and envisaging to include clinical studies should 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)[179]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[180]	Indicative number of projects expected to be funded
		2024		
Opening: 26 Oct 2023 Deadline(s): 11 Apr 2024				

178 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'.

179 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.

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

HORIZON-HLTH-2024-DISEASE-08-12	CSA	2.00	Around 2.00	1
HORIZON-HLTH-2024-DISEASE-08-20	RIA	50.00	7.00 to 8.00	5
Overall indicative budget		52.00		

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

Proposals are invited against the following topic(s):

HORIZON-HLTH-2024-DISEASE-08-12: Pandemic preparedness and response: Maintaining the European partnership for pandemic preparedness

Specific conditions	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 2.00 million.
Type of Action	Coordination and Support Actions
Eligibility conditions	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, legal entities established in the United States of America may exceptionally participate as a beneficiary or affiliated entity, and are eligible to receive Union funding. Coordinators of projects must be legal entities established in an EU Member State or Associated Country.
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.

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, policymakers 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, policymakers 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 research infrastructures[181], 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-08-20: Pandemic preparedness and response: Host-pathogen interactions of infectious diseases with epidemic potential

Specific conditions	
Expected EU contribution per project	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

[181] European Research Infrastructures | European Commission (europa.eu), BY-COVID (https://by-covid.org/), ISIDORe (https://isidore-project.eu/) and PHIRI (https://www.phiri.eu/)

	selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 50.00 million.
Type of Action	Research and Innovation Actions
Eligibility conditions	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. The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.
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.

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, in particular against pathogens with high pandemic potential meeting the criteria identified by the Health Emergency Preparedness and Response Authority (HERA)[182].

Proposals should follow innovative approaches to characterise 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 the following viruses: Hendra and Nipah virus, Lassa virus, Crimean Congo haemorrhagic fever virus, Rift Valley fever virus, Ebola and Marburg virus, Dengue virus, Yellow Fever virus, Zika virus, West Nile fever virus and Chikungunya virus. 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 characterisation 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 to include clinical studies should 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.

[182] https://health.ec.europa.eu/system/files/2022-07/hera_factsheet_health-threat_mcm.pdf

Call - Partnerships in Health (2024)

HORIZON-HLTH-2024-DISEASE-09

Conditions for the Call

Indicative budget(s)[183]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[184]	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	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.

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

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

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

Proposals are invited against the following topic(s):

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

Specific conditions	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 100.00 million.
Type of Action	Programme Co-fund Action
Eligibility conditions	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. Because the US contribution will be considered for the calculation of the EU contribution to the partnership, the concerned consortium of research funders from eligible EU Members States and Associated Countries must expressly agree to this participation.
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 rules are described in General Annex G. The following exceptions apply: Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. 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. Given the type of action and its level of ambition, the maximum amount to be granted to each third party is EUR 10.00 million.

	The funding rate is 30% of the eligible costs.

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 curb antimicrobial resistance (AMR) is improved and the EU is reinforced as an internationally recognised driver of research and innovation on AMR thereby substantially contributing to the achievement of the Sustainable Development Goals related to AMR;
- EU and national agencies, the scientific communities, policymakers 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, policymakers, 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 AMR[185];
- 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 actor 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 transnational research.

Scope: The partnership should 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).

185 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 Europe[186], 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 Programme [187], as well as supporting the objectives of the Farm to Fork Strategy[188].

Thanks to its capacity to bring together different stakeholders (e.g. research funders, health authorities, citizens, healthcare institutions, innovators, policymakers), 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.

186 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761
187 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.107.01.0001.01.ENG
188 https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en

2. Boost Research and Innovation

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 innovative 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 should 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 (WOAH), the Food and Agriculture Organization (FAO), United Nations Environmental Programme (UNEP), 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, policymakers 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 third countries wishing to join.

The Partnership should build on, be complementary to and go beyond the existing initiative JPIAMR[189].

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 (institutionalised and co-funded, such as the future Animal Health and Welfare partnership[190]) and missions as set out in the working document on 'Coherence and Synergies of candidate European partnerships under Horizon Europe'[191] as well as to explore collaborations with other relevant activities at EU and international level. The proposals 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 data[192].

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.

189 https://www.jpiamr.eu/

190 Refer to topic HORIZON-CL6-2023-FARM2FORK-01-2

191 Directorate-General for Research and Innovation, A4 Partnership Sector, October 2020: https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/ec_rtd_coherence-synergies-of-ep-under-he_annex.pdf

192 See definition of FAIR data in the introduction to this work programme part.