EN

Annex IV

Horizon Europe

Work Programme 2026-2027

4. Health

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Introduction

This work programme part is the final instalment for the Health Cluster under Horizon Europe (2021-2027), representing the last opportunity to deliver on the programme's objectives. It aims to address the remaining gaps, emerging research needs, and future challenges identified in the programme's second strategic plan, covering 2025-2027. It also aligns with the European Commission's Political Guidelines for 2024-2029, which focus on strengthening healthcare resilience, leveraging biotechnology and artificial intelligence, and addressing public health needs including supporting the development of critical medicines and strengthening societal preparedness and response. This will contribute to Europe's sustainable prosperity and competitiveness. Research and innovation are key to achieving these goals.

In 2026-2027, the Health Cluster will pursue the following priorities:

- Addressing non-communicable diseases, including mental health, through prevention, treatment, and management, supporting initiatives such as the "Healthier Together" EU Non-communicable Diseases Initiative
- Understanding and mitigating the impacts of climate change, pollution, and biodiversity loss on human health and healthcare systems, supporting both the European Climate Adaptation Plan and the European Green Deal. This dual approach addresses the need to adapt to unavoidable climate impacts while contributing to broader mitigation efforts through transformative healthcare solutions.
- Building pandemic preparedness and response, including addressing antimicrobial resistance, in support of the European Health Union and the European Medical Countermeasures Strategy.
- Transforming Europe's healthcare systems to make them more effective, efficient, equitable, accessible, and sustainable, complementing the work of the European Partnership on Transforming Health and Care Systems.
- Supporting digitalisation in healthcare, leveraging the innovation potential of health data and data-driven approaches, including AI, in the context of the European Health Data Space (EHDS) Regulation.
- Developing and using innovative tools and critical technologies, such as AI and biotechnology, to secure a competitive EU health industry and technological sovereignty in the healthcare sector, in line with the EU's Artificial Intelligence Strategy, Biotechnology and Biomanufacturing Strategy, and Life Science Strategy

In addition to these priorities, the Health Cluster will also continue to address the needs of specific populations, such as persons with disabilities and their families, focusing on their empowerment. This is a crucial step towards ensuring that persons with disabilities can live independently and participate fully in society. Empowerment is also key for behavioural interventions, which this work programme part supports, by inviting proposals for the

development of behavioural interventions as primary prevention for non-communicable diseases, to empower young people to adopt healthy lifestyles and reduce their risk of developing these diseases later in life.

Furthermore, mental health remains a priority, with topics focusing on developing interventions to address the impact of climate change on mental health, as well as promoting healthy lifestyles and preventing mental health disorders. This includes a focus on the mental health of children and young adults, who are particularly vulnerable to the negative effects of digital technologies. The development of innovative interventions to prevent the harmful effects of using digital technologies on the mental health of children and young adults is a key objective, in line with the Commission's Political Guidelines 2024-2029 which call for protecting the mental health of our children and young people in an increasingly digitalised world.

The Health Cluster will also leverage public procurement to drive innovation, with two actions: a pre-commercial procurement action on climate-resilient healthcare and a public procurement of innovative solutions action on integrated care, both aimed at improving healthcare outcomes

Additionally, this Work Programme part supports the second phase of the European Partnerships on Rare Diseases and Pandemic Preparedness, providing continued funding to build on the progress achieved in the first phase and to further address the significant research, medical and societal challenges posed by rare diseases and pandemics.

To realise the potential of new Research and Innovation for society, collaboration between research teams and prospective users of the knowledge and technology developed is paramount. It is therefore essential to involve these users - such as patients, healthy citizens, healthcare professionals, providers and payers, public health authorities, regulators, and innovators from academia and industry - early in the process of knowledge generation and technology development. This involvement can take the form of patient and citizen engagement, community involvement, and other social innovation approaches, ensuring that Research and Innovation activities align with the specific expectations, needs, constraints, and potential of users. Furthermore, effective intellectual property management strategies are crucial to maximise the benefits of such cooperation.

It is in the EU’s strategic interest to cooperate with countries beyond the EU, particularly for multilateral cooperation on (global) health issues. This includes countries associated to Horizon Europe as well as other partner countries and regions worldwide. In line with the EU’s Global Approach to Research and Innovation[1], participation in the Health Cluster of Horizon Europe is open to third countries. Supporting the Global Gateway Strategy[2], projects involving international partners should aim to increase scientific knowledge and facilitate technology transfer among partner countries, addressing global health challenges and

[1] COM(2021) 252 final
[2] JOIN(2021) 30 final

fostering sustainable growth and job creation. Such cooperation should be value-based, creating linkages rather than dependencies.

Applicants are encouraged to explore opportunities for synergies between the Health Cluster and other EU programmes[3] to enhance the reach and impact of their projects, such as through broader stakeholder cooperation and follow-on activities. Synergies are in particular foreseen between the Health Cluster and the EU4Health programme to facilitate the uptake, further development and deployment of new knowledge and technologies in fields such as cancer, non-communicable diseases, mental health, pandemic preparedness and antimicrobial resistance, health systems and digital health. Synergies are also foreseen between the Health Cluster and the Digital Europe Programme to leverage Horizon Europe Research and Innovation results, such as deploying digital, privacy-preserving (distributed) data infrastructures, high-performance computing resources, and developing methods and tools for modelling complex phenomena related to human health.

The European Regional Development Fund (ERDF) -including Interreg- focuses, amongst others, on the development and strengthening of regional and local Research and Innovation ecosystems and smart economic transformation, in line with regional/national smart specialisation strategies. The programme can e.g., support investment in research infrastructure, activities for applied Research and Innovation, including industrial research, experimental development and feasibility studies, building on Research and Innovation stemming from Horizon Europe[4].

To further strengthen the impact of Research and Innovation efforts, Horizon Europe applicants could consider tapping into complementary activities offered by other relevant initiatives funded under the Horizon Europe programme. These include the innovation ecosystems and service provisions of the Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT), particularly EIT-KIC Health and EIT-KIC Digital, or the interregional networks funded under the European Innovation Ecosystems (EIE) component of Pillar III.

In addition, applicants to the Health Cluster are encouraged to explore opportunities for complementary topics and activities in other Clusters or parts of the Horizon Europe programme that address thematically similar challenges and areas of intervention. This can be in the Clusters of Pillar II, in the European Research Infrastructures work programme part (Pillar I), or in the European Innovation Council work programme (Pillar III). More specifically, beneficiaries of Horizon Europe grants are invited to consider possible

[3] E.g., the EU4Health programme, the Digital Europe Programme, European Regional Development Fund (ERDF), including Interreg, European Social Fund (ESF+), Structural Reform Support Programme (SRSP), the Just Transition Fund (JTF), the European Maritime and Fisheries Fund (EMFF), the European Agricultural Fund for Rural Development (EAFRD), the European Defence Fund (EDF) or InvestEU.

[4] Synergies between Horizon Europe and ERDF (including Interreg): See draft Commission notice https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/synergies-guidance-out-2022-07-06_en

collaborations and cross-fertilisation between their project and other projects selected under the same or other relevant calls.

For topics in this Cluster, consortia could consider voluntarily contributing data, indicators, and knowledge to relevant Joint Research Centre (JRC) platforms. This would help capitalise on the knowledge developed in their projects and enhance their relevance to policymaking[5, 6, 7, 8, 9, 10].

In the context of the Health Cluster work programme part for 2026-2027, FAIR data are data which meet the principles of findability, accessibility, interoperability, and reusability. Data may include, amongst others, exploitation of information, digital research data generated in the action, data from European research infrastructures and programmes such as Copernicus, European Space Agency and the GEO initiative. For further details, see the FAIR principles website[11], the FAIR cookbook[12] and the guides for researchers on how to make your data FAIR[13].

Applicants to calls of the Health Cluster are encouraged to consider, where relevant, the services offered by current and future EU-funded European Research Infrastructures, including those prioritised by the European Strategy Forum on Research Infrastructures (ESFRI)[14], European Research Infrastructure Consortia (ERICs)[15] and the European Open Science Cloud[16]. Moreover, if projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, they must make use of European space technologies and services provided by Copernicus and/or Galileo/EGNOS (other data and services may additionally be used)[17].

In the context of the Health Cluster work programme part for 2026-2027, a clinical study covers clinical studies/trials/investigations/cohorts and is defined as any systematic

5 https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf
6 The European Cancer Information System (ECIS - https://ecis.jrc.ec.europa.eu) and the European Network of Cancer Registries (ENCR - https://www.encr.eu)
7 European Commission Initiatives on Breast and Colorectal Cancer: https://healthcare-quality.jrc.ec.europa.eu
8 European Cancer Inequalities Registry: https://cancer-inequalities.jrc.ec.europa.eu
9 European Platform on Rare Disease Registration (EU RD Platform - https://eu-rd-platform.jrc.ec.europa.eu/_en) - for rare cancers
10 Health Promotion and Disease Prevention Knowledge Gateway Horizon Europe: https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway_en
11 https://www.go-fair.org/fair-principles
12 https://faircookbook.elixir-europe.org/content/home.html
13 https://www.openaire.eu/how-to-make-your-data-fair
14 https://ri-portfolio.esfri.eu
15 https://www.eric-forum.eu/the-eric-landscape
16 https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/our-digital-future/open-science/european-open-science-cloud-eosc_en
17 European space technology based earth observation, positioning, navigation and timing services provided by: Copernicus, the European Union's Earth observation programme https://www.copernicus.eu/en/copernicus-services; Galileo, the European Global Satellite Navigation System (GNSS) https://www.gsc-europa.eu/galileo/services/galileo-initial-services; and the European Geostationary Navigation Overlay Service (EGNOS) https://www.euspa.europa.eu/eu-space-programme/egnos

prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

Please note that the European Union (EU) pharmaceutical legislation known as the Clinical Trials Regulation No 536/2014[18] entered into application on 31 January 2022, repealing the Clinical Trials Directive (EC) No. 2001/20/EC and national implementing legislation in the EU Member States, which regulated clinical trials in the EU until the Regulation's entry into application. As a result, from 31 January 2023, all initial clinical trial applications in the European Union (EU) must be submitted via the Clinical Trials Information System (CTIS)[19]. CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data.

The Horizon Europe strategic plan (2025-2027) sets out three Key Strategic Orientations (KSOs) for the last three years of the EU's framework programme for Research and Innovation, namely: KSO 1: "The Green Transition," aiming to support Europe in becoming the world's first climate-neutral continent by 2050, tackling biodiversity loss and pollution; KSO 2: "The Digital Transition," focusing on reinforcing Europe's competitiveness and strategic autonomy through research in core digital technologies; and KSO 3: "A More Resilient, Competitive, Inclusive, and Democratic Europe," aiming to bolster Europe's social rights and democratic values, ensuring they are globally promoted. This includes research in civil security, health and wellbeing, a fair economic model, and democratic participation.

The Health Cluster will support these KSOs by enhancing the understanding of climate change impacts on health, developing tools to protect against global health challenges, and reducing the sector's carbon footprint. It will promote technological and digital advancements to improve healthcare systems, focusing on disease prevention, personalised treatment, and equitable access to health services. Additionally, it will foster inclusive and resilient healthcare systems capable of responding to cross-border health threats and demographic changes, leveraging digital technologies such as AI to accelerate health research and improve health outcomes.

More specifically, the Health Cluster will support the KSOs by contributing to the six expected impacts set out for the Health Cluster in the strategic plan 2025-2027, which translate into the following six destinations of the Health Cluster work programme part for 2026-2027:

[18] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536
[19] https://euclinicaltrials.eu

Destination "Staying healthy in a rapidly changing society": The expected impact is that people of all ages in the EU stay healthy, resilient, and independent even as society changes fast. This will arise from healthier lifestyles and behaviour, healthier diets, healthier environments, improved evidence-informed health policies, and more effective solutions for health and wellbeing promotion, disease prevention and monitoring, and rehabilitation.

Destination "Living and working in a health-promoting environment": The expected impact is that people's living and working environments are health-promoting and sustainable thanks to a better understanding of the environmental, occupational, social, sex and gender-related, and economic determinants of health.

Destination "Tackling diseases and reducing disease burden": The expected impact is that healthcare providers improve their ability to tackle and manage diseases (infectious diseases, including poverty-related and neglected diseases, non-communicable and rare diseases) thereby reducing the disease burden on patients and enabling healthcare systems to perform more effectively. It can be achieved through better understanding, prevention, diagnostics, treatment, management, and cure of diseases and their co- and multi-morbidities, more effective and innovative health technologies and medical countermeasures, better ability and preparedness to manage pandemic and/or epidemic outbreaks, and improved patient safety.

Destination "Ensuring equal access to innovative, sustainable, and high-quality healthcare": The expected impact is that healthcare systems provide equal access to innovative, sustainable and high-quality healthcare thanks to the development and uptake of safe, cost-effective and people-centred solutions. This is to be accompanied by management models focusing on population health, health systems resilience, and health equity and patient safety, and also improved evidence-informed health policies.

Destination "Developing and using new tools, technologies and digital solutions for a healthy society": The expected impact is that health technologies, data, new tools, and digital solutions are applied effectively thanks to their inclusive, ethically sound, secure and sustainable delivery, integration and deployment in health policies and in health and care systems.

Destination "Maintaining an innovative, sustainable, and competitive EU health industry": The expected impact is that the EU health industry is innovative, sustainable, and globally competitive thanks to improved uptake of breakthrough technologies and innovations (including social innovations) that make the EU with its Member States and Associated Countries more resilient and less reliant on imports of critical health technologies.

Calls

Call - Cluster 1 - Health (Single stage - 2026)

HORIZON-HLTH-2026-01

Overview of this call[20]

Proposals are invited against the following Destinations and topic(s):

Topics	Type of Action	Budgets (EUR million) 2026	Expected EU contribution per project (EUR million)[21]	Indicative number of projects expected to be funded
Opening: 10 Feb 2026 Deadline(s): 16 Apr 2026				
Destination - Staying healthy in a rapidly changing society				
HORIZON-HLTH-2026-01-STAYHLTH-02: Behavioural interventions as primary prevention for NCDs among young people	RIA	21.00	9.00 to 10.00	2
Destination - Living and working in a health-promoting environment				
HORIZON-HLTH-2026-01-ENVHLTH-01: Towards a better understanding and anticipation of the impacts of climate change on health	RIA	55.00	7.00 to 8.00	7
HORIZON-HLTH-2026-01-ENVHLTH-04: Towards climate resilient, prepared and carbon neutral populations and healthcare systems	RIA	50.00	7.00 to 8.00	7

[20] 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 2026 and 2027

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

HORIZON-HLTH-2026-01-ENVHLTH-05: Support for a multilateral initiative on climate change and health research	CSA	3.00	Around 3.00	1
Destination - Tackling diseases and reducing disease burden				
HORIZON-HLTH-2026-01-DISEASE-02: Innovative interventions to prevent the harmful effects of using digital technologies on the mental health of children and young adults	RIA	50.00	Around 8.00	7
HORIZON-HLTH-2026-01-DISEASE-03: Advancing research on the prevention, diagnosis, and management of post-infection long-term conditions	RIA	40.00	6.00 to 8.00	5
HORIZON-HLTH-2026-01-DISEASE-04: Development of novel vaccines for pathogens with epidemic potential	RIA	50.00	Around 10.00	5
HORIZON-HLTH-2026-01-DISEASE-06: Development of monoclonal antibodies to prevent and treat infections from Flaviviridae	RIA	50.00	Around 10.00	5
HORIZON-HLTH-2026-01-DISEASE-09: Multisectoral approach to tackle chronic non-communicable diseases: implementation research maximising collaboration and coordination with sectors and in settings beyond the healthcare system (GACD)	RIA	12.00	3.00 to 4.00	3
HORIZON-HLTH-2026-01-DISEASE-11: Gender/sex differences in CVD	RIA	45.00	5.00 to 7.00	7
Destination - Ensuring equal access to innovative, sustainable, and high-quality healthcare				
HORIZON-HLTH-2026-01-CARE-01: Public procurement of innovative solutions (PPI) for improving citizen's access to healthcare through integrated care	PPI	25.00	3.00 to 5.00	5
HORIZON-HLTH-2026-01-CARE-03: Identifying and Addressing Low-Value Care in Health and Care Systems	RIA	50.00	Around 10.00	5
Destination - Developing and using new tools, technologies and digital solutions for a healthy society				

HORIZON-HLTH-2026-01-TOOL-03: Integrating New Approach Methodologies (NAMs) to advance biomedical research and regulatory testing	RIA	50.00	5.00 to 8.00	7
HORIZON-HLTH-2026-01-TOOL-06: Support to European Research Area (ERA) action on accelerating New Approach Methodologies (NAMs) to advance biomedical research and testing of medicinal products and medical devices	CSA	3.00	Around 3.00	1
Destination - Maintaining an innovative, sustainable, and competitive EU health industry				
HORIZON-HLTH-2026-01-IND-03: Regulatory science to support translational development of patient-centred health technologies	RIA	20.00	4.00 to 6.00	4
Overall indicative budget		524.00		

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.

Call - Partnerships in Health (2026/1)

HORIZON-HLTH-2026-02

Overview of this call[22]

Proposals are invited against the following Destinations and topic(s):

Topics	Type of Action	Budgets (EUR million)		Expected EU contribution per project (EUR million)[23]	Indicative number of projects expected to be funded
		2026	2027		
Opening: 10 Feb 2026 Deadline(s): 15 Sep 2026					
Destination - Tackling diseases and reducing disease burden					
HORIZON-HLTH-2026-02-DISEASE-12: European Partnership on Rare Diseases (ERDERA) (Phase 2)	COFUND	30.00	63.00	Around 93.00	1
Overall indicative budget		30.00	63.00		

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.

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

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

Call - Partnerships in Health (2026/2)

HORIZON-HLTH-2026-03

Overview of this call[24]

Proposals are invited against the following Destinations and topic(s):

Topics	Type of Action	Budgets (EUR million)		Expected EU contribution per project (EUR million)[25]	Indicative number of projects expected to be funded
		2026	2027		
Opening: 10 Feb 2027 Deadline(s): 13 Apr 2027					
Destination - Tackling diseases and reducing disease burden					
HORIZON-HLTH-2026-03-DISEASE-13: European partnership for pandemic preparedness (Phase 2)	COFUND	40.00	33.00	Around 73.00	1
Overall indicative budget		40.00	33.00		

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

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

	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.

Call - Partnerships in Health (2026/3)

HORIZON-HLTH-2026-04

Overview of this call[26]

Proposals are invited against the following Destinations and topic(s):

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[27]	Indicative number of projects expected to be funded
		2026		
Opening: 10 Feb 2026 Deadline(s): 15 Sep 2026				
Destination - Ensuring equal access to innovative, sustainable, and high-quality healthcare				
HORIZON-HLTH-2026-04-CARE-04: Enhancing and enlarging the European Partnership on Personalised Medicine (EP PerMEd) (Top-up)	COFUND	15.00	Around 15.00	1
Overall indicative budget		15.00		

[26] 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 2026 and 2027

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

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.

Call - Cluster 1 - Health (Single stage - 2027/1)

HORIZON-HLTH-2027-01

Overview of this call[28]

Proposals are invited against the following Destinations and topic(s):

Topics	Type of Action	Budgets (EUR million) 2027	Expected EU contribution per project (EUR million)[29]	Indicative number of projects expected to be funded

[28] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for 2026 and 2027

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

Opening: 10 Feb 2027 Deadline(s): 13 Apr 2027				
Destination - Staying healthy in a rapidly changing society				
HORIZON-HLTH-2027-01-STAYHLTH-01: Addressing disabilities through the life course to support independent living and inclusion	RIA	50.00	6.00 to 8.00	7
Destination - Living and working in a health-promoting environment				
HORIZON-HLTH-2027-01-ENVHLTH-02: Integrating climate-related exposures into the human exposome and characterising its changes in response to climate change	RIA	45.00	10.00 to 11.00	4
HORIZON-HLTH-2027-01-ENVHLTH-MISSCLIMA-03: Tools and technologies to support health adaptation to climate change	PCP	20.00 [30]	4.00 to 5.00	4
Destination - Tackling diseases and reducing disease burden				
HORIZON-HLTH-2027-01-DISEASE-05: Development of novel broad spectrum small molecule antiviral therapeutics for pathogens with epidemic potential	RIA	50.00	Around 10.00	5
HORIZON-HLTH-2027-01-DISEASE-07: Development of monoclonal antibodies to prevent and treat infections from Filo- Phenui-, Picorna- and Toga Viridae	RIA	50.00	Around 10.00	5
HORIZON-HLTH-2027-01-DISEASE-08: Development of innovative antimicrobials or antibody-based therapies against critical pathogens resistant to antimicrobials (AMR)	RIA	50.00	8.00 to 10.00	5
HORIZON-HLTH-2027-01-DISEASE-10: Prevention and management of chronic non-communicable diseases in children and young people (GACD)	RIA	12.00	3.00 to 4.00	3
Destination - Ensuring equal access to innovative, sustainable, and high-quality healthcare				
HORIZON-HLTH-2027-01-CARE-02:	RIA	50.00	8.00 to	5

[30] Of which EUR 10.00 million from the 'Climate, Energy and Mobility' budget.

Personalised approaches to reduce risks from Adverse Drug Reactions due to administration of multiple medications			10.00	
Destination - Developing and using new tools, technologies and digital solutions for a healthy society				
HORIZON-HLTH-2027-01-TOOL-01: Development of predictive biomarkers of disease progression and treatment response by using AI methodologies for chronic communicable diseases	RIA	50.00	6.00 to 8.00	7
HORIZON-HLTH-2027-01-TOOL-04: Virtual Human Twins (VHTs) for integrated clinical decision support in prevention and diagnosis	RIA	50.00	10.00 to 12.00	4
HORIZON-HLTH-2027-01-TOOL-05: FP10 pilot on "follow-on funding"	RIA	45.00	4.00 to 6.00	8
Destination - Maintaining an innovative, sustainable, and competitive EU health industry				
HORIZON-HLTH-2027-01-IND-01: Cell-free protein synthesis platforms for discovery and/or production of biologicals	RIA	40.00	6.00 to 8.00	5
Overall indicative budget		512.00		

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 *Award criteria*	The criteria are described in General Annex C. 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.

Call - Cluster 1 - Health (Two stage - 2027)

HORIZON-HLTH-2027-02

Overview of this call[31]

Proposals are invited against the following Destinations and topic(s):

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[32]	Indicative number of projects expected to be funded
		2027		
Opening: 10 Feb 2027 Deadline(s): 13 Apr 2027 (First Stage), 21 Sep 2027 (Second Stage)				
Destination - Tackling diseases and reducing disease burden				
HORIZON-HLTH-2027-02-DISEASE-01-two-stage: Innovative healthcare interventions for non-communicable diseases	RIA	80.00	7.00 to 8.00	10
Destination - Maintaining an innovative, sustainable, and competitive EU health industry				
HORIZON-HLTH-2027-02-IND-02-two-stage: Portable and versatile Point-of-care diagnostics	IA	50.00	5.00 to 7.00	7
Overall indicative budget		130.00		

General conditions relating to this call

[31] 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 2026 and 2027

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

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.

Call - Cluster 1 - Health (Single stage - 2027/2)

HORIZON-HLTH-2027-03

Overview of this call[33]

Proposals are invited against the following Destinations and topic(s):

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[34]	Indicative number of projects expected to be funded
		2027		
Opening: 03 Jun 2027				

[33] 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 2026 and 2027

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

Deadline(s): 21 Sep 2027				
Destination - Developing and using new tools, technologies and digital solutions for a healthy society				
HORIZON-HLTH-2027-03-TOOL-02: Advancing bio-printing of living cells for regenerative medicine	RIA	50.00	7.00 to 10.00	5
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.
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.

Destinations

Destination - Staying healthy in a rapidly changing society

Topics under this destination are directed towards the Key Strategic Orientations "A *more resilient, competitive, inclusive, and democratic Europe*" and "*The Digital* transition" of Horizon Europe's strategic plan 2025-2027.

Research and Innovation supported under this destination should contribute to the following expected impact, set out in the strategic plan impact summary for the Health Cluster: *"people of all ages in the EU stay healthy, resilient, and independent even as society changes fast. This will arise from healthier lifestyles and behaviour, healthier diets, healthier environments, improved evidence-informed health policies, and more effective solutions for health and well-being promotion, disease prevention and monitoring, and rehabilitation".*

People´s healthcare needs are different, depending on their age, gender, stage of life, health status and socioeconomic background. In 2019, nearly 650,000 premature deaths across the EU[35] could have been prevented with effective primary prevention and other public health measures. In addition, an estimated 135 million people in Europe live with a disability[36], highlighting the critical need for healthcare systems that are both accessible and adaptable. This number is expected to rise due to population ageing and the increasing prevalence of chronic conditions resulting from noncommunicable diseases and injuries. It is also important to consider disabilities arising from other causes, such as war-related injuries and post-traumatic stress disorder (PTSD), which add to the complexity and diversity of healthcare needs

Aligning with the Political Guidelines for the European Commission 2024-2029, which calls for stepping up work on preventive health, this destination aims to strengthen disease prevention and early detection, placing support and empowerment of citizens regarding their own health, well-being and living and working conditions at the core of future public health programmes.

Research and Innovation under this destination should help enhance the dialogue and coordination among stakeholders and policymakers, ensuring integration across different care settings for holistic health promotion and disease prevention. Funded activities should seek to leverage the wealth of data sources, including real-world health data and establish a European interconnected health data ecosystem to develop integrated and personalised health promotion and disease prevention strategies. These activities will benefit from and actively support and enrich emerging data resources such as the European Health Data Space (EHDS)[37] and

35 https://health.ec.europa.eu/document/download/3f9d55be-9e36-43d9-99ad-b96ac63a5b9b_en?filename=2022_healthatglance_rep_en_0.pdf

36 https://www.who.int/europe/news-room/fact-sheets/item/disability The WHO European Region comprises 53 countries, covering a vast geographical region from the Atlantic to the Pacific oceans.

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

European Open Science Cloud (EOSC)[38], and contribute to the European care strategy[39] and the digital transformation of health and care in the EU[40]. Since Horizon Europe's launch in 2021, this destination has addressed important issues such as obesity prevention, understanding health-to-disease transitions, life course approaches to physical and mental health, healthy ageing, digital health literacy, and Artificial Intelligence (AI) for chronic disease risk prediction.

In this work programme, destination "Staying healthy in a rapidly changing society" will focus on: i) addressing disabilities through the life course to support independent living and inclusion, with an emphasis on empowering persons with disabilities and their families. This priority aligns with the EU Strategy for the Rights of Persons with Disabilities 2021-2030; ii) developing behavioural interventions as primary prevention for non-communicable diseases (NCDs), with an emphasis on promoting healthy habits and sustained behavioural change among youth. This priority aligns with the Healthier together' EU non-communicable diseases initiative.

To increase the impact of EU investments under Horizon Europe, the European Commission encourages collaboration between EU-funded projects to foster synergies through networking, joint workshops, knowledge exchange, best practices, and joint communication activities. Synergies can be explored between projects funded under the same or different topics, Clusters or pillars of Horizon Europe. This includes collaborations between projects funded under Cluster 1 and Cluster 2 for complementary actions, such as promoting social inclusion, health equity (including gender equality and support for marginalised groups), and mental health initiatives in education, work, and daily life (including through culture, the arts and sports).

Expected impacts:

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

- Citizens, including persons with disabilities and other vulnerable groups, adopt and maintain healthier lifestyles and behaviours, make healthier choices, and achieve, where applicable, longer healthy, independent, and active lives with a reduced burden of preventable disease throughout the life course

- Citizens are empowered to effectively manage their physical and mental health and well-being, monitor their health status, and interact with healthcare providers to optimise their

[38] https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/our-digital-future/open-science/european-open-science-cloud-eosc_en

[39] Communication from the European Commission on the European care strategy, COM(2022) 440, 7.9.2022

[40] Communication from the European Commission on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, COM(2018) 233, 25.4.2018

well-being throughout life through improved health literacy, increased engagement in and adherence to health promotion strategies.

- Children and young people are aware and empowered to better monitor and manage their physical, social and mental health with a view to lifelong healthy lifestyles.
- Society benefits from reduced economic and health burdens due to preventable illness and premature mortality, with efficiency increased by targeting scarce resources in appropriate, cost-effective ways to areas of high social return, thereby driving improvements in health and well-being for all citizens, and specifically reducing health inequalities

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

Proposals are invited against the following topic(s):

HORIZON-HLTH-2027-01-STAYHLTH-01: Addressing disabilities through the life course to support independent living and inclusion

Call: Cluster 1 - Health (Single stage - 2027/1)	
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 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. 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

	4 (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: 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) [41].

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

- Persons with disabilities are empowered and can enjoy their rights to live independently and be included in the community on equal basis with others.
- The scientific community develops innovative solutions with a focus on removing barriers faced by persons with disabilities to live independently and they are provided with community support services where they live in the community, including personal assistance and disability inclusive and accessible community-based services - medical, technological, digital or others -, ensuring prevention of isolation or segregation and supporting deinstitutionalisation. Special attention is to be paid to children and young people transitioning to adulthood and older persons to facilitate they remain living at their homes.
- Policymakers, health and care services, patient organisations, funders, the scientific community, and other relevant bodies are informed of the research advances and best practices addressing the health and needs of persons with disabilities to support them living independently and being included in society.

Scope: The focus of this topic is human-centred on persons with long-term disabilities[42] - physical, mental, intellectual or sensory - aiming at supporting independent living across the life-course from a health perspective. Persons with disabilities have an equal right to live independently and be included in the community. Independent living requires a differentiated

[41] 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

[42] Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others (Art. 1 of the Convention on the Rights of Persons with Disabilities - https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-persons-disabilities).

landscape of quality, accessible, person-centred and affordable, community- and family-based services comprising personal assistance, medical and social care and interventions by social workers, thereby facilitating everyday activities and providing choice to persons with disabilities and their families.[43]

The objective of this topic is to explore new ways to promote independent living and inclusion in society of persons with disabilities, reducing the impact of barriers faced in their daily lives, and supporting the transition from institutions to living in the community while addressing all-encompassing aspects of personal support, such as community transformation, service provision, assistive and accessible technologies and environments.

Research actions under this topic should address several of the following areas:

- Prevention of barriers faced by persons with disabilities, detection of risks factors leading to a loss of autonomy, and supporting active participation in society and healthy lives on equal basis with others.

- Health related research addressing disabilities looking into finding the causes of the disease(s) leading to the disability and/or disease treatment with a purpose of supporting independent living. Innovative solutions to be developed can include among others diagnoses, medicines, treatments, protocols, technologies or digital solutions (technologies and digital solutions must adhere to the relevant standards and be grounded in scientific evidence), as well as non-obtrusive low-tech high impact solutions, that can help to reduce the impact of the disability, to increase self-management and to improve the autonomy of persons with disabilities.

- Applicants may choose to have a special focus on children with disabilities from the perinatal period, and/or young people with disabilities transitioning to adulthood, and/or older persons. The proposal should foster ways to improve autonomy and quality of life by enhancing cognitive, psychosocial and motor abilities among others.

- Access to habilitation and rehabilitation services, including psychological rehabilitation and innovative rehabilitation with assistive technologies when appropriate, to increase, maintain, substitute or improve functional capabilities of persons with disabilities or for, alleviation and compensation of impairments, activity limitations or participation restrictions contributing to increasing independence.

- In the area of prevention, address different aspects that could have an impact on persons with disabilities, such as gender, socio-economic background, ethnicity, the risk of overweight/obesity and related co-morbidities (e.g. diabetes, cardiovascular diseases), hospitalisation, nutrition (e.g. mother and child nutrition from pregnancy), high level of inactivity/sedentary lifestyle and related co-morbidities (e.g. frailty), physical

[43] https://op.europa.eu/en/publication-detail/-/publication/3e1e2228-7c97-11eb-9ac9-01aa75ed71a1/language-en

activity/sports, screen-time dependency, smoking, drug use, alcohol abuse, stress, loneliness and/or isolation.

- Addressing the conditions for successful transition from institutions to living in the community and research for the removal of barriers faced for participation in the community on equal basis with others as well as tools, methods and instruments to achieve it, such as needs assessments, service provision, budget and resources, management plans, governance, monitoring, quality control, etc.

- Propose innovative solutions, care models and strategies for high quality person-centred, accessible and targeted social and health care services to support independent living, including self-care to empower persons with disabilities, as well as different choices of care across the life-course. For many persons with disabilities, the lack of support and care services and insufficient support for families and unavailability of personal assistance undermines their independence and inclusion in the community

Data collection is essential to understand the living situation of persons with disabilities and remains a challenge to collect data disaggregated per type of disability, sex, and age. In addition, data collected often lacks comparability as it follows different definitions in each Member State and Associated Countries. Thus, applicants are encouraged to try to harmonize data collection using Eurostat variables and existing international sets of questions in their areas of research.

Persons with disabilities should be involved in the research through their representative organisations as actors in the research process. Research can also address and involve their families, friends, colleagues, supporters and carers and other service providers, as needed for the subject matter of the work, Policymakers and public authorities, social services, and civil society organisations, could also be considered.

This topic requires the effective contribution of social sciences and humanities (SSH) disciplines and the involvement of SSH experts, organisations 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.

Projects are also encouraged to explore potential complementarities with projects funded under the Cluster 2 topic HORIZON-CL2-2025-01-TRANSFO-10: “Good practices for increased autonomy of persons with disabilities, including physical, mental, intellectual and sensory disabilities” and Cluster 1 topic HORIZON-HLTH-2025-03-STAYHLTH-01-two-stage: “Improving the quality of life of persons with intellectual disabilities and their families”.

Applicants envisaging to include clinical studies[44] should provide details of their clinical studies in the dedicated annex using the template provided in the submission system.

HORIZON-HLTH-2026-01-STAYHLTH-02: Behavioural interventions as primary prevention for NCDs among young people

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 9.00 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 21.00 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 4 (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 "Staying healthy in a rapidly changing society". To that end, proposals under this topic should aim at delivering results towards the achievement of most of the following expected outcomes:

- Healthcare professionals have access to behavioural interventions that can be used to establish and reinforce healthy habits and sustain behavioural changes.

[44] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

- Health professionals and educators have access to strategies to mitigate NCD risks for youth, with clear metrics that can be used to assess health outcomes.

- Youth have increased individual responsibility through targeted education, digital services, including easily accessible tools for self-monitoring, and community-based support, stemming from increased collaboration between healthcare professionals, educators and families.

- Researchers have access to real-world data, existing health data infrastructure and digital tools, including AI, which can contribute to the sustained success of behavioural health interventions.

- Policy makers at local, regional, and EU levels have new knowledge on behavioural interventions on NCDs among youth, which they can use to improve interventions in diverse European contexts.

Scope: The topic is focused on **behavioural interventions** for **youth**, defined as 12 to 25 years old, for the **primary prevention** of the top **Non-Communicable Diseases (NCD)** later in life, where "top NCD's" refers to the most prevalent NCD's. For the purpose of this call, NCDs explicitly exclude cancer, addiction/substance abuse, as they are covered by other topics.

Existing behavioural interventions should be implemented and should have an emphasis on empowerment and self-management (e.g., health literacy, health education, health promotion). As self-monitoring is an essential element of self-management, proposals should include user-friendly hard- and software for efficient self-monitoring (i.e., wearables and point-of-care devices for measuring various physiological parameters and other biomarkers and the corresponding apps for easy readout and tracking, possibly also including gamification elements). Proposals should ensure that gender-sensitive approaches are integrated, addressing potential gender-specific barriers, as well as cultural and socioeconomic backgrounds, and should also outline how digital tools, including artificial intelligence (AI) and real-world data and biomarkers (e.g. genomic data, wearables…) or existing relevant administrative dataset, will be integrated to enhance the scalability, personalisation, and effectiveness of interventions in the long-term. **Applicants should present a clear, evidence-based strategy** showing how the interventions will be tailored, deployed, and assessed at individual, family, community, and societal levels, while considering social inequalities and lifestyle factors (i.e. nutrition, sleep rhythm) and ensuring a robust methodological framework for evaluating the effectiveness of interventions (e.g. randomized controlled trails, quasi-experimental designs…), with clearly defined indicators of success of the intervention (e.g. biometric markers, psychosocial wellbeing metrics, physical activity change…). Applicants should also include formats that will increase collaboration between healthcare professionals, educators, families, and policymakers in promoting preventive health and should include plans for longer-term follow-up to estimate health impact and cost savings over time. Related to this, applicants should outline how policy changes related to the intervention (e.g. school meal programmes, safe urban infrastructure for exercise, digital literacy campaigns, circadian

alignment, stress reduction strategies) can reinforce and scale up successful behavioural interventions, whilst taking into account how they can be replicated or adapted to different cultural, geographic and socio-economic contexts.

This topic requires the effective contribution of social sciences and humanities (SSH) disciplines and the involvement of SSH experts, organisations 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.

Evaluations of unintended consequences are mandatory for all interventions.

Applicants should provide details of their clinical studies[45] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

[45] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

Destination - Living and working in a health-promoting environment

Topics under this destination are directed towards the Key Strategic Orientation 1 "*The Green transition*" and Key Strategic Orientation 3 "*A more resilient, competitive, inclusive, and democratic Europe*" of Horizon Europe's strategic plan 2025-2027.

Research and innovation supported under this destination should contribute to the following expected impact, set out in the strategic plan impact summary for the Health Cluster: "*people's living and working environments are health-promoting and sustainable thanks to a better understanding of the environmental, occupational, social, sex and gender-related, and economic determinants of health*".

The environment we live and work in is a major determinant of our health and wellbeing and climate change acts as a risk multiplier, exacerbating the health effects of environmental stressors, increasing the incidence of non-communicable diseases, mental health conditions, and infectious diseases, particularly for vulnerable populations. The climatic crisis is a health crisis with impacts at the global level. Across Europe, the fastest-warming continent, heat and floods have caused devastating human and economic impact in recent years. In 2025, the European Commission published a Strategic Research and Innovation Agenda on Health and Climate Change[46], providing a forward-looking overview of the current and emerging research needs and gaps in the field. This agenda informs the focus and objectives of this destination, aligning with the Commission's Political Guidelines 2024-2029, which emphasise the need to step up work on preventive health, climate resilience, adaptation, preparedness, and the green transition, while promoting circularity.

In this work programme part, Destination "*Living and working in a health-promoting environment*" focuses on understanding and addressing the impacts of climate change on human health, increasing climate adaptation and resilience and reducing the health sector's contribution to climate change The results will support the EU Strategy on Adaptation to Climate change, the European Climate Adaptation Plan (thematic window on health) and the European Climate Risk Assessment by enhancing understanding of health risks and informing prevention, adaptation, and mitigation actions for populations and healthcare systems. Moreover, this destination aims to identify and amplify the co-benefits of climate action for health outcomes. This integrated approach recognizes that climate mitigation measures can simultaneously deliver significant health benefits, creating positive feedback loops between climate protection and public health. Strong collaborations across sectors and with other Horizon Europe Clusters dealing with issues such as agriculture, food, environment, climate, biodiversity, mobility, security, urban planning, social inclusion and gender will be needed to ensure that maximal societal benefits are reached. 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 create synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, development and adoption of best practices, or joint

[46] Reference to be provided once the strategy is published

communication activities. All topics are open to international collaboration to address global climate and health challenges.

Expected impacts:

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

- Policy-makers and regulators are aware and well informed about climatic, environmental, socio-economic and occupational risk factors as well as health-promoting factors across society;
- Climatic, environmental, occupational, social, economic, and health policies and practices at the EU, national and regional level are sustainable and based on solid scientific evidence.
- The upstream determinants of health are known, understood and reduced;
- The health threats and burden and patient safety burdens resulting from exposure to climate drivers are lessened, so that the related number of deaths and illnesses is substantially reduced;
- Living and working environments in European cities and regions are healthier, more inclusive, safer, resilient and sustainable;
- The healthcare sector reduces its environmental footprint and transitions towards carbon neutrality.
- The adaptive capacity and resilience of populations and health systems in the EU to climate and environmental change-related to mental and physical health risks are strengthened;
- Citizens' health and wellbeing are protected and promoted, and premature deaths, diseases and inequalities related to climate related risks are prevented;
- Citizens understand better complex climate, environment and health issues, and effective measures to address them and support related policies and regulations.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2026-01-ENVHLTH-01: Towards a better understanding and anticipation of the impacts of climate change on health

Call: Cluster 1 - Health (Single stage - 2026)
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 55.00 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 4 (Implementation). The cumulative threshold will be 12.
Procedure	The procedure is described in General Annex F. The following exceptions apply: In order to ensure a balanced project portfolio with regard to the broad focus area targeted[47], grants will be awarded (within available budget) to proposals not only in order of ranking but also in function of the highest ranked proposals in different broad focus areas, provided that the applications attain all thresholds available.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: In order to maximise synergies and increase the impact of the projects, all proposals selected for funding from this topic will form a cluster and be required to participate in common networking and joint activities (and in determining modalities for their implementation and the specific responsibilities of projects). These activities will be included in a dedicated work package, having sufficient budget allocated to it (around 2% of the total requested budget). Depending on the scope of proposals selected for funding, these activities may include:

[47] Broad focus area i to iii, as given in the scope of this topic.

	• Attendance of regular joint meetings (e.g., common kick-off meeting and annual meetings). • Periodic report of joint activities (delivered at each reporting period). • Common dissemination and communication activities (which may include, for example: a common dissemination and communication strategy, web portal and visual identity, brochure, newsletters). • Common Data Management Strategy and Common Policy Strategy (including joint policy briefs). • Thematic workshops/trainings on issues of common interest. • Working groups on topics of common interest (e.g. data management and exchange, communication and dissemination, science-policy link, scientific synergies). 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) [48].

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

- Citizens, patients, public authorities and policy makers have a better understanding of the climatic health risks and determinants of disease and are better equipped to address health outcomes through enhanced prevention, resilience, adaptation, and response, including better diagnosis and treatment.
- Governments, public health authorities, researchers and civil society organisations are supported to tackle societal challenges linked to the health impacts of climatic factors.
- Public authorities, organisations and the research community can rely on data collection and sharing according to FAIR principles and leveraging of data availability and quality.

[48] 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

- Policy makers and public authorities develop evidence-based climate change and health policies and interventions.

Scope: The climate crisis poses an existential challenge to planetary and human health with larger effects on vulnerable populations, groups and regions. Climate change increases the incidence of non-communicable diseases and the prevalence of mental health conditions and facilitates the emergence and spread of infectious diseases. Climate change can act as a risk multiplier, exacerbating the health effects of other environmental and socioeconomic stressors.

Proposals under this topic should focus on one of the following broad focus areas:

- Non communicable diseases (NCDs) and individual safety (e.g. injuries or fatalities), excluding mental health aspects: proposals should explore evidence on the complex interactions between climate change (e.g. changes in the frequency and intensity of extreme weather events) and NCDs and individual safety, which often involve multiple climate exposure pathways and compound and cascading climatic events;

- Mental health, considering interactions with brain health if relevant: in the broad focus area of mental health and psychosocial well-being, proposals should increase the evidence on the acute and long-term impacts of climate change and the understanding of new syndromes related to climate stress;

- Infectious diseases, including vector-borne and non-vector-borne: proposals should increase the understanding of the factors driving climate-related burden from infectious diseases.

In general proposals should develop approaches to prevent and reduce the impacts of climate factors in the studied health outcomes and increase population and workforce resilience. Applicants should explicitly state in their proposal which of the three abovementioned broad focus areas they target. The proposed work should address only said specific area (with possible exceptions if the reasoning is clearly explained). A One Health approach should also be applied where relevant.

More specifically, research actions under this topic should include several of the following activities, depending on the relevance of each group of activities to the broad focus area targeted in the proposal:

- Increase the understanding of correlations, causal pathways and mechanistic effects between climate change and disease, developing unified and standard methodologies and metrics to assess short- and long-term positive and negative impacts of climate change with an adequate level of granularity. Consider individual and/or cascading climatic events and exposure patterns, and risks and drivers of vulnerability and inequality.

- Develop longitudinal studies to better ascertain differential effects of climatic stressors on health including multiple scales of impacts, ranging from the molecular level to population health outcomes. Consider variability across populations and life phases,

regions and occupations, and collect real-world exposure and health data in living and occupational settings, considering the use of emerging ecosystems such as the European Health Data Space (EHDS)1.

- Study differential acute and long-term health impacts of climate (including a wide range of factors and cumulative effects) on vulnerable, sensitive or exposed population groups. Consider also differences in geographical vulnerabilities including geographical settings outside of urban areas and in low- and middle-income countries (LMICs). Understand the role of inequalities and societal vulnerability in determining climate-related health impacts and adaptive capacity.

- Advance the knowledge on the climate and environmental drivers of pathogen abundance, including mechanisms and determinants of distribution, life-cycle patterns, transmission, virulence and survival. Consider climate change drivers of disease severity. Study host/pathogen and vector/host interactions clarifying the role of secondary reservoir/sylvatic/wildlife hosts in the maintenance of pathogen life cycle. Assess the efficacy, cost-effectiveness and impact of control measures.

- Explore the role of climate-driven human and wildlife mobility (e.g. bird migration patterns, human migration) in enhancing the global spread of pathogens and creating opportunities for their local establishment. Collect better field data and develop tools for disease modelling, risk and scenario projections that encourage interoperable data systems and cross border collaboration.

- Increase the availability, accessibility, quality and standardisation of diagnostic testing for early diagnosis of infections and determining immune responses and vaccine efficacy. Increase the capacity for pathogen subtyping, and genomic surveillance for early warning and investigations of climate-related outbreaks. Develop rapid, portable, and affordable standardised diagnostic tools that can withstand climate extremes.

- Increase the understanding of the factors that strengthen health resilience to climate change at the individual, local and societal levels. Investigate the role of individual mechanisms, community resilience and local solutions in mitigating the health impacts of climate change and related environmental degradation.

In order to maximise synergies and increase the impact of the projects, all proposals selected for funding from this topic will form a cluster and be required to participate in common networking and joint activities. Without the prerequisite to detail concrete joint activities, proposals should allocate a sufficient budget for the attendance of regular joint meetings and to cover the costs of any other potential common networking and joint activities. Guidance on the potential activities to be developed can be obtained by consulting the clusters of projects ongoing under the Environment, Climate and Health research portfolio[2].

Applicants should provide details of their clinical studies[49] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2027-01-ENVHLTH-02: Integrating climate-related exposures into the human exposome and characterising its changes in response to climate change

Call: Cluster 1 - Health (Single stage - 2027/1)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 10.00 and 11.00 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
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 4 (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: In order to maximise synergies and increase the impact of the projects, all proposals selected for funding from this topic will form a cluster and be required to participate in common networking and joint activities (and in determining modalities for their implementation and the specific responsibilities of projects). These activities will be included in a

[49] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	dedicated work package, having sufficient budget allocated to it (around 2% of the total requested budget). Depending on the scope of proposals selected for funding, these activities may include: • Attendance of regular joint meetings (e.g., common kick-off meeting and annual meetings). • Periodic report of joint activities (delivered at each reporting period). • Common dissemination and communication activities (which may include, for example: a common dissemination and communication strategy, web portal and visual identity, brochure, newsletters). • Common Data Management Strategy and Common Policy Strategy (including joint policy briefs). • Thematic workshops/trainings on issues of common interest. • Working groups on topics of common interest (e.g. data management and exchange, communication and dissemination, science-policy link, scientific synergies).

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

- Researchers, policy makers, healthcare practitioners and the public have a more comprehensive understanding of the human exposome and the interactions between climatic, environmental and socio-behavioural factors, supported by FAIR[1] data linking these exposures to health outcomes.
- Researchers, governments, policy makers and healthcare practitioners have improved knowledge on the links between the climatic, social, lifestyle and environmental factors of the exposome and global health burden, supporting their efforts to adopt the exposome approach to identify and address relevant health impacts.
- The public has access to the latest information on the influence of global environmental exposures on health, enabling the adoption of health-promoting, climate-resilient and environmentally friendly behaviours.

Scope: The exposome is the totality of exposures (and their interactions) experienced by an individual throughout their lifetime, including chemical, physical, biological and psychosocial factors, from conception onwards. Many of these factors originate in the environment, including climate-related exposures such as extreme heat, heightened air pollution or drought. Climate change may amplify or interact synergistically with other better-established

exposures, dynamically altering the human exposome and its health implications. Despite this, climate factors remain underrepresented in large-scale human exposome studies.

Research activities under this topic should strengthen the use of the exposome approach to study global exposures and generate evidence on their health implications. Proposals must focus on integrating climate-related factors into exposome research and understanding how the exposome changes in response to climate change. Moreover, research activities should be multiscale and multidisciplinary and account for the complexity and multifactorial nature of health determinants and the most pressing unmet medical needs in relation to environmental degradation. Proposals must include climate-relevant social determinants of health as part of their proposed activities.

More specifically, research actions under this topic should include all of the following activities:

- Incorporate multiple climate exposures into exposomics studies and provide insights on their influence on disease burden, through interactions with other exposome factors.
- Predict, identify and monitor changes in the exposome (including environmental and social exposures) due to climate-related pressures and study the health implications of said changes to identify emerging health risks and potential benefits of climate change.
- Advance data generation, analysis, integration and interpretation in human exposomics, developing methodologies and integrating novel approaches (e.g., AI technologies and machine learning) for advanced data analytics, including for real-world data.

In addition, research actions should include several of the following targeted activities:

- Establish and investigate the biological pathways and mechanisms by which the exposome drives health impacts, jointly considering climate-related and other exposures. Build upon and study longitudinal cohorts that combine individual exposome data with the corresponding medical, omics and biological data.
- Identify exposome-relevant indicators and biomarkers and derive early-warning indicators of exposome-related health risks and potential benefits using comprehensive exposome studies that combine climate, environmental, behavioural and social exposures. Account for disparities in individual trajectories and exposure patterns where relevant.
- Report on health-relevant exposome findings using, where possible, standardised metrics to ensure harmonised reporting of exposome-driven disease burden across regions and sectors. Build on existing exposome toolboxes and increase their robustness and coverage by integrating climate related exposures.
- Study the role of socioeconomic (e.g., income, energy poverty, occupation), demographic (e.g., gender, racial origin[2], age) and behavioural (e.g., public trust, risk perception) factors in determining patterns of exposure, using the exposome approach to

generate knowledge on intersectional vulnerability and resilience to exposome-driven (including climate-driven) health impacts. Identify disproportionately affected populations and develop interventions to reduce disparities.

Projects must also leverage the knowledge, data and tools already generated under past initiatives such as EHEN[1] and ongoing initiatives such as IHEN[2], ICOS ERIC[5], and EIRENE RI[3]. In order to maximise synergies and increase the impact of the projects, all proposals selected for funding from this topic will form a cluster and be required to participate in common networking and joint activities. Without the prerequisite to detail concrete joint activities, proposals should allocate a sufficient budget to cover the costs of any potential common networking and joint activities. Guidance on the potential activities to be developed can be obtained by consulting the ongoing clusters of projects under the Environment, Climate and Health research portfolio[4].

Applicants should provide details of their clinical studies[50] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2027-01-ENVHLTH-MISSCLIMA-03: Tools and technologies to support health adaptation to climate change

Call: Cluster 1 - Health (Single stage - 2027/1)	
Specific conditions	
Expected EU contribution per project *Indicative budget*	The Commission estimates that an EU contribution of between EUR 4.00 and 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts. The total indicative budget for the topic is EUR 20.00 million.
Type of Action	Pre-commercial Procurement
Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: In order to achieve the expected outcomes, and safeguard the Union's strategic interests, namely to support authorities in the EU and associated countries to prevent, reduce and mitigate the health risks from climate change, participation is limited to legal entities established in Member States and associated countries. Proposals including entities established in countries outside the scope specified in the topic will be ineligible.

[50] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	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). The specific conditions for actions with PCP/PPI procurements in section H of the General Annexes apply to grants funded under this topic.
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 4 (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 must ensure that the subcontracted work is performed in Member States and associated countries - unless otherwise approved by the granting authority. The specific conditions are described in General Annex H. PCP/PPI procurement costs are eligible. 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) [51].

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination "Living and working in a health-promoting environment" and the EU Mission on Adaptation to Climate Change. To that end, proposals under this topic should aim to deliver results that are directed, tailored and contributing to most of the following expected outcomes:

- Populations, public authorities and healthcare systems benefit from innovative solutions, technologies, tools and models to increase surveillance and prevention and support the adaptation, resilience and preparedness to climatic and environmental health risks.

[51] 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

- Policy makers and public authorities develop and implement environment, climate change and health policies and interventions supported by nearly fit-for-use solutions that can be further upscaled and deployed.

Scope: **Enhancing the adaptive capacity and resilience of healthcare systems and communities is crucial to prevent and reduce the health impacts of climate change. However, many of the urgently needed technologies, tools, systems and solutions are still at an early developmental stage, relying on further support for development and testing. Proposals under this topic are expected to close this gap and build on innovations being developed in the field, supported through, among others, EU Research and Innovation (R&I) funding. In this context, Precommercial procurement (PCP) projects can drive innovation and speed up the development of technologies for health adaptation to climate change by supporting the research and development of solutions to increase the resilience and preparedness of healthcare systems and communities against climate change. By focusing on early-stage solutions, PCP fosters collaboration between public sector buyers (e.g. public authorities, local authorities, health organisations) and private developers to create climate adaptation technologies, systems and solutions in the context of human health. These solutions will accelerate the transition to more climate-resilient healthcare systems and societies.**

Pre-commercial procurement (PCP) actions target consortia of procurers with similar needs that want to jointly procure the development of innovative solutions for supporting adaptation efforts. This topic does not provide direct funding to developers, industry or research organisations to perform R&D. They will be able to respond to the call for tenders launched by consortia of procurers funded under this call. Specific guidance on PCP actions and minimum eligibility requirements can be found in General Annexes H of the Horizon Europe work programme.

Proposals under this topic will support the development of innovative solutions, tools and models to enhance surveillance, prediction, prevention, risk management and diagnosis (e.g. testing), supporting the adaptation, resilience, and preparedness of healthcare systems and populations to climatic and climate-related environmental health risks.

More specifically proposals can support any of the areas listed below:

- Geospatial technologies and decision-support frameworks that help local authorities and healthcare providers track at “high resolution” and better manage direct and indirect health risks related to climate change.

- Real-time risk surveillance and early-warning technologies and monitoring tools that provide critical information for timely decision-making and responses related to the health risks of climate change.

- Technologies and solutions that facilitate the transition to climate-resilient healthcare facilities and services (activities targeting the general infrastructure (e.g. ventilation, construction or refurbishment) are out of scope).

- Technologies, tools and solutions for health risk management, prevention and resilience enhancing climate adaptation strategies and interventions in communities and occupational settings.

- Innovative tools reducing risk and exposure to climate related environmental factors that exacerbate health risks.

This topic considers tools and technologies that could be developed and tested to support adaptation at both the community and healthcare system levels. This approach would comprehensively address the needs of health authorities and those of local authorities and public organisations involved in risk management. The focus can extend beyond climate variables to include other related environmental and ecological factors that interact with climate change and impact public health.

Continuous dialogue between demand and supply side is required for the success of PCPs, therefore the effective involvement of end users needs to be considered in the proposal. Furthermore, to stimulate dialogue with the supply side, procurers are required to organise an open market consultation before launching the procurement and to promote the call for tenders widely across Europe to potentially interested suppliers.

Involvement of procurement decision makers is needed to ensure that end solution(s) are adopted by healthcare systems and/or local authorities and public organisations increasing the societal impact of the related research activities. Therefore, procurers should declare in the proposal their interest to purchase at least one solution resulting from the PCP in case the PCP delivers successful solutions and indicate whether they will (1) procure the solution(s) as part of the PCP or (2) in a separate follow-up procurement after the PCP. In the first case, procurers can implement the project as a fast-track PCP (see general annex H) and foresee the budget to purchase at least one solution during the PCP. In the second case, the procurers must include in the proposal a deliverable that prepares the follow-up procurement to purchase successful solution(s) after the PCP.

This topic is co-financed by the EU Mission on Adaptation to climate change and supports the follow up to the 2023 Communication on the Missions. Proposals are encouraged to channel their activities through the Mission platform.

HORIZON-HLTH-2026-01-ENVHLTH-04: Towards climate resilient, prepared and carbon neutral populations and healthcare systems

Call: Cluster 1 - Health (Single stage - 2026)	
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. 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 4 (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: In order to maximise synergies and increase the impact of the projects, all proposals selected for funding from this topic will form a cluster and be required to participate in common networking and joint activities (and in determining modalities for their implementation and the specific responsibilities of projects). These activities will be included in a dedicated work package, having sufficient budget allocated to it (around 2% of the total requested budget). Depending on the scope of proposals selected for funding, these activities may include: • Attendance of regular joint meetings (e.g., common kick-off meeting and annual meetings). • Periodic report of joint activities (delivered at each reporting period). • Common dissemination and communication activities (which may include, for example: a common dissemination and communication strategy, web portal and visual identity, brochure, newsletters). • Common Data Management Strategy and Common Policy Strategy (including joint policy briefs). • Thematic workshops/trainings on issues of common interest. • Working groups on topics of common interest (e.g. data

	management and exchange, communication and dissemination, science-policy link, scientific synergies). 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) [52].

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

- The healthcare sector is supported with new technological developments and frameworks for greening, decarbonizing and adapting to climate change.
- Governments, public health authorities, healthcare providers and practitioners, and civil society have access to the best available evidence on the health costs and benefits (including co-benefits) of climate adaptation and mitigation actions and interventions.
- Policy makers and public authorities develop environment, climate change and health policies and interventions based on robust frameworks and incorporating innovative solutions and technologies.
- Governments and public health authorities are supported in their adoption of robust frameworks and interventions to tackle societal challenges linked to the health impacts of climatic and environmental factors.

Scope: The health sector accounts for nearly 5% of global GHG emissions and generates significant demands for energy and materials, as well as dangerous polluting streams. Proactive mitigation efforts in the health sector can significantly reduce GHG emissions and pollution, saving many lives. However, specific mechanisms for emission reductions in the health sector remain less defined compared to those in other sectors.

At the same time, the climate crisis subjects healthcare systems to unprecedented pressures (e.g. on infrastructure, workforce, overall systems) while simultaneously having to respond to increasing healthcare needs. To reduce pressure in healthcare systems and generally improve public health, it is crucial to design interventions that prevent the health impacts of climate

[52] 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

change and related environmental degradation, increase resilience and preparedness of individuals and communities and foster the adoption of health-protective behaviours.

Research activities under this topic should generate evidence on the opportunities and health co-benefits of mitigation in the health sector as well as foster the development of low-carbon medical technologies and digital solutions for the sector. Proposals should also support the design of effective, scalable and transferable interventions and frameworks that can be applied across a wide range of healthcare settings and/or in population, community and societal contexts. Proposals can consider both living and working environments.

More specifically research actions under this topic should include several of the following activities:

- Develop and/or pilot effective and impactful interventions to address the impact of climate change in healthcare systems and/or across populations, sectors and regions. Consider where relevant the involvement of local communities and/or end users in the development of these interventions.
- Develop methodologies and analytical tools to assess the effectiveness and cost-benefit of health-related climate change adaptation strategies.
- Generate evidence on the health co-benefits of climate change mitigation and propose frameworks to quantify the magnitude of their positive impacts.
- Develop harmonised frameworks, assessment metrics and reporting methods to evaluate alternative mitigation strategies and interventions, as well as harmonised methodologies to assess the cost-benefit of different mitigation measures.
- Explore and estimate the impact of preventive healthcare and lifestyle practices for mitigating the impacts of climate change in the health sector and increasing the resilience and preparedness of communities.
- Propose best practices to enhance the climate resilience of healthcare infrastructure, healthcare professionals and relevant supply chains and logistics.
- Gather evidence on the role of primary care in increasing the preparedness of communities and reduce the health impacts of climate change.
- Develop low-carbon medical technologies (including medical devices) and digital solutions to reduce the emissions of healthcare practices. Health technology assessment activities to evaluate new or alternative low carbon medical solutions may be included where appropriate.

Funded projects under this topic should consider the scalability and transferability of the developed solutions to ensure that any knowledge, frameworks, methodologies, pilots, etc., developed are actionable and applicable across different healthcare settings and community contexts. Proposals should also consider the use of implementation science approaches to

support the relevance and broad applicability of the research outcomes. Proposed projects should take into consideration the broader socio-economic challenges faced by healthcare systems (e.g. funding challenges, workforce shortages, population ageing and increase of chronic diseases) Additionally solutions and interventions proposed under this topic should consider the Do No Significant Harm principle.

In order to maximise synergies and increase the impact of the projects, all proposals selected for funding from this topic will form a cluster and be required to participate in common networking and joint activities. Without the prerequisite to detail concrete joint activities, proposals should allocate a sufficient budget to cover the costs of any potential common networking and joint activities. Guidance on the potential activities to be developed can be obtained by consulting the clusters of projects ongoing under the Environment, Climate and Health research portfolio[1].

Applicants should provide details of their clinical studies[53] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2026-01-ENVHLTH-05: Support for a multilateral initiative on climate change and health research

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project *Indicative budget*	The Commission estimates that an EU contribution of around EUR 3.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts. 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.

[53] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	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 4 (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: 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) [54].

[54] 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

Destination - Tackling diseases and reducing disease burden

Topics under this destination are directed towards the Key Strategic Orientation 3 "*A more resilient, competitive, inclusive, and democratic Europe*" of Horizon Europe's strategic plan 2025-2027.

Research and Innovation supported under this destination should contribute to the following expected impact, set out in the strategic plan impact summary for the Health Cluster: "*healthcare providers improve their ability to tackle and manage diseases (infectious diseases, including poverty-related and neglected diseases, non-communicable and rare diseases) thereby reducing the disease burden on patients and enabling healthcare systems to perform more effectively. It can be achieved through better understanding, prevention, diagnostics, treatment, management, and cure of diseases and their co- and multi-morbidities, more effective and innovative health technologies and medical countermeasures, better ability and preparedness to manage pandemic and/or epidemic outbreaks, and improved patient safety*".

Communicable and non-communicable diseases pose a significant health, societal, and economic threat worldwide, causing premature deaths and disabilities. Despite being largely preventable, only 6% of healthcare budgets are spent on prevention][55]. To address this, there is an urgent need to develop new public health interventions, preventive, diagnostic, and therapeutic approaches, alternatives to antimicrobials, as well as to improve existing preparedness and response strategies to create tangible impacts, considering sex/gender-related issues. To address these challenges , Research and Innovation will require international cooperation to leverage global expertise, access world-class research infrastructures and invest in priority needs., aligning 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 and respond to public health needs, including rare diseases and the global burden of non-communicable diseases.

In this work programme part, Destination "*Tackling diseases and reducing disease burden*" will focus on major societal challenges linked to the Commission's political priorities such as the fight against non-communicable and communicable diseases, mental health, preparedness and response to and surveillance of health threats and epidemics, reduction and treatment of the number of antimicrobial-resistant infections. In particular, the topics under this destination will support activities aiming at: i) new treatment and disease management options to reduce burden on non-communicable diseases and long-term conditions after post-bacterial and post-viral infections; ii) improve and protect mental health of children and young adults; iii) new prevention and treatment options for infectious diseases with epidemic potential; iv)

[55] Preventive healthcare expenditure as a share of the current expenditure on healthcare https://ec.europa.eu/eurostat/statistics-explained/index.php?title=File:Preventive_healthcare_expenditure_as_a_share_of_current_expenditure_on_healthcare,_2021_(%25)_HCE2024.png

innovative therapies for antimicrobial resistant pathogens (AMR); and v) support to second phases of European Partnerships on Rare Diseases and Pandemic Preparedness. OBJ

To increase the impact of EU investments under Horizon Europe, the European Commission encourages cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities, such as participating in joint workshops, exchanging knowledge, developing and adopting best practices, or undertaking joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic, as well as between projects funded under different topics, clusters, or pillars of Horizon Europe. For example, synergies could be sought with projects funded under the European health research infrastructures (Pillar I of Horizon Europe), the EIC strategic challenges on health (Pillar III of Horizon Europe), or with projects on themes that cut across the clusters under Pillar II of Horizon Europe, such as health security/emergencies under Cluster 3 "Civil Security for Society", AI-based tools and technologies under Cluster 4 "Digital, Industry and Space", or antimicrobial resistance under Cluster 6 "Food, Bioeconomy, Natural Resources, Agriculture and Environment".

The European Commission aims to foster synergies between Horizon Europe and other EU programmes. To this end, applicants are encouraged to explore the funding opportunities available through the EU4Health Programme (2021-2027), [56] the EU's public health programme, as a means of capitalising on potential collaborations and maximizing impact

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:

- Disease burden in the EU and worldwide is reduced through effective disease management, including through the development and integration of innovative preventive, diagnostic and therapeutic approaches, digital and other people-centred solutions for healthcare.

- Premature mortality from non-communicable diseases is reduced by one third (by 2030), mental health and wellbeing are promoted, and the targets of the WHO Global Action Plan for the Prevention and Control of NCDs[57],[58] are attained, with an immediate impact on the related disease burden (Disability-Adjusted Life Years - DALYs)[59] OBJ.

56

57 https://www.who.int/publications/i/item/9789241506236

58 https://www.who.int/publications/m/item/implementation-roadmap-2023-2030-for-the-who-global-action-plan-for-the-prevention-and-control-of-ncds-2023-2030

59 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.

- Healthcare systems benefit from strengthened Research and Innovation expertise, human capacities and know-how for combatting communicable and non-communicable diseases, including through international cooperation.

- Citizens benefit from reduced (cross-border) health threat of epidemics and AMR pathogens, in the EU and worldwide[60,61].

- 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 protection of European communication networks has been identified as an important security interest of the Union and its Member States. Entities that are assessed as high-risk suppliers[62] of mobile network communication equipment (and any entities they own or control) are not eligible to participate as beneficiaries, affiliated entities and associated partners to topics identified as "subject to restrictions for the protection of European communication networks". Please refer to the Annex B of the General Annexes of this Work Programme for further details.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2027-02-DISEASE-01-two-stage: Innovative healthcare interventions for non-communicable diseases

Call: Cluster 1 - Health (Two stage - 2027)	
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 80.00 million.
Type of Action	Research and Innovation Actions
Eligibility	The conditions are described in General Annex B. The following

60 WHO global action plan on antimicrobial resistance, 2015

61 EU One Health Action Plan against AMR, 2017

62 Entities assessed as "high-risk suppliers", are currently set out in the second report on Member States' progress in implementing the EU toolbox on 5G cybersecurity of 2023 (NIS Cooperation Group, Second report on Member States' progress in implementing the EU Toolbox on 5G Cybersecurity, June 2023) and the related Communication on the implementation of the 5G cybersecurity toolbox of 2023 (Communication from the Commission: Implementation of the 5G cybersecurity Toolbox, Brussels, 15.6.2023 C(2023) 4049 final).

conditions	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: For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 4 (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: 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) [63].

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

- Researchers, developers and clinical practitioners have access to state-of-the-art knowledge, data, technologies, tools, methods, best practices, and trainings to develop innovative healthcare interventions aimed at reducing burden of non-communicable diseases (NCDs) such as cardiovascular diseases, diabetes, chronic respiratory diseases or chronic kidney diseases.

- Scientific and clinical communities can use innovative healthcare interventions to generate meaningful advances in clinical practice and care for patients with NCDs following validation in late-stage clinical trials.

[63] 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

- Scientific and clinical communities make wide use of relevant databases and/or integrate them with existing infrastructures for storage and sharing of collected data according to FAIR[64] principles, thereby encouraging further use of the data.

- Policymakers, scientific and clinical communities, developers, patient organisations, regulators, and other relevant bodies are informed of the research advances made and the requirements for a widespread implementation of the innovative therapeutic interventions and complementary approaches.

- Patients and caregivers are constructively engaged with the research, ensuring that their needs are catered for, with the aim of tangibly benefitting from the interventions.

Scope: Non-communicable diseases represent over 80% of the disease burden in Europe and the leading cause of avoidable premature deaths. Innovative and effective healthcare interventions are required to provide treatment and disease management solutions and assure best quality of care for patients suffering from NCDs when prevention strategies have failed. Proposals should address all the following aspects:

- Perform rigorous early stage[65] clinical trial(s) to validate novel or refined healthcare interventions[66] for treatment and/or disease management solutions for patients suffering from following NCDs: cardiovascular diseases, diabetes, chronic respiratory diseases or chronic kidney diseases. Whenever relevant, existing co- and multimorbidities should be addressed in the trial design.

- Clinical trial(s) should be supported by completed proof-of-concept[67] of clinical safety and efficacy.

- Both preclinical research and the draft clinical trial protocol should be completed at the time of submission of the proposal. Proposals should also demonstrate evidence of preliminary consultations with ethics and regulatory authorities at the time of submission.

- A sound feasibility assessment, including an appropriate patient selection and realistic recruitment plans, justified by publications or preliminary results should be provided.

- Take into account sex and gender differences in all relevant aspects throughout the research process, and consider stratification criteria such as age, disability, ethnicity, socio-economic status, etc., where relevant.

- Use and/or develop technologies, including digital ones (e.g., (generative) Artificial Intelligence, wearable technologies) to help implement and monitor the long-term

64 See definition of FAIR data in the introduction to the work programme part.
65 For pharmacological interventions: phase 1 and/or phase 2 clinical trials.
66 Applicants may address any mono- or combinatorial pharmacological and/or non-pharmacological interventions.
67 Comparative effectiveness studies are not within the scope of this topic.

efficacy of the intervention(s), as well as manage the disease and/or monitor their progression (e.g. with unobtrusive technologies suitable for patient monitoring at home and in real-world conditions), whilst also ensuring they are bias-free, inclusive, and ethically sound. The use of virtual human twins could also be considered, where relevant[68].

- Exploit existing data, health data infrastructures[69], biobanks, registries and/or cohorts, together with the generation of new data that should be managed in line with the FAIR principles, when relevant.

- Advance research by leveraging already existing and emerging state-of-the-art research infrastructures as well as results stemming from EU-supported research projects, where applicable.

- Engage all relevant stakeholders (especially patients and patients' representatives, caregivers, clinicians, counsellors, regulators, etc.) to design end-user optimised interventions.

- Engage with national public health authorities and regulators to ensure a robust development pathway and further uptake of the intervention.

- Present a thorough health-economic assessment and real-world data analysis to enhance sustainability and scalability of novel interventions.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs) [70] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

All projects funded under this topic are encouraged to participate in networking and joint activities, as appropriate[71].

Applicants invited to the second stage should provide details of their clinical studies[72] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

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68 https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins#:~:text=The%20European%20Virtual%20Human%20Twins%20Initiative%20is%20an,representation%20of%20a%20human%20health%20or%20disease%20state.

69 For instance BBMRI, ELIXIR, EU-OPENSCREEN, EATRIS, ECRIN, EATRIS, etc.

70 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361

71 Proposals should 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.

72 Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

HORIZON-HLTH-2026-01-DISEASE-02: Innovative interventions to prevent the harmful effects of using digital technologies on the mental health of children and young adults

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
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. 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 4 (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 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim to deliver results that are directed, tailored towards and contributing all of the following expected outcomes:

- Researchers and health care professionals have an improved understanding of the neuro-biological and cognitive/behavioural evidence base on the correlation and impact of digital technologies on mental health, including brain development.

- Policymakers and digital technology and content developers are provided with a robust evidence base on the impact (positive or negative) of digital technologies on mental health in children and young adults[73].

- Policymakers, digital technology developers, and educational institutions amongst others make use (e.g. developing guidelines) of the evidence base and widely implement the newly developed interventions aimed at promoting children and young adults' mental health while mitigating any negative impacts of digital technology use.

- Children, young adults, families, guardians, educators, and carers have access to the newly developed interventions designed to prevent harm and promote the positive use of digital technologies.

- Children and young adults are empowered and develop resilience, including digital literacy, enabling them to engage in a healthy and positive way with digital technologies.

Scope: Already before the COVID-19 pandemic, 1 in 6 people in the EU suffered from mental health issues, at an estimated cost of 4% of GDP[74] and since then these figures worsened[75] in particular among vulnerable groups such as children and adolescents. Digital technologies have the potential to enhance mental health for instance by providing access to information, support networks and therapy services[76]. However, there are indications that the excessive or misguided use of digital technologies, particularly among children and young adults, can negatively affect mental health and exacerbate mental disorders. There is an urgent need for more robust data to foster a safer, responsible and healthier use of digital technologies among children and young adults, prioritising the protection of their mental health.

Therefore, proposals should aim at generating robust scientific evidence on the impact of digital technologies, as well as developing and testing context-specific digital interventions that promote the positive and responsible use of them to improve mental health, avoiding the development or exacerbation of mental disorders. These innovative digital interventions should leverage multi-source data (e.g. sleep patterns, heart rate, stress levels, screen-time analytics, social media use, biological data, clinical data), including the use of AI.

The applicants should generate the neuro-biological and cognitive/behavioural evidence base on the correlation and impact of digital technologies on mental health, including brain development (both positive and negative), while also providing innovative interventions aiming for example at: counteracting addictive design patterns (e.g. on social media and gaming platforms), gaining insights into risk patterns and enabling early risk detection (e.g. detecting early warning signs of mental disorders or digital addiction), redirecting users

[73] There is no universal definition of youth and young adults. For the purpose of this topic, we follow the WHO definition of young adult a person aged 15-24 https://www.who.int/southeastasia/health-topics/adolescent-health

[74] https://health.ec.europa.eu/system/files/2020-02/2018_healthatglance_rep_en_0.pdf

[75] https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/751416/EPRS_BRI(2023)751416_EN.pdf

[76] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023DC0298

towards healthy use and positive engagement with digital technologies, and/or reducing exposure to harmful content.

Furthermore, they should assess the changes in behaviour in children and young adults of the newly developed interventions, aiming at fostering their resilience and promoting responsible use and healthy digital habits.

The topic is open to address any mental disorder[77] caused or aggravated by the use of digital technologies such as addiction, self-harm behaviour, increased anxiety or decreased self-esteem, sleeping-disorders, post-traumatic stress disorders.

Cohort studies and clinical studies are in the scope for this call. Applicants envisaging to include longitudinal cohort studies are invited to indicate a sustainability plan on how those cohorts are maintained over an extended period beyond the end period of the project for a long-term follow-up. They should make use of existing longitudinal cohorts when available. Applicants are welcome to consider recruiting participants transnationally and from diverse settings in the clinical study design to ensure generalizability of findings. In addition, it should be detailed in the proposal how the proposed intervention(s) could be scaled-up and transferred to other settings. Applicants should also consider the inclusion of end-users in the codesign of the interventions, for example for the young age groups, this includes the involvement of families, carers, educators. Applicants should access and make best-use of already existing European Research Infrastructures relevant for brain-research (e.g. EBRAINS[78], Euro-BioImaging[79]). Successful projects should liaise with relevant European projects on mental health[80] and the European partnership for Brain Health[81].

The participation of start-ups and/or micro, small and medium-size enterprises (SMEs)[82] is encouraged with the aim to strengthen their scientific and technological basis and valorise their innovations and to advance commercial exploitation.

Proposals should adhere to the FAIR data principles[83], adopt wherever relevant, data standards and data sharing/access good practices, and apply good practices for GDPR[84] compliant personal data protection. Sex and gender aspects should be considered, where relevant. The 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.

77 ICD11, Chapter 6: https://icd.who.int/browse/2025-01/mms/en#334423054
78 https://www.ebrains.eu/
79 https://www.eurobioimaging.eu/
80 From topics HORIZON-HLTH-2022-STAYHLTH-01-01 and HORIZON-HLTH-2024-STAYHLTH-01-02
81 https://www.brainhealth-partnership.eu/
82 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361
83 See definition of FAIR data in the introduction to this work programme part
84 General Data Protection Regulation: https://gdpr-info.eu

Applicants should provide details of their clinical studies[85] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2026-01-DISEASE-03: Advancing research on the prevention, diagnosis, and management of post-infection long-term conditions

Call: Cluster 1 - Health (Single stage - 2026)	
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 40.00 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 4 (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: 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

[85] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	Research and Training Programme of the European Atomic Energy Community (2021-2025) [86].

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 have access to evidence-based treatment and management strategies for post-infection conditions and improve patient recovery and quality of life across diverse populations.
- Public health authorities and healthcare practitioners have access to effective prevention, diagnostic and treatment tools, ensuring better allocation of healthcare resources.
- Healthcare systems improve their efficiency and reduce long-term economic burdens by streamlining post-infectious disease care and addressing disparities in healthcare access.
- Public health authorities have access to evidence-based information to integrate research findings into policy for improved public health preparedness and resilience, including training of health care staff and enhanced long-term disease management guidelines.

Scope: Microbial infections can lead to long-lasting consequences on patients' quality of life, leading to long-term conditions characterised by persistent inflammation, organ damage, and impaired functional capacity, which pose a growing public health and economic challenge. These conditions are insufficiently understood, underdiagnosed, and lack effective treatments. Advancing research into their prevention, treatment and management is essential to improving patient outcomes, reducing healthcare burdens, and strengthening workforce productivity.

The topic is open to long-term conditions resulting from infections by any type of microorganism (including viruses, bacteria, parasites, and fungi), which persist after the initial infection has resolved. Research linked to cancer is excluded as it will be covered by the Cancer Mission.

Proposals should aim to develop innovative approaches for the prevention, diagnosis, and management of post-infection conditions. Proposals should address most of the following research areas:

- Identify protective and risk factors associated with the development of post-infection conditions to inform targeted prevention strategies, by integrating relevant information such as genetics, epigenetics, immune or inflammatory responses, and/or other relevant factors.

[86] 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

- Increased understanding of the pathophysiology of post-infection conditions (including inflammatory aspects) to identify biomarkers and develop clinically validated diagnostic approaches for early detection, disease progression and/or treatment optimisation.

- Develop and validate preventive and/or therapeutic interventions, including targeted pharmacological treatments, repurposing of existing drugs or precision medicine approaches, through early-stage clinical trials[87] that demonstrate clinical safety and efficacy.

- Identify effective supportive rehabilitation approaches, including physical therapy, cognitive interventions, and psychological support, to enhance patient recovery, mental health and quality of life and evaluate their effectiveness.

- Examine best practices for integrating post-infectious disease management into primary and specialised healthcare settings, improving coordination among healthcare professionals.

Specific attention should be given to sex and gender, as women often experience post-infectious diseases differently due to biological, hormonal, and social factors, which can affect their diagnosis, treatment, and recovery. Moreover, age, ethnicity, socio-economic, lifestyle and behavioural factors should also be considered, and special emphasis should be placed on vulnerable populations and groups with pre-existing conditions to ensure equitable and inclusive healthcare solutions.

A multidisciplinary, cross-sectoral approach is encouraged, involving all relevant stakeholders (medical and non-medical), including patients, researchers, healthcare professionals, and policymakers.

Proposals should develop a harmonised approach to collection, storage, sharing and analysis of FAIR data, leveraging existing European (research) infrastructures, including biobanks or cohorts' data[88] where relevant and contribute to emerging research infrastructure, established in the framework of the European Health Data Space.

Proposals should demonstrate complementarity with ongoing EU initiatives, including projects funded under relevant topics[89], and outline plans for collaboration where applicable, to maximise synergies and avoid duplication of research efforts. All projects funded under this topic are expected to participate in networking and joint activities[90].

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87 For pharmacological interventions: phase 1 and phase 2 clinical trials.

88 ORCHESTRA data portal, Pathogens portal cohorts browser.

89 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2021-corona-01-02, https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2023-disease-03-07 and HORIZON-HLTH-2025-01-DISEASE-07.

90 The details of these joint activities will be defined during the grant agreement preparation phase. Applicants should plan the necessary budget to cover those activities without the prerequisite to define concrete common actions at this stage.

Clinical studies are expected in this topic, designed to be inclusive. The clinical studies template is mandatory for all proposals involving clinical studies. Successful applicants are expected to engage early on with the European Medicines Agency (EMA) to ensure adequacy of the actions from a regulatory point of view. Where relevant, a Health Technology Assessment (HTA) should be conducted to evaluate the clinical, economic, and social implications of interventions.

Applicants are encouraged to incorporate artificial intelligence (AI) tools and advanced computational modelling / virtual human twin (VHT)-powered tools to predict disease risk and progression, ensuring these tools are developed and tested for diverse populations to minimize bias.

Participation of start-ups, micro, small and medium-sized enterprises (SMEs) [91] is also encouraged to strengthen their scientific and technological foundations and enhance their innovation potential.

Applicants should provide details of their clinical studies[92] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2026-01-DISEASE-04: Development of novel vaccines for pathogens with epidemic potential

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project *Indicative budget*	The Commission estimates that an EU contribution of around EUR 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts. 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.

[91] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361

[92] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	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 4 (Implementation). The cumulative threshold will be 12.
Procedure	The procedure is described in General Annex F. The following exceptions apply: In order to ensure a balanced project portfolio with regard to the viral families targeted, grants will be awarded (within available budget) to proposals not only in order of ranking but also in function of the highest ranked proposals for each prototype virus, provided that the applications attain all thresholds available.

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

- The scientific and clinical communities have a better understanding of and access to experimental vaccines for the prevention and treatment of emerging or re-emerging viral infections, as well as for further clinical investigation.
- Candidate vaccines are available for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

Scope: Infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is already being accelerated by climate change, and thus a proactive approach to the development of vaccine-based antiviral prophylactics and therapeutics in preparedness for future infectious disease outbreaks is needed. The availability of vaccines that can be adjusted to variants would provide a critical preparedness measure against future health threats, due to infectious disease epidemics or pandemics.

Proposals should exclusively pursue the development of existing prophylactic and therapeutic vaccine candidates targeting at least one of the following prototype viruses:

- Arenaviridae: Junin mammarenavirus, Lassa mammarenavirus
- Flaviviridae: Tick-borne encephalitis virus
- Hantaviridiae: Andes virus, Hantaan virus, Sin Nombre virus

- Paramyxoviridae: Hendra virus,
- Picornaviridae: Enterovirus D68
- Togaviridae: Venezuelan equine encephalitis virus.

Proposals are expected address one or several prototype viruses. In order to enable the portfolio approach, proposals need to specify virus(es) targeted.

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

Proposals should address all the following research areas:

- If necessary, finalisation of the in vitro characterisation of existing vaccine candidates with regard to target specificity, epitope recognised, and their ability to impair or inactivate viral functions.
- In vivo tests in at least one animal model or, if available in humanised immune system animal models, to demonstrate the protective function of the vaccine candidates deemed sufficient for moving to first clinical trials.
- If requested by regulators as pre-requisite for clinical studies, in vivo tests in a non-human primate model.
- Production of batches of the most promising vaccine candidates under GMP [1] standard in the EU or the European Economic Area.
- First in human clinical safety studies demonstrating a clear regulatory pathway for market authorisation. Attention should be paid to critical biological and social factors such as sex, age, ethnicity and disability.

Participation of third countries where viruses addressed in the proposal are endemic or where outbreaks have occurred or are ongoing is encouraged.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs)[2] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

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

Proposals should advance research by leveraging already existing and emerging state-of-the-art research infrastructures such as those having established services under the ISIDORe project[3].

The projects funded under this topic should synergize with projects funded by the future 'Pandemic Preparedness Partnership'.

Applicants should provide details of their clinical studies[93] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2027-01-DISEASE-05: Development of novel broad spectrum small molecule antiviral therapeutics for pathogens with epidemic potential

Call: Cluster 1 - Health (Single stage - 2027/1)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
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. 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 4 (Implementation). The cumulative threshold will be 12.
Procedure	The procedure is described in General Annex F. The following exceptions apply: In order to ensure a balanced project portfolio with regard to the viral families targeted, grants will be awarded (within available budget) to

[93] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	proposals not only in order of ranking but also in function of the highest ranked proposals for each prototype virus, provided that the applications attain all thresholds available.

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

- The scientific and clinical communities have a better understanding of and access to experimental antivirals for the prevention and treatment of emerging or re-emerging viral infections, as well as for further clinical investigation.
- Candidate antiviral therapies are available for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

Scope: Infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is already being accelerated by climate change, and thus a proactive approach to the development of antiviral prophylactics and therapeutics in preparedness for future infectious disease outbreaks is needed. The availability of broad-spectrum antivirals targeting conserved viral or host mechanisms would provide a critical preparedness measure against future health threats caused by (re)emerging infectious disease epidemics or pandemics, due to infectious disease epidemics or pandemics. Antibodies and antibody derived proteins are excluded from the scope of this topic.

Proposals should pursue the development of novel or existing broad spectrum antiviral candidates targeting at least one of the following prototype viruses:

- Arenaviridae: Junin mammarenavirus, Lassa mammarenavirus
- Flaviviridae: Tick-borne and Japanese encephalitis virus
- Hantaviridiae: Andes virus, Hantaan virus, Sin Nombre virus
- Paramyxoviridae: Hendra virus,
- Picornaviridae: Enterovirus D68
- Togaviridae: Venezuelian equine encephalitis virus.

Proposals are expected address one or several prototype viruses. In order to enable the portfolio approach, proposals need to specify virus(es) targeted.

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

Proposals should address some of the following research areas:

- Discovery and selection of candidate antivirals with consideration for cross-family, and/or intra-family and/or variant-transcending potential.
- Optimisation of selected candidates to improve potency, selectivity, pharmacokinetics, and developability, using structure-activity relationship (SAR) studies or equivalent methodologies.
- In vitro characterisation of antiviral activity, mechanism of action, and, where appropriate, resistance potential across multiple viruses or strains.
- In vivo tests in at least one animal model or, if available in human organoid or organotypic models,to demonstrate the protective function of the antiviral candidates and deemed sufficient for moving to first clinical trials.
- If requested by regulators as pre-requisite for clinical studies, in vivo tests in a non-human primate model.
- Production of batches of the most promising antiviral candidates under GMP standard in the EU or the European Economic Area of the most promising therapeutics solution.
- First in human clinical safety studies demonstrating a clear regulatory pathway for market authorisation. Attention should be paid to critical biological and social factors such as sex, age, ethnicity and disability.

Participation of third countries where viruses addressed in the proposal are endemic or where outbreaks have occurred or are ongoing is encouraged.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs)[2] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

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

Proposals should advance research by leveraging already existing and emerging state-of-the-art research infrastructures such as those having established services under the ISIDORe project[3].

The projects funded under this topic should synergize with projects funded by the future ‘Pandemic Preparedness Partnership’.

Applicants should provide details of their clinical studies[94] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2026-01-DISEASE-06: Development of monoclonal antibodies to prevent and treat infections from Flaviviridae

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
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. 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 4 (Implementation). The cumulative threshold will be 12.
Procedure	The procedure is described in General Annex F. The following exceptions apply: In order to ensure a balanced project portfolio with regard to the viral families targeted, grants will be awarded (within available budget) to proposals not only in order of ranking but also in function of the highest ranked proposals for each prototype virus, provided that the applications

[94] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	attain all thresholds available.

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

- The scientific and clinical communities have a better understanding of and access to experimental monoclonal antibodies for the prevention and treatment of emerging or re-emerging viral infections, as well as for further clinical investigation.
- Candidate antiviral therapies are available for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

Scope: Infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is already being accelerated by climate change, and thus a proactive approach to the development of antiviral prophylactics and therapeutics in preparedness for future infectious disease outbreaks is needed. The capacity to produce antibodies that can target new variants and rapidly increase production would serve as an essential preparedness strategy against future health threats, whether from infectious disease epidemics or pandemics.

Proposals should exclusively pursue the development of existing prophylactic and therapeutic monoclonal antibody candidates targeting at least one of the following prototypes of Flaviviridae: Dengue Virus, Tick-borne and Japanese Encephalitis Virus, West Nile Fever Virus, Yellow Fever Virus, and Zika Virus

Proposals should focus on antibodies produced or dervied from a single cell clone through recombinant expression, such as B-cell derived antibodies, hybridoma derived antibodies and nanobodies.

Proposals are expected address one or several prototype viruses. Proposals may focus on one or more antibody candidates for a given prototype virus. In order to enable the portfolio approach, proposals need to specify virus(es) targeted.

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

Proposals should address all the following research areas:

- If necessary, finalisation of the in vitro characterisation of existing monoclonal antibody candidates with regard to target specificity, epitope recognised, and their ability to impair or inactivate viral functions.

- In vivo tests in at least one animal model or, if available in humanised immune system animal models, to demonstrate the protective function of the monoclonal antibodies deemed sufficient for moving to first clinical trials.
- If requested by regulators as pre-requisite for clinical studies, in vivo tests in a non-human primate model.
- Evaluation of antibody-dependent enhancement (ADE) risk where scientifically relevant.
- Production of batches of the most promising antibody candidates under GMP standard in the EU or the European Economic Area.
- First in human clinical safety studies demonstrating a clear regulatory pathway for market authorisation. Attention should be paid to critical biological and social factors such as sex, age, ethnicity and disability.

Participation of third countries where viruses addressed in the proposal are endemic or where outbreaks have occurred or are ongoing is encouraged.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs)[2] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

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

Proposals should advance research by leveraging already existing and emerging state-of-the-art research infrastructures such as those having contributed to the services developed those having established services under the ISIDORe project[3].

Applicants should provide details of their clinical studies[95] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2027-01-DISEASE-07: Development of monoclonal antibodies to prevent and treat infections from Filo- Phenui-, Picorna- and Toga Viridae

Call: Cluster 1 - Health (Single stage - 2027/1)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal

[95] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	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. 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 4 (Implementation). The cumulative threshold will be 12.
Procedure	The procedure is described in General Annex F. The following exceptions apply: In order to ensure a balanced project portfolio with regard to the viral families targeted, grants will be awarded (within available budget) to proposals not only in order of ranking but also in function of the highest ranked proposals for each prototype virus, provided that the applications attain all thresholds available.

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

- The scientific and clinical communities have a better understanding of and access to experimental monoclonal antibodies for the prevention and treatment of emerging or re-emerging viral infections, as well as for further clinical investigation.
- Candidate antiviral therapies are available for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

Scope: Infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is already being accelerated by climate change, and thus a proactive approach to the development of antiviral prophylactics and therapeutics in

preparedness for future infectious disease outbreaks is needed. The capacity to produce antibodies that can target new variants and rapidly increase production would serve as an essential preparedness strategy against future health threats, whether from infectious disease epidemics or pandemics.

Proposals should exclusively pursue the development of existing prophylactic and therapeutic monoclonal antibody candidates targeting at least one of the following prototypes of the following virus families:

- Filoviridae: Ebola Virus, Marburg Virus
- Phenuiviridae: Rift Valley Fever Virus
- Picornaviridiae: Enterovirus D68
- Togaviridae: Chikungunya Virus

Proposals should focus on antibodies produced or derived from a single cell clone through recombinant expression, such as B-cell derived antibodies, hybridoma derived antibodies and nanobodies

Proposals are expected address one or several prototype viruses. Proposals may focus on one or more antibody candidates for a given prototype virus. In order to enable the portfolio approach, proposals need to specify virus(es) targeted.

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

Proposals should address all the following research areas:

- If necessary, finalisation of the in vitro characterisation of existing monoclonal antibody candidates with regard to target specificity, epitope recognised, and their ability to impair or inactivate viral functions.
- In vivo tests in at least one animal model or, if available in humanised immune system animal models, to demonstrate the protective function of the monoclonal antibodies deemed sufficient for moving to first clinical trials.
- If requested by regulators as pre-requisite for clinical studies, in vivo tests in a non-human primate model.
- Evaluation of antibody-dependent enhancement (ADE) risk where scientifically relevant.
- Production of batches of the most promising antibody candidates under GMP [1] standard in the EU or the European Economic Area.

- First in human clinical safety studies demonstrating a clear regulatory pathway for market authorisation. Attention should be paid to critical biological and social factors such as sex, age, ethnicity and disability.

Participation of third countries where viruses addressed in the proposal are endemic or where outbreaks have occurred or are ongoing is encouraged.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs)[2] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

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

Proposals should advance research by leveraging already existing and emerging state-of-the-art research infrastructures such as those having contributed to the services developed those having established services under the ISIDORe project[3].

Applicants should provide details of their clinical studies[96] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2027-01-DISEASE-08: Development of innovative antimicrobials or antibody-based therapies against critical pathogens resistant to antimicrobials (AMR)

Call: Cluster 1 - Health (Single stage - 2027/1) **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 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.

[96] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	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 4 (Implementation). The cumulative threshold will be 12.
Procedure	The procedure is described in General Annex F. The following exceptions apply: In order to ensure a balanced project portfolio with regard to the viral families targeted, grants will be awarded (within available budget) to proposals not only in order of ranking but also in function of the highest ranked proposals for each prototype virus, provided that the applications attain all thresholds available.

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

- The scientific and clinical communities have a better understanding of and access to new and innovative products for the treatment of antimicrobial resistant bacteria and fungi, as well as for further clinical investigation.
- Candidate therapies are available for antimicrobial resistant bacteria and fungi, increasing therapeutic options for clinical deployment in the fight against AMR.

Scope: The rapid rise of Antimicrobial Resistance (AMR) presents a formidable threat to public health, challenging our ability to treat infections that were once easily managed with standard antimicrobials. As pathogens continually adapt and develop resistance to existing drugs, the efficacy of these treatments diminishes, leading to more severe and prolonged illnesses, increased healthcare costs and productivity losses, and a higher mortality rates. This escalating crisis underscores an urgent need for viable therapeutic alternatives required to reduce the burden of diseases caused by antibiotic resistance. Innovative solutions are crucial to maintaining effective disease management and safeguarding public health.

Proposals should pursue the development of innovative and effective antibacterial and antifungal agents, including antibody-based therapies, which meet at least one of the four WHO innovation criteria [1] (1) new chemical class, (2) new target, (3) new mode of action and (4) no evidence of cross-resistance.

Proposals under this topic should not pursue the development of phage-therapies.

Proposals should exclusively pursue the development of existing therapeutic candidates targeting at least one of the following critical pathogens:

- Carbapenem resistant *Acinetobacter baumanii* (CRAB).
- Carbapenem-resistant Enterobacterales (CRE) and third-generation cephalosporin-resistant Enterobacterales (C3GRE).
- Carbapenem resistant *Pseudomonas aeruginosa.*
- (Drug)-resistant *Aspergillus fumigatus.*
- (Drug)-resistant *Candida spp.*

Proposals are expected to conduct advanced preclinical studies of antimicrobial candidates, prepare Good Manufacturing Practice (GMP) [2] , quality test batches and carry out human clinical trials, including safety and efficacy studies against specific conditions in human.

Proposals should thus aim to accelerate testing of novel candidates in human trials, diversify and accelerate the global prophylactic and therapeutic research and development portfolio for AMR bacterial and fungal infections, and to strengthen the leading role of the EU in prophylactic and therapeutic research and development.

Proposals should address all the following areas:

- If necessary, finalisation of in vivo tests in at least one animal model or, if available in humanised immune system animal models, to demonstrate the protective function of the antibodies and antibody-derived therapeutics deemed sufficient for moving to first clinical trials.
- If requested by regulators as pre-requisite for clinical studies, in vivo tests in a non-human primate model.
- Production of GMP quality test batches of the most promising candidates in the EU or the European Economic Area.
- In human clinical safety and efficacy studies, demonstrating a clear regulatory pathway for market authorisation. Attention should be paid to critical biological and social factors such as sex, age, ethnicity and disability.

Participation of third countries where AMR bacteria and fungi in the proposal are endemic or where outbreaks have occurred or are ongoing is encouraged.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs) [3] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

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

Proposals should advance research by leveraging already existing and emerging state-of-the-art research initiatives such as the European partnership on One Health Antimicrobial Resistance (EUP OHAMR).

Applicants should provide details of their clinical studies[97] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2026-01-DISEASE-09: Multisectoral approach to tackle chronic non-communicable diseases: implementation research maximising collaboration and coordination with sectors and in settings beyond the healthcare system (GACD)

Call: Cluster 1 - Health (Single stage - 2026)	
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 12.00 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 4 (Implementation). The cumulative threshold will be 12.
Legal and financial set-up of the Grant	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

[97] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

Agreements	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) [98].

HORIZON-HLTH-2027-01-DISEASE-10: Prevention and management of chronic non-communicable diseases in children and young people (GACD)

Call: Cluster 1 - Health (Single stage - 2027/1)	
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 12.00 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 4 (Implementation). The cumulative threshold will be 12.
Legal and financial set-up of	The rules are described in General Annex G. The following exceptions apply:

[98] 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 Grant Agreements	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) [99].

HORIZON-HLTH-2026-01-DISEASE-11: Gender/sex differences in CVD

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 5.00 and 7.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 45.00 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 4 (Implementation). The cumulative threshold will be 12.
Legal and financial set-up of the Grant	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

[99] 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

Agreements	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) [100].

HORIZON-HLTH-2026-02-DISEASE-12: European Partnership on Rare Diseases (ERDERA) (Phase 2)

Call: Partnerships in Health (2026/1)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 93.00 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 93.00 million.
Type of Action	Programme Co-fund Action
Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: The proposal must be submitted by the coordinator of the consortium funded under topic HORIZON-HLTH-2023-DISEASE-07-01: "European Partnership on Rare Diseases". This eligibility condition is without prejudice to the possibility to include additional partners. 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.
Procedure	The procedure is described in General Annex F. The following exceptions apply: The evaluation will take into account the existing context and the scope of the initial evaluation as relevant, and related obligations enshrined in

[100] 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 grant agreement. If the proposal is successful, the next stage of the procedure will be grant agreement amendment preparations. If the outcome of amendment preparations is an award decision, the coordinator of the consortium funded under topic HORIZON-HLTH-2023-DISEASE-07-01: "European Partnership on Rare Diseases" will be invited to submit an amendment to the grant agreement, on behalf of the beneficiaries.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: This action is intended to be implemented in the form of an amendment of the grant agreement concluded pursuant to Article 24(2) of the Horizon Europe Regulation. For the additional activities covered by this action: • The funding rate is 50% of the eligible costs. • Beneficiaries may provide financial support to third parties (FSTP). 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 this action in order to be able to achieve its objectives. The maximum amount to be granted to each third party is EUR 10.00 million for the duration of the partnership. However, if the objectives of the action would otherwise be impossible or overly difficult (and duly justified in the proposal) the maximum amount may be higher. • The starting date of the grant awarded under this topic may be as of the submission date of the application. Applicants must justify the need for a retroactive starting date in their application. Costs incurred from the starting date of the action may be considered eligible (and will be reflected in the entry into force date of the amendment to the grant agreement).
Total indicative budget	The total indicative budget for the topic is EUR 93 million committed in annual instalments over the 2 years, 2026-2027 (EUR 30 million from the 2026 budget and EUR 63 million from the 2027 budget).

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 present action is planned as second instalment for the topic HORIZON-HLTH-2023-DISEASE-07-01: "European Partnership on Rare Diseases" and foresees an amendment to an existing grant agreement, the proposal should thus present the specific activities foreseen for the second instalment of the Partnership. The Partnership should continue to 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) 2021/522152).

This partnership should also contribute to achieving the objectives of the Pharmaceutical Strategy for Europe, in terms of fulfilling unmet medical needs (e.g. for rare diseases with so called “orphan medicinal products”) 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 foster the reinforcement of the ecosystem, with a critical mass of resources, and 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;

• Further develop and deploy different components of a 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 and diagnostic methodologies;

• Develop and consolidate the capacity building of the RD data ecosystem by supporting the federated access/sharing of FAIR research data, information resources to ensure the effective and fast translation of the research results to safe and effective health innovations;

• Integrate basic, pre-clinical and clinical research to reduce the burden for people living with a rare disease.

• Support research in relevant medical fields and intervention areas (prevention, diagnosis, treatment), while improving the utilisation of existing health technologies in clinical practice;

• Support the scientific work of the International Rare Disease Research Consortium (IRDiRC)[101].

HORIZON-HLTH-2026-03-DISEASE-13: European partnership for pandemic preparedness (Phase 2)

Call: Partnerships in Health (2026/2)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 73.00 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 73.00 million.
Type of Action	Programme Co-fund Action

[101] https://irdirc.org/

Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: The proposal must be submitted by the coordinator of the consortium funded under topic HORIZON-HLTH-2024-DISEASE-12-01: "European partnership for pandemic preparedness". This eligibility condition is without prejudice to the possibility to include additional partners. Subject to restrictions for the protection of European communication networks. 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.
Procedure	The procedure is described in General Annex F. The following exceptions apply: The evaluation will take into account the existing context and the scope of the initial evaluation as relevant, and related obligations enshrined in the grant agreement. If the proposal is successful, the next stage of the procedure will be grant agreement amendment preparations. If the outcome of amendment preparations is an award decision, the coordinator of the consortium funded under topic HORIZON-HLTH-2024-DISEASE-12-01: "European partnership for pandemic preparedness" will be invited to submit an amendment to the grant agreement, on behalf of the beneficiaries.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: This action is intended to be implemented in the form of an amendment of the grant agreement concluded pursuant to Article 24(2) of the Horizon Europe Regulation. For the additional activities covered by this action: • The funding rate is 50% of the eligible costs. • Beneficiaries may provide financial support to third parties (FSTP). 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 this action in order to be able to achieve its objectives. The maximum amount to be granted to each third party is EUR 3.00 million for the duration of the partnership. However, if the objectives of the action would otherwise be impossible or overly difficult (and duly justified in the proposal) the maximum amount may be higher. • The starting date of the grant awarded under this topic may be as of the submission date of the application. Applicants must justify the need for a retroactive starting date in their application. Costs incurred from the starting date of the action may be considered eligible (and will be reflected in the entry into force date of the amendment to the grant agreement).
Total indicative budget	The total indicative budget for the topic is EUR 73 million committed in annual instalments over the 2 years, 2026-2027 (EUR 40 million from the 2026 budget and EUR 33 million from the 2027 budget).

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". The Partnership should be firmly anchored within the framework of the European Health Union package [102] and ensure synergies with the European Health Emergency Preparedness and Response Authority (HERA) and other relevant European Commission services. The Partnership's activities are expected to be key enablers of the EU Global Health Strategy[103].

Proposals under this topic are expected to build on the first phase of this Partnership[104], and should aim for delivering results that are directed, tailored towards, and contributing to all of the following expected outcomes:

- The EU offers a valued operational network of clinical research sites (both interventional and observational) that have the capacity to implement well-coordinated large-scale multi-country quality clinical studies in different target populations, which are able to smoothly transition to interventions relevant for cross-border health threats in readiness for or response to a public health emergency.
- Key stakeholders, including relevant EU and national entities, the scientific communities, policymakers and funders enhance their collaboration and coordination to strengthen research on pandemic preparedness and response, forming a strong, structured and comprehensive ecosystem with shared evidence, tools and methodologies cutting across sectors.

102 1
103 2
104 Cf. selected proposal under HORIZON-HLTH-2024-DISEASE-12-01.

- Research funders, policymakers, relevant EU and national entities, and the research community recognise and rapidly close relevant research and related infrastructure gaps and break existing silos on pandemic preparedness research and response.

- Healthcare authorities, regulatory authorities, policymakers and other stakeholders utilise research results to develop evidence-based strategies and policies for pandemic preparedness and response, and deploy good practices to European countries and regions, and beyond whenever relevant.

- The research community benefits from and uses an improved comprehensive knowledge framework integrating the EU, national/regional data and information infrastructures to improve transnational research in the area of pandemic preparedness and response.

- The EU is strengthened as an internationally recognised actor for pandemic preparedness research and response, as such substantially contributing to global cooperation and coordination.

Scope: The Partnership should contribute to the actions proposed in the Joint Communication on the European Preparedness Union Strategy (JOIN(2025) 130 final) which recognises the essential contribution of research and innovation to allow "continuously adapted, optimised and state-of-the-art responses to crisis". It should also contribute to the upcoming Strategy for European Life Sciences that is in preparation.

The co-funded Partnership on pandemic preparedness should enable improved coordination and cooperation on national and European levels (and contributing globally), building on the strategic research and innovation agenda established in the first phase of the Partnership. The Partnership's implementation is grounded in coordinating and jointly funding transnational research, combined with a strong focus on integrative 'in-house' activities, ultimately reinforcing the readiness of Europe's research ecosystem.

The Partnership should cover the full scope of preparedness research, ranging from basic and pre-clinical research, to clinical, public health, social sciences and implementation research. The Partnership will consider the interplay between environmental and climatic factors and the emergence and spread of health threats and will adopt a One Health approach to better understand and mitigate the risks of emerging infectious diseases.

Of particular interest is the consolidation and further development of the ever-warm clinical research network, comprising both observational and interventional studies, ensuring continuous clinical research activity across diverse sites, and with the in-built capacity to rapidly respond to public health emergencies. In this regard, the Partnership should ensure close coordination with the clinical trial coordination mechanism (CT-CM) [105], by facilitating the provision of scientific advice on the clinical research needs in preparedness and response to public health emergencies, and by promoting a coordinated approach to the national and EU funding of identified clinical research needs.

[105] 1

The Partnership should strengthen the European Research Area by supporting excellence in innovative research and capacity building, widening the engagement of countries not yet involved. As a demonstration of its added value, the Partnership should be able to attract the engagement of a broad range of stakeholders beyond European health authorities and research funders, such as private and philanthropic actors and innovators.

When defining calls for proposals, the Partnership needs to consider sex and gender-related differences. If relevant, it also 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, to produce meaningful and significant effects enhancing the societal impact of the related research activities.

The Partnership will consolidate a suitable health research data ecosystem aligned with the European Health Data Space, supporting the harmonisation and standardisation as well as the federated access of FAIR research data in the context of pandemic preparedness and response. The Partnership's work should comply with the appropriate ethical, regulatory and legal frameworks, and should ensure the timely translation of research outcomes into effective clinical and public health policy and innovation.

Destination - Ensuring equal access to innovative, sustainable, and high-quality healthcare

Topics under this destination are directed towards the Key Strategic Orientation 2 "*The Digital transition*" and Key Strategic Orientation 3 "*A more resilient, competitive, inclusive, and democratic Europe*" of Horizon Europe's strategic plan 2025-2027.

Research and Innovation supported under this destination should contribute to the following expected impact, set out in the strategic plan impact summary for the Health Cluster: *"healthcare systems provide equal access to innovative, sustainable and high-quality healthcare thanks to the development and uptake of safe, cost-effective and people-centred solutions. This is to be accompanied by management models focusing on population health, health systems resilience, and health equity and patient safety, and also improved evidence-informed health policies".*

Health systems are affected by limitations in sustainability and resilience, and face inequalities in access to high-quality and acceptable healthcare services. Our health systems need to become more effective, efficient, accessible, fiscally and environmentally sustainable, and resilient in order to cope with public health emergencies, support healthcare workforce, adapt to environmental challenges like climate change, and contribute to social justice and cohesion. The transformation and modernisation of our health systems will remain an important challenge for many years to come, but it also holds a significant opportunity to generate evidence, leverage existing and emerging solutions, implement digital and data-driven innovation and develop more accessible, cost-effective, flexible and equitable health systems.

Research and Innovation under this destination should aim to support the transformation of healthcare systems ensuring fair access to high-quality, acceptable, sustainable healthcare for all. Funded activities will focus on developing innovative, practical, scalable and financially sound solutions, that improve governance, provide decision-makers with new evidence, tools, and technologies, and ensure long-term fiscal, environmental and climate sustainability. A patient-centered approach should be adopted, improving patients' health outcomes, empowering patients, fostering active dialogue among stakeholders (e.g., citizens, patients, caregivers, healthcare providers), and encouraging social innovation. Research and Innovation actions should prioritise supporting healthcare professionals and providers, ensuring they have the resources and tools needed to meet the diverse needs and preferences of citizens. Research and Innovation should facilitate scalable and transferable solutions that can be applied across different healthcare systems and national, regional, and local contexts. This should include generating knowledge that supports the transfer of solutions between countries, including measures to address health inequalities. Research and Innovation activities under this destination will contribute to, among other things, the European Care Strategy[106], the digital

[106] Communication from the European Commission on the European care strategy, COM(2022) 440, 7.9.2022

transformation of health and care in the EU[107], the European Pillar of Social Rights[108] [109], the EU strategy on adaptation to climate[110], the Pharmaceutical Strategy for Europe[111], the European Health Data Space, the European Life Science Strategy and the European Green Deal. They align with the Commission political guidelines 2024-2029, which include efforts to complete the European Health Union by promoting access for all to high-quality and affordable healthcare, fostering a resilient and innovative health ecosystem, and strengthening the competitiveness of the European Union.[112]

In this work programme part, the focus of this destination will be on public procurement of innovative solutions for integrated care, aiming to develop and test solutions that improve access to health and care. It will also support personalised medicine approaches to reduce adverse drug reactions due to the administration of multiple medication, and research to identify and address low-value care in health and care systems, improving healthcare outcomes, efficiency, and fiscal sustainability.

To increase the impact of EU investments under Horizon Europe, the European Commission encourages and supports cooperation among EU-funded projects to foster cross-fertilisation and synergies. This includes networking, joint activities such as workshops, knowledge exchange, best practices development, and joint communication activities. Synergies can be explored not only between projects funded under the same topic, but also between projects funded under other topics, Clusters or pillars of Horizon Europe. For instance, collaborations may arise between projects related to European health research infrastructures (under Pillar I), the EIC strategic challenges on health (under Pillar III), or across the Clusters of Pillar II such as Cluster 2 “Culture, Creativity and Inclusive Society” focusing e.g., on the long-term sustainability of public health systems (e.g., economic and organisational models and measures for cost effectiveness and fiscal sustainability), or Cluster 4 “Digital, Industry and Space” focusing on the digitalisation of the health sector, including the use of AI.

The European Commission aims to foster synergies between Horizon Europe and other EU programmes. To this end, applicants are encouraged to explore the funding opportunities available through the EU4Health Programme (2021-2027), the EU's public health programme, as a means of capitalising on potential collaborations and maximizing impact.

Expected impacts:

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107 Communication from the European Commission on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, COM(2018) 233, 25.4.2018

108 https://employment-social-affairs.ec.europa.eu/policies-and-activities/european-pillar-social-rights-building-fairer-and-more-inclusive-european-union_en

109 Commission Communication on Artificial Intelligence for Europe; COM(2018) 237 final: https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:237:FIN

110 https://climate.ec.europa.eu/eu-action/adaptation-climate-change/eu-adaptation-strategy_en

111 https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en

112

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

- Health and social care services and systems have improved governance mechanisms, making them more effective, efficient, accessible, resilient, trusted and sustainable, from fiscal, organisational and environmental perspectives. This includes shifting from hospital-centred to community-based, people-centred and integrated healthcare structures, embedding technological innovations and prioritising health promotion and disease prevention and management.

- Healthcare providers are trained and equipped with the skills and competences needed for future healthcare systems that are modernised, digitally transformed and equipped with safe innovative tools, technologies and digital solutions for healthcare. This will involve better patient management, improved patient engagement and health outcomes, reorganised workflows, and improved resource management.

- Citizens play a key role in managing their own healthcare, informal carers (including unpaid carers) are fully supported (e.g. by preventing overburdening and economic stress) and the specific needs of vulnerable groups are recognised and addressed. This includes improved access to healthcare services, financial risk protection, timely access to quality healthcare services including essential medicines and vaccines.

- Health policy and systems adopt a holistic approach - considering individuals, communities, organisations, society - in evaluating health outcomes, public health interventions, healthcare organisation, and decision-making. They benefit from evidence based, scalable and transferable healthcare solutions (e.g., between countries and healthcare settings) including for addressing health inequalities and ensuring environmental and climate sustainability in the health sector.

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

Proposals are invited against the following topic(s):

HORIZON-HLTH-2026-01-CARE-01: Public procurement of innovative solutions (PPI) for improving citizen's access to healthcare through integrated care

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per	The Commission estimates that an EU contribution of between EUR 3.00 and 5.00 million would allow these outcomes to be addressed

project	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	Public Procurement of Innovative Solutions
Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: In order to achieve the expected outcomes, and safeguard the Union's strategic interests and security, namely regarding the deployment of innovative solutions in healthcare settings (including digital solutions capturing sensitive patients' data), participation is limited to legal entities established in Member States and associated countries. Proposals including entities established in countries outside the scope specified in the topic will be ineligible. 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). The specific conditions for actions with PCP/PPI procurements in section H of the General Annexes apply to grants funded under this topic.
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 4 (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: The specific conditions are described in General Annex H. PCP/PPI procurement costs are eligible.

Expected Outcome: This topic aims to support innovation activities that enable or contribute to one or several expected impacts of Destination 4: "Ensuring access to innovative, sustainable, and high-quality healthcare." Proposals under this topic should aim to deliver results that are directed, tailored, and contribute to several of the following expected outcomes:

- Patients and their carers, health authorities and health professionals will benefit from the deployment of innovative solutions that facilitate integration and coordination of care, allowing for better access to and better quality of health and care;

- Patients will benefit from improved care experiences and health outcomes and are more engaged in their care and better equipped to make informed decisions on their health, in collaboration with health professionals;

- Health professionals will be better equipped with, and thus benefit from, improved means for care delivery and coordination, with multi-disciplinary approaches and closer patient engagement, thanks to digital tools and enhanced use of health data;

- Health systems will improve their accessibility, coordination mechanisms, effectiveness and resilience, thanks to innovative solutions and a better use of resources stemming from an enhanced integration of care.

Scope: Public procurement of innovative solutions (PPI)[113] can boost the wider market uptake of high impact innovations in health systems, while enhancing capacity of providers and improving access to healthcare for citizens. This supports enhancement of social rights[114] and the EU economic competitiveness by providing business opportunities and thus incentives to innovate. By acting as early adopters of innovative solutions, procurers can open up new growth markets for the EU industry. Joint/collaborative demand-side initiatives can help create economies of scale and facilitate the wider adoption of innovations in the health sector for the benefits of patients in need.

PPI actions target consortia of procurers with a similar need that want to procure together the deployment of innovative solutions for supporting integration of care. This topic does not provide direct funding to developers, industry or research organisations to perform R&D. They will be able to respond to the call for tenders launched by consortia of procurers funded under this call. Specific guidance on PPI actions and minimum eligibility requirements can be found in General Annexes H of the Horizon Europe work programme.

Proposals will need to specify which segment of the patient population they target, the specific organisational and/or technological innovations to be procured, and why the proposed innovative solutions would be fit for purpose adhering to the principles of integrated care[115].

Examples of target groups that could be covered by this action are: patients at risk of vulnerability such as children and older or frail people with complex needs for health and

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113 https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/shaping-eu-research-and-innovation-policy/new-european-innovation-agenda/innovation-procurement/horizon-europe-funding-pcp-and-ppi_en; For PPI executed by a group of procurers, the lead procurer must coordinate the preparation and implementation of one joint or several coordinated public procurements of innovative solutions, based on common specifications defined jointly by the buyers' group. Each PPI must focus on one concrete need identified as a common challenge that requires the deployment of innovative solutions. Projects that aim to implement a PCP/PPI must contain a preparation and execution stage.

114 European Pillar of Social Rights: https://employment-social-affairs.ec.europa.eu/european-pillar-social-rights-20-principles_en

115 https://integratedcarefoundation.org/nine-pillars-of-integrated-care ;
See also diagram: https://cordis.europa.eu/docs/results/h2020/634/634288_PS/001-eur-selfie2020-infographic-implementation.png
and relevant corresponding article: https://www.sciencedirect.com/science/article/pii/S0277953621000605?via%3Dihub

social care; people with multi-morbidities or non-communicable diseases of high burden; people with both physical and mental health conditions; people living with rare diseases; as well as other groups of patients in need of highly integrated and coordinated care. Proposals should pay attention to how gender and intersectional factors (e.g., caregiving responsibilities, work-related health disparities etc.) affect healthcare access and outcomes.

Proposals should demonstrate, with qualitative and quantitative indicators, how they contribute to the above expected outcomes and clearly describe the application of the principles of integrated care in the deployed solutions. This would also include embedding the innovation in the existing health systems, addressing gaps and avoiding overlaps, while fostering change management across organisations, professions and sectors.

Solutions envisaged within this action are for example digital solutions, including AI elements, to facilitate delivery of integrated care across hospitals, primary care, long-term care (LTC) facilities and home settings.

The actions shall target deployment of innovative solutions across different health and care jurisdictions in Europe by engaging public and/or private procurers from each participating country (at national, regional or local level) that have deployment responsibilities and budget control in the provision of health and care services. Procurers will specify, purchase and deploy solutions addressing their relevant and shared unmet needs, while engaging together in a supply and demand side dialogue. Proposals should be based on clearly identified user needs and well-structured work plans, explaining how the procurement of the innovative solutions will contribute to the expected outcomes. In addition, cost-effectiveness analyses as well as estimates of the wider economic impact are highly desirable.

Activities covered should include cooperation with policymakers to reinforce national policy frameworks and mobilise substantial additional national budgets for the PPI, to raise awareness, for technical assistance and/or capacity building beyond the project, to mainstream PPI implementation and remove obstacles to introduce innovative solutions to the market.

A wide variety of settings are potentially relevant for the implementation of such innovative solutions, for example primary health care settings, hospitals, specialised centres, long-term care facilities and home settings. The involvement of end-users (including for analysing the impact of the deployed solutions on health professionals and patients across the care continuum) and the use of cross-sectorial approaches are necessary. The use of real-world data is encouraged.

Transfer and adaptation of solutions and/or interventions from other sectors to healthcare is possible. The topic is open both to innovations bringing improvements mainly based on one specific solution/technology field, as well as to innovations delivering end-to-end solutions that need combinations of different types of innovative elements. Proposals are strongly encouraged to build upon past work and build synergies with past or ongoing EU-funded

initiatives, for example the Joint Actions JADECARE [116] and Xt-EHR [117], the projects Procure4Health[118], XpanDH[119], i2X, MyHealth@MyHands, the European Partnerships on Transforming Health and Care Systems[120], Personalised Medicine and Rare diseases[121], as well as with actions supported under the Technical Support Instrument and the Cohesion Policy Funds.

HORIZON-HLTH-2027-01-CARE-02: Personalised approaches to reduce risks from Adverse Drug Reactions due to administration of multiple medications

Call: Cluster 1 - Health (Single stage - 2027/1)	
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 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. 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 4 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting research and innovation activities that are enabling or contributing to one or several expected impacts of destination 4 "Ensuring access

116 https://www.jadecare.eu/
117 https://www.xt-ehr.eu/
118 https://cordis.europa.eu/project/id/101057209; https://procure4health.eu; https://procure4health.eu/wp-content/uploads/2025/04/P4H-Action-Plan-v.2.pdf (Action Plan released on 5 May 2025)
119 https://cordis.europa.eu/project/id/101095594
120 https://cordis.europa.eu/project/id/101095654 ; https://www.thcspartnership.eu/
121 https://cordis.europa.eu/project/id/101156595; https://erdera.org/

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

- Patients benefit from decreased incidence of adverse drug reactions (ADRs) caused by the administration of multiple medications (three or more) and enhanced health outcomes by ensuring safer and more effective use of medication.
- Healthcare professionals can adopt adverse drug reactions prevention and reduction strategies to integrate genetic and other biomarker information into clinical decision-making to optimise the use of medication, especially in situations of comorbidities.
- Healthcare systems will benefit from cost savings thanks to reduced hospital admissions and other costs associated with ADRs related to the intake of multiple medicines.
- Clinical and regulatory guidelines and policies for medication management in case of multiple medications can be revised supported by robust evidence.
- Educational programs for healthcare providers and patients can benefit from improved awareness and management of polypharmacy and ADRs.

Scope: While medicinal products contribute considerably to the health of EU citizens, they can also have adverse effects. It is estimated that around 5% of all hospital deaths are due to an adverse drug reaction. On average, 16% of hospitalised older patients experience significant ADRs, varying in severity and mostly preventable, with commonly prescribed drug classes (such as diuretics, anti-bacterials, antithrombotic agents, analgesics, antineoplastics, etc.) accounting for most ADRs[122]. Overall, ADRs increase morbidity, mortality, hospitalisations, and healthcare costs.

ADRs from multiple medications contribute significantly to healthcare costs due to increased hospitalisations and treatments, making this an area of focus to achieve cost efficiency. At the same time, the EU has an increasing proportion of older adults among its population, who have multiple chronic conditions with the related increased likelihood of polypharmacy and ADRs, warranting better management strategies. Therefore, it is important to find better ways of tailoring treatments to the individual genetic and health conditions of the patients, having also in mind the demographic challenge of an aging population.

Initial failure to recognise ADRs can generate inappropriate prescription cascades, in which the side effects of drugs are misdiagnosed as symptoms of new problems, resulting in further prescriptions and further side effects that tend to accumulate, confusing and complicating the diagnostic while aggravating the evolution. Therefore, there is a distinct need for research to help identify and prevent such prescription cascades, possibly by maximising the use of technology, as well as to improve multiple drug management in order to reduce patient harm.

[122] Emma L. M. Jennings et al., In-hospital adverse drug reactions in older adults; prevalence, presentation and associated drugs—a systematic review and meta-analysis, *Age and Ageing* 2020; 49: 948–958 doi: 10.1093/ageing/afaa188

Research activities under this topic should make use of the constantly improving health technologies and data analytics that provide new opportunities to address these issues more effectively, by better integrating medication management into healthcare practices, including into electronic health records (EHR) and decision support systems.

Identifying and validating relevant biomarkers for better patient stratification can contribute to significantly decreasing the risk of adverse drug reactions. Biomarkers can also help to detect adverse drug reactions early before occurrence of clinical symptoms and enable early countermeasures. Generating knowledge on the interaction and complexity of biochemical pathways can improve the understanding of patients' response to ADRs and thus provide better tailored treatments and early responses to adverse reactions.

For this purpose, any biomedical strategy that allows a better stratification of patients to identify drug response patterns in well-defined patient groups could be used, including in-vitro or in-silico models for adverse drug reactions, drug-drug/drug-gene/drug-food interactions, imaging biomarkers, therapeutic dose reduction and pharmaco-exposomics, nutrition and beverage interference, pollution etc. De-escalation studies in view of improving multiple drug management can be also considered. Projects should be sufficiently robust to examine differences across various populations, and also consider sex difference in drug reactions.

The further use of results generated by the projects should be ensured through data sharing with the relevant stakeholders and the European Medicines Agency, in view of possible adoption of deprescribing or adjusted-prescribing guidelines by relevant authorities at EU and national levels.

Applicants are strongly encouraged to follow all relevant guidelines in the relevant scientific fields, including but not limited to:

- Joint EMA/HMA/EC Workshop recommendations on pharmacogenomics in medicines regulation and on implementation into clinical practice[123];
- Pharmaceutical development of medicines for use in the older population, Scientific guideline from the European Medicines Agency (EMA)[124];
- Guidelines from the Pharmacogenetics Implementation Consortium (‘CPIC guidelines’)[125].

Proposals funded under this topic should address all of the following aspects:

- Leverage the role of pharmacogenomics, pharmacokinetics and pharmacodynamics in predicting and preventing adverse drug reactions in situations of multiple medications

123 https://www.ema.europa.eu/en/documents/report/report-joint-ec-hma-ema-multi-stakeholder-workshop-pharmacogenomics-24-september-2024_en.pdf

124 https://www.ema.europa.eu/en/pharmaceutical-development-medicines-use-older-population-scientific-guideline

125 https://cpicpgx.org/guidelines/

(three or more drugs administered concomitantly), and propose personalised medicine approaches, such as targeted therapies and biomarker-driven treatment strategies, to reduce the rate of adverse drug reactions and limit multiple medications;

- Maximise the use of technology, such as electronic health records, artificial intelligence and clinical decision support systems, to support safe medication use and prevent adverse drug reactions;
- Address the ethical, regulatory, and implementation challenges associated with integrating personalised medicine into clinical practice to address adverse drug reactions due to the administration of multiple medications;
- Generate evidence on the clinical utility and cost-effectiveness of treatment guided by pharmacogenomics and other relevant biomarkers-based approach, for single drugs and for combinations of drugs;
- Develop and implement strategies, including regulatory science approaches, for efficient integration of project results into daily healthcare;
- Align with similar work in other EU-funded projects or partnerships, such as the European Partnership for Personalised Medicine, the European Partnership for Transforming Health and Care Systems[126] etc. while avoiding any potential overlaps.

Applicants should provide details of their clinical studies[127] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2026-01-CARE-03: Identifying and Addressing Low-Value Care in Health and Care Systems

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 50.00 million.
Type of Action	Research and Innovation Actions
Eligibility	The conditions are described in General Annex B. The following

126 https://cordis.europa.eu/project/id/101095654 ; https://www.thcspartnership.eu/

127 Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

conditions	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 4 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims to support research and innovation activities that enable or contribute to one or several expected impacts of Destination 4: "Ensuring access to innovative, sustainable, and high-quality healthcare." Proposals under this topic should aim to deliver results that are directed, tailored, and contribute to all of the following expected outcomes:

- Healthcare providers and policymakers make use of evidence-based indicators and methodologies to identify low-value care[128] practices, as well as opportunities for improvement and tools to monitor such improvements.
- Healthcare professionals are equipped with the knowledge and tools to implement guidelines for reducing or discontinuing low-value care activities and maintaining effective and patient-centred practices that ensure quality of care.
- Patients and citizens benefit from more effective healthcare, by understanding and endorsing measures that reduce low-value care, recognising the potential to achieve higher-quality healthcare and better health outcomes overall.
- Health and care systems benefit from a reduction of low-value care practices, which enables enhanced patient safety and quality of care, while contributing to their efficiency as well as fiscal and environmental sustainability.
- Healthcare organisations can, by identifying low-value care practices, reallocate valuable healthcare resources to other areas of need.

[128] Definition of low-value care from the Report by the Expert Group on Health Systems Performance Assessment: *"From a health system perspective, low-value care encompasses overuse, misuse and underuse of healthcare services (for example, prevention, diagnostics, treatment, medication). Overuse and/or misuse comprise the delivery of harmful, ineffective, inappropriate, or not cost-effective healthcare services. Underuse refers to healthcare services not provided or used despite being necessary. Low-value care can lead to negative consequences for patients, their caregivers, the healthcare workforce, the health system as a whole and the wider environment."*

Scope: Low-value care, as defined in the footnote, can have widespread negative consequences for patients, caregivers, healthcare professionals, the health and care system, and the broader environment. A 2017 OECD report[129] estimated that "wasteful healthcare spending is common" and that "up to one-fifth of healthcare spending could be redirected towards better uses". Low-value care represents a significant challenge, contributing to waste, costs, misuse of resources, and inefficiencies. Addressing low-value care can free up and allow reallocation of valuable healthcare resources to other areas of need, thereby maximising health outcomes, improving health and care systems resilience, and reducing their environmental impact. In this context, a recent report[130] by the Expert Group on Health Systems Performance Assessment (HSPA)[131] establishes the methodological basis and metrics to identify, measure and reduce low-value care.

Research activities under this topic should adopt a patient-centred approach that considers the needs and preferences of patients and citizens. They should promote socially acceptable solutions, taking into account relevant ethical, social and legal aspects and foster dialogue and collaboration between policymakers, healthcare providers, healthcare professionals, and patients/citizens. By doing so the projects will contribute to better use of healthcare resources - including time and personnel - in ways that significantly improve patient outcomes and alleviate the increasing burden on healthcare professionals and health systems. Implementation research and multidisciplinary approaches should be considered to foster adoption and ensure effective interventions and long-term sustainability.

Proposed activities may include clinical studies[132] to provide evidence on the value of any interventions or processes and, therefore, facilitate justified removal of any type of low value care. Proposed activities may also include data models, digital and artificial intelligence-based analysis, models and/or tools to identify and/or address low-value care. Proposed activities may examine the design and impact of healthcare payment systems, that could unintentionally incentivise low-value care and evaluate alternative financing models that better align incentives with patient outcomes and high-value care. Additionally, activities that facilitate learning and best practice transfers between countries or regions may also be considered as element of the proposal (for instance, to leverage best practice-sharing initiatives from international platforms such as the Knowledge Hub of the European Partnership on Transforming Health and Care Systems or any other relevant European or global initiatives).

Research actions should address all of the following objectives:

- Develop a deeper understanding of how low-value care can be identified and measured throughout the healthcare process, including testing related indicators and producing

129 OECD (2017), Tackling Wasteful Spending on Health, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264266414-en

130 Report by the Expert Group on Health Systems Performance Assessment: "Identifying, Measuring And Reducing Low-Value Care In The Context Of Health System Performance Assessment". https://health.ec.europa.eu/publications/identifying-measuring-and-reducing-low-value-care-context-health-system-performance-assessment_en

131 https://health.ec.europa.eu/health-systems-performance-assessment_en

132 See introduction to this work programme part.

evidence-based methodologies that enable the pursuit of improved efficiency and quality of care.

- Identify instances of overuse, misuse, underuse and unwarranted variation in specific healthcare contexts across different stages of the healthcare process. This analysis should provide actionable insights for policymakers, healthcare providers and healthcare professionals to evaluate the potential of possible strategies for reducing low-value care, allowing for more informed decision-making and improved care practices.

- Develop and pilot effective strategies for reduction of low-value care in specific settings. These pilots should demonstrate scalability and transferability across diverse health and care systems in Europe.

Proposals should consider how gender norms and roles influence utilisation patterns, ensuring that strategies to reduce low-value care do not inadvertently exacerbate existing gender and social inequalities in healthcare access and outcomes. In addition, attention should be paid to intersectional factors that may further affect healthcare access and outcomes. If handling data and indicators, sex- and gender-disaggregated data should be collected and analysed, incorporating intersectional factors where feasible.

Proposals should consider the work and output of any EU level (e.g. the Expert Group on Health Systems Performance Assessment, the European Partnership on Transforming Health and Care Systems [133], relevant projects or Joint Actions funded under the EU4Health programme and under EU Research & Innovation Framework Programmes, etc.) or international initiatives in this area (e.g. the 2017 OECD report mentioned above).

Applicants should provide details of their clinical studies[134] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2026-04-CARE-04: Enhancing and enlarging the European Partnership on Personalised Medicine (EP PerMEd) (Top-up)

Call: Partnerships in Health (2026/3)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 15.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

[133] https://cordis.europa.eu/project/id/101095654 ; https://www.thcspartnership.eu/

[134] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

Indicative budget	The total indicative budget for the topic is EUR 15.00 million.
Type of Action	Programme Co-fund Action
Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: The proposal must be submitted by the coordinator of the consortium funded under topic HORIZON-HLTH-2023-CARE-08-01: "European Partnership on Personalised Medicine". This eligibility condition is without prejudice to the possibility to include additional partners. 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.
Procedure	The procedure is described in General Annex F. The following exceptions apply: The evaluation will take into account the existing context and the scope of the initial evaluation as relevant, and related obligations enshrined in the grant agreement. If the proposal is successful, the next stage of the procedure will be grant agreement amendment preparations. If the outcome of amendment preparations is an award decision, the coordinator of the consortium funded under topic HORIZON-HLTH-2023-CARE-08-01: "European Partnership on Personalised Medicine" will be invited to submit an amendment to the grant agreement, on behalf of the beneficiaries.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: This action is intended to be implemented in the form of an amendment of the grant agreement concluded pursuant to Article 24(2) of the Horizon Europe Regulation. For the additional activities covered by this action: • The funding rate is 30% of the eligible costs. • Beneficiaries may provide financial support to third parties (FSTP). 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 this action in order to be able to achieve its objectives. The maximum amount to be granted to each third party is EUR 10.00 million for the duration of the partnership. However, if the objectives of the action would otherwise be impossible or overly difficult (and duly justified in the proposal) the maximum amount may be higher. • The starting date of the grant awarded under this topic may be as of the submission date of the application. Applicants must justify the need for a retroactive starting date in their application. Costs incurred from the starting date of the action may be considered eligible (and will be reflected in the entry into force date of the amendment to the grant agreement).
Total indicative budget	The total indicative budget for the duration of the co-funded Partnership is EUR 110 million.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4, notably "Ensuring access to innovative, sustainable and high-quality healthcare". It will complement the co-fund action launched under the call "Partnerships in Health (2023) (HORIZON-HLTH-2023-CARE-08)" by allowing new partners to join the EU Partnership on Personalised Medicine in order to perform additional activities. Partners from Countries recently Associated to Horizon Europe from 2024 onwards (2024 included) are particularly welcome. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- European countries and regions, along with international partners, are engaged in enhanced collaborative research efforts for the development of innovative personalised medicine approaches regarding prevention, diagnosis and treatment;

- Healthcare authorities, policymakers and other stakeholders develop evidence-based strategies and policies for the uptake of personalised medicine in national or regional healthcare systems;

- Health industries, policymakers and other stakeholders have access to efficient measures and investments to allow swift transfer of research and innovation into market;

- Health industries and other stakeholders can accelerate the uptake of personalised medicine through the adoption of innovative business models;

- Healthcare authorities, policymakers and other stakeholders use improved knowledge and understanding of the health and costs benefits of personalised medicine to optimise healthcare and make healthcare systems more sustainable;

- Healthcare providers and professionals improve health outcomes, prevent diseases and maintain population health through the implementation of personalised medicine;

- Stronger and highly connected local/regional ecosystems of stakeholders, including innovators, are in place and facilitate the uptake of successful innovations in personalised medicine, thus improving healthcare outcomes and strengthening European competitiveness; Citizens, patients and healthcare professionals have a better knowledge of personalised medicine and are better involved in its implementation;

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

Scope: This call targets an action under Article 24(2) HE Regulation aiming to add additional activities to existing grant agreements, together with additional partners that would deliver on those activities. The existing action, the European Partnership on Personalised Medicine (EP PerMed) can only reasonably be enhanced and enlarged on the basis of the existing consortium, which was awarded the grant pursuant to the call "Partnerships in Health (2022) HORIZON-HLTH-2022-CARE-08". This consortium was involved in the associated H2020 actions, submitted the proposal which resulted in the identification of the partnership in the strategic planning, and it is otherwise obvious that the co-funded framework established could not simply be replaced without significant disruption given the top-quality, long-term expertise and wide coverage of the beneficiaries comprising this consortium.

The additional activities to be performed by applicants under this call topic will consists of several of the following:

- Organisation of activities or tools according to their expertise and interests, e.g.:
    - Personalised Medicine (PM) Innovation related activities and tools, business and entrepreneur relations and support, case studies and guides,
    - PM public health and social care, people's engagement, activities to support health system's ability to turn scientific discoveries into new or improved treatments and services, support the scientific community to tackle complex health and social care challenges, international outreach,
    - PM and diversity, underrepresented populations, gender aspects, health data and knowledge mobilisation activities, PM and rare diseases,
    - PM related genomics, expert and societal exchange on genomics, opportunities by genomics for innovations and economic growth.
- Contribute to the design and implementation of the specific topics and features of the Transnational Joint Calls as of 2026 to which new partners will contribute national commitments;

- Specific, tailored contributions to other EP PerMed calls such as: Fast Track, Venture Creation Programme, Networking, Twinning calls, Call for surveys, Education calls, etc.
- Organisation of specific EP PerMed events, such as in-situ visits (WP5), summer schools (WP3/4);
- Contribution to the development and dissemination of strategic documents in additional geographical areas, for example the SRIA updates;
- Development and implementation of other new PM tailored activities within the related WPs.

While the award of a grant to enhance and enlarge the Partnership in accordance with this call should be based on a proposal submitted by the coordinator of the consortium funded under "HORIZON-HLTH-2023-CARE-08-01" and the additional activities (which may include additional partners) to be funded by the grant should be subject to an evaluation, this evaluation should take into account the existing context and the scope of the initial evaluation as relevant, and related obligations enshrined in the grant agreement.

Taking into account that the present action is an enhancement and enlargement of the topic "HORIZON-HLTH-2023-CARE-08-01: European Partnership on Personalised Medicine" and foresees an amendment to an existing grant agreement, the proposal should present the additional activities (including additional partners) to be covered by the award primarily in terms of grant agreement revisions.

Destination - Developing and using new tools, technologies and digital solutions for a healthy society

Topics under this destination are directed towards the Key Strategic Orientation 2 "*The Digital Transition*" and Key Strategic Orientation 3 "*A More Resilient, Competitive, Inclusive, and Democratic Europe*" of Horizon Europe's strategic plan 2025-2027.

Research and Innovation supported under this destination should contribute to the following expected impact, set out in the strategic plan impact summary for the Health Cluster: "*Health technologies, data, new tools, and digital solutions are applied effectively thanks to their inclusive, ethically sound, secure and sustainable delivery, integration and deployment in health policies and in health and care systems*."

The Health Cluster will continue to drive the development and adoption of innovative technologies and digital solutions to improve healthcare and health systems. This will ensure that the EU remains at the forefront of breakthrough health and medical technologies and can achieve open strategic autonomy in essential medical supplies and digital innovations.

In line with the Commission's political guidelines 2024-2029, this destination will support research and innovation in tools and technologies strengthening the competitiveness of European health industry and reinforcing EU autonomy. This effort will contribute to the completion of the European Health Union which aims to enhance the resilience of healthcare systems, facilitate access to innovative and affordable healthcare solutions, and ensure that all citizens have access to high-quality, equitable, and sustainable healthcare.

The development and use of innovative tools and technologies for biomedical research are the basis for prevention, early diagnosis, efficacious therapy and patient monitoring, essential components of efficient healthcare. These include enabling technologies, not least innovative biotechnological approaches, and emerging technologies like synthetic biology, digital tools including those based on ML/AI and other data-driven approaches which will enable the development of more personalised medicine. Hence the combination of innovative tools, high-quality health data (incl. real world data), digital technologies, modelling and AI tools holds great potential not only for advancing biomedical Research and Innovation but for developing health technologies that improve healthcare.

However, the implementation of these tools and technologies faces specific barriers such as scalability, regulatory frameworks and public acceptance and trust. To overcome these challenges cross-sectoral cooperation among stakeholders including researchers, regulatory bodies, policymakers, industry, healthcare providers and patients, is necessary. This collaboration will facilitate the design and development of innovative health products and services, tailored to specific population groups, ultimately improving patient outcomes and reducing health inequalities.

By taking a comprehensive and inclusive approach, this destination will prioritise the development of novel tools and technologies that address key considerations such as the rights

of the individual, safety, effectiveness, appropriateness, accessibility, comparative value-added and fiscal sustainability while also ensuring ethical, legal and regulatory compliance.

In this work programme part, Destination "*Developing and using new tools, technologies and digital solutions for a healthy society*" is driven mainly by three key Commission policies, the "Biotechnology and Biomanufacturing Strategy[135]" the "Artificial Intelligence Strategy[136]" and the European Life Science Strategy[137] and focus on developing and applying innovative technologies to improve human health and healthcare systems. The topics under this destination cover efforts to develop AI based predictive biomarkers for disease prognosis and treatment response, advancing bio-printing of living cells for regenerative medicine, and integrating new approach methodologies (NAMs) to advance biomedical research, as well as developing virtual human twins for integrated clinical decision support

To increase the impact of EU investments under Horizon Europe, the European Commission encourages cooperation between EU-funded projects to enable cross-fertilisation and other synergies. For example, this cooperation could take the form of networking, to joint activities, such as the participation in joint workshops, exchange of knowledge, development and adoption of best practices, or joint communication activities. Opportunities for such activities and potential synergies exist between projects funded under the same topic but also between other projects funded under different topics, Clusters or pillars of Horizon Europe. Specifically, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health (under pillar III of Horizon Europe) or with projects on themes that cut across the clusters of Pillar II such as with Cluster 4 "Digital, Industry and Space" on digitalisation of the health sector or key enabling technologies.

Expected Impacts:

Proposals for topics under this destination should set out a credible pathway towards the development and use of new tools, technologies and digital solutions for a healthy society, and more specifically to one or several of the following impacts:

- Europe's scientific and technological expertise and know-how, its capabilities for innovation in new tools, technologies and digital solutions, and its ability to take-up, scale-up and integrate innovation in healthcare is world-class.

- Citizens benefit from targeted and faster research resulting in safer, more sustainable, efficient, cost-effective and affordable tools, technologies and digital solutions for improved (personalised) disease prevention, diagnosis, treatment and monitoring for

[135] Commission Communication on Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU; COM(2024) 137 final: https://research-and-innovation.ec.europa.eu/document/download/47554adc-dffc-411b-8cd6-b52417514cb3_en

[136] Commission Communication on Artificial Intelligence for Europe; COM(2018) 237 final: https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:237:FIN

[137] Reference to be added once the strategy published (June)

better patient outcome and wellbeing, in particular through increasingly shared health resources (interoperable data, infrastructure, expertise, citizen/patient driven co-creation)[138].

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

Proposals are invited against the following topic(s):

HORIZON-HLTH-2027-01-TOOL-01: Development of predictive biomarkers of disease progression and treatment response by using AI methodologies for chronic communicable diseases

Call: Cluster 1 - Health (Single stage - 2027/1)	
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 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.

[138] Commission Communication on the digital transformation of health and care; COM(2018) 233 final

	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 4 (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 "Developing and using new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contribute to all of the following expected outcomes:

- Clinical researchers and developers have access to novel predictive biomarkers to guide a more accurate assessment of disease progression and treatment response and tackle the unmet clinical needs of non-communicable chronic diseases.
- Clinicians and healthcare professionals use clinically validated predictive biomarkers for implementing more effective clinical research and personalised medicine with better health outcomes in chronic non-communicable diseases.
- All stakeholders have access to trustworthy AI-tools to support the validation of multimodal predictive biomarkers of higher accuracy and clinical value when compared to the established practice.
- The citizens benefit of better health outcomes thanks to improved clinical guidelines and the implementation of effective biomarker-guided clinical research and personalized healthcare.

Scope: Biomarkers[139] are invaluable tools for improving patient outcomes, guiding treatment decisions, accelerating personalised medicine, more effective clinical research and the development of better medicines.

However, despite the scientific discoveries of many clinically relevant biomarkers, estimated on the scale of tens of thousands, only a few biomarkers have been implemented in clinical practice. The traditional 'one biomarker' paradigm is insufficient for addressing the unmet clinical needs of chronic, progressive and multifactorial diseases, due to the complexity of the clinical phenotypes characterized by broad inter-and intra-patient heterogeneity. The established biomarkers have limitations in their use as prognostic and predictive indicators,

[139] See definition as in the IHI JU Strategic Research and Innovation Agenda

for the assessment of the disease progression and the choices of the optimal therapeutic interventions tailored to the patients' characteristics.

Therefore, the topic focuses on the clinical development of predictive biomarkers of disease progression and treatment response for chronic non-communicable diseases (excluding cancer) by using mature AI methodologies able to combine data of clinically used and candidate biomarkers, with available data from relevant clinical studies, longitudinal and real-world data[140] (RWD). This topic is expected to support collaborative projects paving the way for future innovations in personalized medicine and enabling more timely and effective therapeutic interventions.

The proposals should address all the following research and innovation activities:

- Set-up a multidisciplinary collaboration to map and evaluate the available information and data on biomarkers currently used in the clinical setting, candidate biomarkers from past and ongoing clinical studies, which are scientifically proven as clinically relevant to the disease progression and treatment response for the chronic non-communicable diseases under study.

- Adapt and apply of established AI methods rather than developing novel ones from scratch, to deliver novel prognostic and predictive biomarkers of disease progression and treatment response, by integrating data of currently used and candidate biomarkers, with suitable data from available longitudinal and other relevant clinical studies, including RWD, as necessary. To guarantee a solid and fast optimisation and training of the AI tools, the applicants should document their access to the appropriate clinical data. The biomarkers under study should be multimodal, covering for instance molecular, cellular, physiological, imaging, behavioural and digital markers, and/or their combinations The applicants should convincingly justify their rationale why the development of the multimodal biomarkers proposed is imperative to tackle the unmet clinical needs of the chronic non-communicable diseases under study.

- Use AI and, where needed, other relevant data and knowledge integration methods, to describe the relationships among different biomarkers and support the robust prioritisation of predictive biomarkers tailored to the characteristics of the patients' and their disease stage and treatment response. Proposals should have strong emphasis on the trustworthiness of AI tools and develop the adequate performance metrics to assess their technical robustness, in terms of accuracy, reliability, reproducibility, including the assessment of possible inherent bias introduced. Moreover, proposals should consider the development of user-friendly and fit-for-purpose visualization interfaces to help clinicians understand and guide them for better clinical assessment across diverse patient groups.

[140] EMA definition: "Real-World Data are routinely collected data relating to patient health status or the delivery of health care from a variety of sources other than traditional clinical trials (e.g. claims databases, hospital data, electronic health records, registries, mhealth data, etc.)".

- Assess the clinical utility of the predictive biomarkers in independent disease cohorts, RWD and exploratory clinical studies to demonstrate their clinical value as prognostic and predictive indicators for more effective clinical research and better patient health outcomes as compared to the established clinical practice of chronic non-communicable diseases. Prospective clinical studies are expected to be led by entities in the EU to strengthen the EU leadership in clinical research.

- Develop a business plan for the market exploitation of the research outputs and a regulatory strategy to support the alignment to the regulatory requirements for the qualification of the biomarkers and/or AI tools and engage with the regulators in a timely manner. The applicants should prioritise the exploitation of their research results in the EU and hence boost the EU competitiveness in the health innovations and technologies developed. SME(s) participation is encouraged with the aim to strengthen the scientific and technological basis of SME(s) and valorise their health innovations.

It is imperative that applicants should adhere to GDPR-compliant personal data protection and implement the appropriate measures.

Applicants should provide details of their clinical studies[141] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2027-03-TOOL-02: Advancing bio-printing of living cells for regenerative medicine

Call: Cluster 1 - Health (Single stage - 2027/2)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 7.00 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 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.

[141] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	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 4 (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 "Developing and using new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contribute to most of the following expected outcomes:

- Biomedical scientists from academia and industry will gain access to entire bio-printing units designed to regenerate human tissue.
- Healthcare professionals acquire information on the safe and effective use of equipment enabling advanced therapies with bio-printed human tissue.
- Healthcare providers dispose of tools enabling them to treat conditions of unmet medical need.
- Individual patients will benefit from a personalised approach to their respective medical condition thanks to the bio-printed regenerative medicine solution.

Scope: Tissue-specific functional 3D bio-printing of living cells has made significant progress as a new approach for transplantation applications in regenerative medicine. There are currently several types of bio-printing technologies under development for the repair of different targeted tissues or organs. To fully unleash the potential of bio-printed cell constructs for regenerative medicine several bottlenecks still need to be overcome. Various studies in pre-clinical models have shown that bio-printed cell constructs or tissues hold great promise for transplantation medicine, by allowing autologous tissue grafts being printed thus avoiding adverse graft-host reactions. However, translation of such approaches into clinical settings (i.e. humans) and their application to internal organs still needs to be investigated and demonstrated. Dependant on the actual target site (i.e. the defect tissue or organ in the human body) different bio-printing approaches may be preferable. "In-situ" bio-printing, sometimes also referred to as "in-vivo", or as "intraoperative", reflects a bioprinting process performed on a live subject in a surgical setting and has been proposed to have significant advantages over an in-vitro bio-printing technique followed by transplantation. In-situ bio-printing involves direct patterning of bio-inks onto a patient's body at the target site, allowing for precise construction of a site-matching tissue-structure within the actual physiological location where regeneration or repair is needed. As such, in situ bio-printing allows for high

adaptability, reduced risk of contamination, improved cell viability, function and host integration. The high cell densities present in the human vital organs underscore the importance of bio-inks which contain less additional biomaterials as matrix. Hence the bio-printing of cell constructs that comprise native tissue-like cell densities may facilitate repair and/or regeneration of defect internal organs. For such approaches meticulous engineering of the bio-printing equipment is necessary, involving sophisticated micro-surgical instrumentation and medical imaging platforms.

To address these challenges, researchers should work in multidisciplinary teams with engineers, biomedical scientists, cell biologists and medical doctors. Proposals should be based on the use of human cells and address all the following activities:

- Develop or improve existing bioprinting equipment that comprises all steps of the bio-printing suite to print bio-constructs with high cell-density for improved vascularization and faster repair of the defect in the body;
- Scale-up the chosen bio-printing technology to a GMP-conform/compliant manufacturing process;
- Perform all necessary regulatory work enabling the conduct of clinical studies and assess the clinical value of the developed bio-printing technology in first in-human studies.

Priority should be given to bio-printing approaches that either target vital internal organs followed by surgical grafting or employ in-situ approaches depositing the cell-laden bioink directly from the printhead on the defect target site in the body.

Regulatory knowledge of the field is desired and should be documented through contacts with relevant national or international European regulatory authorities. A good understanding of the different steps involved and the inherent risks in each of these steps will be a basis to identify appropriate safety and quality requirements. Requirements from the different established EU frameworks on substances of human origin (SoHO), medical devices and pharmaceuticals including advanced therapy medicinal products (ATMP) are to be considered for manufacturing/preparation as well as for clinical outcome monitoring. A combination of requirements from different frameworks might be most appropriate to allow for responsible and fast uptake.

The chosen medical area (tissue, organ, condition) should be duly justified. Sex differences at the cellular level should be taken into consideration.

Preclinical stage and clinical development are eligible. The involvement of SMEs is encouraged.

Applicants should provide details of their clinical studies[142] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2026-01-TOOL-03: Integrating New Approach Methodologies (NAMs) to advance biomedical research and regulatory testing

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 5.00 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. 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 4 (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: 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

[142] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	Research and Training Programme of the European Atomic Energy Community (2021-2025) [143].

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination "Developing and using new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contribute to several of the following expected outcomes:

- Researchers are in possession of improved human-relevant platforms that capture the genetic, phenotypic, age-related, immune, microbiome, and environmental exposure variability of the human population. These innovations support more equitable healthcare solutions, personalized treatment strategies across diverse life stages. and more accurate safety assessment of industrial chemicals and other substances.

- Industry gets access to platforms that allow a faster pace of innovation for the development of more cost-effective targeted therapeutic interventions and improvement of the safety assessment of chemicals, medicinal products, and medical devices.

- Patients benefit from innovative platforms and strategies that improve prediction, prevention and treatment of diseases, in particular through enhanced understanding of disease pathways and mechanisms.

- The general population is protected through a safer environment, as these platforms enhance the detection and mitigation of risks posed by chemicals and other potentially harmful substances.

- Regulatory bodies gain confidence and trust in NAMs, supporting their integration into product development, risk assessment, and approval processes.

- Fewer live animals are used in biomedical research and regulatory testing.

Scope: This topic aims to catalyse a paradigm shift in biomedical research and safety assessment of chemical compounds by fully integrating New Approach Methodologies (NAMs) across the entire research and regulatory spectrum, from basic discovery phase to clinical application, and regulatory testing of medicinal products and medical devices, or industrial and environmental chemicals.

NAMs include a wide range of innovative and human-relevant technologies such as *in vitro* assays, organoids, Organ-on-Chip (OoC) systems, human tissue models, induced pluripotent stem cell (iPSC) applications, virtual twin tools, *in silico* methods, and artificial intelligence (AI)-driven modeling.

[143] 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

Although the European Commission and several Member States have supported the development of NAMs for over two decades, primarily in the context of chemical risk assessment, regulatory uptake remains limited. Therefore, the time is ripe to take a decisive step forward by delivering validated NAMs solutions that can be adopted by industry and accepted by the regulators for the safety assessment of chemicals. In parallel, there is a growing readiness to expand the development and application of NAMs across the entire biomedical research spectrum, from early discovery through to clinical translation and regulatory testing of medicinal products and medical devices.

Proposal(s) should bring together stakeholders from academia, SMEs, industry, and regulators to develop new platforms or improve existing ones that closely replicate human physiological and pathological conditions. These platforms should enhance disease modeling precision, especially in areas where animal models are of limited translational relevance or where they can be effectively complemented by human-relevant alternatives. These approaches should also strengthen the safety assessment of chemicals, other medicinal products and medical devices.

Proposal(s) should focus on biomedical applications and/or regulatory testing. For proposal(s) addressing regulatory use, the intended context(s) of use must be clearly defined, with validation strategies and methodologies aligned with current OECD and/or EMA guidance. Proposal(s) should also demonstrate early, proactive, and sustained engagement with relevant regulators.

Proposal(s) should develop or optimize scalable and reproducible platforms based on one or more of the following:

- Advanced *in vitro* assays;
- Induced pluripotent stem cells (iPSC)-based models, organoid or complex Organ-on-Chip systems derived from patients and/or healthy donors;
- Use of human tissues that closely replicate physiological and pathological conditions.

Proposal(s) should integrate embedded sensors to enable real-time monitoring of physiological responses. They should also address biological diversity, reflecting variations in genetics, phenotype, age, immune status, and microbiome across the population.

Where appropriate, proposal(s) may incorporate one or both of the following complementary approaches to enhance predictive power and clinical relevance:

- AI-driven predictive modelling trained on high-quality, curated, bias-minimised datasets to predict outcomes of biomedical interventions, or risk assessment;
- Use of virtual twin technology to simulate disease progression, responses to interventions, and support the optimization of clinical trials.

To maximise scientific impact, interoperability, and reuse, all data generated should comply with FAIR principles (Findable, Accessible, Interoperable, Reusable). Proposal(s) should

describe how data will be curated, standardised, and shared within or linked to the European Health Data Space (EHDS) and/or relevant ESFRI research infrastructures.

Applicants should provide details of their clinical studies[144] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2027-01-TOOL-04: Virtual Human Twins (VHTs) for integrated clinical decision support in prevention and diagnosis

Call: Cluster 1 - Health (Single stage - 2027/1)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 10.00 and 12.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
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. 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 4 (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 "Developing and using new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contribute to all the following expected outcomes:

[144] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

- Clinicians and other healthcare professionals have access to and/or use multi-scale, multi-organ computational models of individual patients that aim to improve the current standard for prevention and diagnosis in areas of high disease burden.

- Health professionals benefit from enhanced knowledge of complex diseases and co-morbidities by recourse to multi-scale, multi-organ models.

- Patients of any age group benefit from improved, integrated and personalised prevention and diagnostics tools, tailored to their individual condition.

- Health professionals and patients benefit from the use of 'virtual twin' models which enable integration of other preventive and diagnostic tools and modalities.

Scope: Virtual human twins (VHTs) are digital representations and in-silico models of an individual's health and disease at different levels of human anatomy (e.g. cells, tissues, organs or organ systems) for the prevention, prediction, screening, diagnosis and treatment of a disease, as well as the selection and personalisation of intervention options[145]. Multi-scale[146], multi-organ VHT solutions, have a potential for tailored, more optimal prevention and diagnosis, particularly in areas of high disease burden, including when integrated with other decision support tools in care pathways. They can have a significant positive impact on citizens' health and contributing to the efficiency of EU health systems.

The proposals should take into account the work of call HORIZON-HLTH-2023-TOOL-05-03, which had a predominant focus on disease management, and focus on high potential multi-disciplinary approaches at greater complexity (multiscale, multiorgan, longitudinal), strengthening their deployment in health and care, including the integration into care pathways and links with other decision support tools. A further aim is to accelerate translational research towards cost-effective adoption and integration of advanced health technologies in healthcare.

The proposals should address all of the following activities:

- Select clinical use cases to deliver multi-disciplinary high impact solutions requiring multi-organ, multi-scale approaches to modelling complex pathophysiology over time, as a basis from where prevention and diagnosis of diseases with high morbidity and mortality could be enhanced. Proposals can put forward use cases in any areas of high disease burden; example areas include and are not limited to co-morbidities, chronic cardiovascular conditions, infection and (auto)immunity, inflammation and cancer, diabetes and related conditions, rare diseases, degenerative diseases (including their interaction with mental health conditions), the exposome and its impact on human health and disease.

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145 See the 'European Virtual Human Twin' Coordination and Support Action, EDITH, funded under the DIGITAL programme https://www.edith-csa.eu/

146 In the context of this topic, multi-scale refers to modelling at different levels of human anatomy, e.g. at (sub-) cellular, tissue, organ or organ system level.

- Building on current approaches, standards, data repositories (for example, biobanks, environmental data, others) and modelling assets (e.g. those of the EDITH CSA and the Advanced VHT Platform funded by the Digital Europe Programme), and new data if relevant, design, develop, extend and validate multi-organ, multi-scale, dynamic computational models that accurately simulate a person's health and disease states, as necessary.

- Evaluate, select, extend and validate diverse modelling methodologies, resulting in integrated, advanced, interoperable, patient-specific VHT models that can integrate diverse data sources and methodologies, addressing the chosen clinical use case requirements. Methodologies may include and are not limited to physics-based modelling, artificial intelligence (AI), including for example explainable AI approaches, generative AI and in-silico modelling, agent-based and network physiology approaches. Evaluation, selection and extension of these must be documented during the design phase. Availability and integration of the multi-modal data must be documented, and the ethical and sex/gender dimensions be investigated.

- Demonstrate integration of these models with other advanced preventive and diagnostic modalities, tools and techniques enabling integration across pathways.

- Generate evidence, including clinical validation, that these advanced, integrated solutions deliver clinically meaningful decision support, addressing use case requirements. Lessons-learned for broader application should be documented. Evidence should also be gathered via health economic and/or feasibility studies in healthcare settings, confirming cost-effectiveness vis-à-vis current practice in real-world health settings (e.g. cost-effectiveness analysis or other suitable methodology). An exploitation plan on regulatory compliance (e.g. with Medical Devices Regulations, AI Act) and intellectual property should be produced for enabling uptake.

Proposals should be multidisciplinary; solution design and development should be end-user-focused and draw on user (and non-user) input. Best practice in VHT model software development including responsible AI development (i.e. development in a safe, trustworthy and ethical manner) should be followed, examples include and are not limited to risk assessment and management, requirements definition process. SME(s) participation is encouraged to strengthen their scientific and technological basis and validate their innovations for citizen benefit.

Proposals are expected to contribute to the objectives of the European Virtual Human Twins Initiative[147] and contribute to the Platform for Advanced VHT Models supported under the Digital Europe Programme[148], with project assets aligned and made available on the Platform, and interoperable with this platform's technical specifications. Relevant consortia members

147 https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins

148 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/tender-details/16cc3c6a-844a-42d4-9746-dcc7444b8001-CN

are to join the Platform User Community of the Advanced VHT platform. Budget should be reserved to participate in these activities. No contact with the developer of the Advanced VHT Platform is requested at the proposal stage. Proposals are also expected to collaborate with the group of EU-funded projects working on VHTs[149].

Projects are also expected to align with other relevant EU initiatives, such as for example the European Cancer Imaging Initiative, the 1+Million Genomes Initiative, the Intensive Care Unit Data Space under the DIGITAL Programme, the European Partnership for Personalised Medicine, and projects on co-advancing AI in healthcare funded under the EU4Health programme where relevant.

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 should provide details of their clinical studies[150] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2027-01-TOOL-05: FP10 pilot on "follow-on funding"

Call: Cluster 1 - Health (Single stage - 2027/1)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 4.00 and 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 45.00 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

149 Including the projects funded under call HORIZON-HLTH-2023-TOOL-05-03.

150 Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	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 4 (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: 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) [151].

HORIZON-HLTH-2026-01-TOOL-06: Support to European Research Area (ERA) action on accelerating New Approach Methodologies (NAMs) to advance biomedical research and testing of medicinal products and medical devices

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project *Indicative budget*	The Commission estimates that an EU contribution of around EUR 3.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts. 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.

[151] 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

	Coordinators of projects must be legal entities established in an EU Member State or Associated Country. 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 4 (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: 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) [152].

[152] 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

Destination - Maintaining an innovative, sustainable, and competitive EU health industry

Topics under this destination are directed towards the Key Strategic Orientation 3 "*A more resilient, competitive, inclusive, and democratic Europe*" of Horizon Europe's strategic plan 2025-2027. In addition, Key Strategic Orientation 2 *"The Digital Transition"* and Key Strategic Orientation 1 "*The Green Transition*" are supported.

Research and Innovation supported under this destination should contribute to the following expected impact, set out in the strategic plan impact summary for the Health Cluster: *"the EU health industry is innovative, sustainable, and globally competitive thanks to improved uptake of breakthrough technologies and innovations (including social innovations) that make the EU with its Member States and Associated Countries more resilient and less reliant on imports of critical health technologies*".

The health industry is a key driver for growth and has the capacity to provide health technologies to the benefit of patients and providers of healthcare services. The relevant value chains involve a broad variety of key players from supply, demand and regulatory sides. In addition, the path of innovation in health is long and complex. The development of novel health technologies is generally associated with uncertainties and market barriers due to expensive and risky development (e.g., high attrition rate in pharmaceutical development), high quality and security requirements (e.g., clinical performance, safety, data privacy and cybersecurity) and market specificities (e.g., strong regulation, pricing and reimbursement issues). In addition, the growing concern about environmental issues is putting more pressure on this industry. Therefore, there is a need for Research and Innovation integrating various stakeholders to facilitate market access of innovative health technologies (medical technologies, pharmaceuticals, biotechnologies, digital health technologies).

In line with the European Commission's political guidelines for 2024-2029, and building on the recommendations of the reports by Mario Draghi[153]i and Enrico Letta[154], as well as the EU's Life Science Strategy[155], this destination will support research and innovation to enhance the competitiveness of the European health industry, thereby reinforcing EU autonomy, consolidating its Single Market, and empowering Europe to effectively address the burden of both communicable and non-communicable diseases. In this work programme part, Destination "*Maintaining an innovative, sustainable and competitive EU health industry*" focuses on collaborative efforts to advance cell-free protein synthesis platforms, ready-to-use point-of-care diagnostics, and regulatory science to support translational development of patient-centred health technologies. The results will support the EU Industrial Policy, with a focus on strengthening the resilience of the single market, addressing the EU's strategic dependencies, gaining technological sovereignty and accelerating the green and digital

153 The future of European competitiveness Mario Draghi https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059

154 Much more than a market. Enrico Letta https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf

155 Enter reference when the LS strategy is published in June

transitions. The results will further strengthen the single market, by providing evidence and guidelines for stakeholders and regulators to ensure adoption of innovations, supporting environmental, fiscal and socio-economic sustainability and at the same time fostering healthcare access and reducing health inequities. The results will also support the implementation of the relevant Regulations like those on Medical Devices (MDR) and *In Vitro* Medical Devices (IVDR) as well as the general uptake of innovative health technologies by health systems, with a special view to aspects related to ensuring industry competitiveness, fostering innovation and sustainability, while maintaining the high level of quality, safety and efficacy of these health technologies.

In view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, development and adoption of best practices, or joint communication activities. All topics are open to international collaboration to address global environment and health challenges.

Expected impacts:

Proposals for topics under this destination should set out a credible pathway to contributing to maintaining an innovative, sustainable and competitive EU health industry, and more specifically to one or several of the following expected impacts:

- Health industry in Europe and Associated Countries is more competitive and sustainable, assuring European leadership in breakthrough health technologies and open strategic autonomy in essential medical supplies and (digital) technologies, contributing to job creation and economic growth, in particular with small and medium-sized enterprises (SMEs).

- Health industry is supported by cross-sectoral Research and Innovation in the context of convergence of health technologies (integrating medical technologies, pharmaceuticals, biotechnologies, digital health, and e-health technologies) while strengthening key market positions.

- Health industry is working more efficiently along the value chain from the identification of needs to the scale-up and take-up of solutions at national, regional or local level, including through early engagement with patients, healthcare providers, health authorities and regulators ensuring suitability and acceptance of solutions.

- Citizens, healthcare providers and health systems benefit from a swift uptake of innovative health technologies and services through the provision of evidence and guidelines for stakeholders, policymakers and regulators. These efforts offer significant improvements in health outcomes, also potentially strengthening access to healthcare for all and reducing health inequities while health industry benefits from decreased time-to-market.

- Citizens, healthcare providers and health systems benefit from increased health security in Europe and Associated Countries due to reliable access to key manufacturing capacity, including timely provision of essential medical supplies and technologies of particularly complex or critical supply and distribution chains.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2027-01-IND-01: Cell-free protein synthesis platforms for discovery and/or production of biologicals

Call: Cluster 1 - Health (Single stage - 2027/1)	
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 40.00 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 4 (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 "Maintaining an innovative, sustainable, and competitive EU health industry". To that end, proposals under this topic should aim to deliver results that are directed towards and contribute to all the following expected outcomes:

- Biopharmaceutical industries get access to streamlined development and production processes for peptide- or protein-based biologicals.

- Health systems benefit from the availability of decentralized production systems for innovative health technologies that involve peptides or proteins, and which improve health and care.

- Citizens and patients will benefit from better access, availability and affordability of pharmaceuticals based on biologicals.

Scope: Cell-free protein synthesis (CFPS) has been employed in fundamental biological research for decades, however, interest for the approach as a viable means for drug development and production has only emerged in recent years. The advantages that CFPS provides in terms of efficiency, simplicity, flexibility, cost- and time savings outweigh the hurdles that are still to be overcome for CFPS to become a routine manufacturing system for peptide- or protein-based biologicals.

Currently, there are several CFPS systems used that are either based on prokaryotic or eukaryotic cell lysates (including mammalian) or fully synthetic systems consisting of all the molecular machinery necessary to create functional proteins. The choice of a specific lysate is dictated by the target protein and the end-use application. Proteins that require post-translational modification are generally produced using lysates of mammalian cells. Hence systems based on mammalian cells are of particular interest as they combine properties inherent to eukaryotic cells and their ability to produce human-like glycosylated proteins with the advantages of cell-free synthesis. These proteins include antibody fragments, antigens, virus-like particles, cytokines, enzymes, antimicrobial peptides and proteins containing non-natural amino acids. The benefits of CFPS are manifold, from ease of handling and scalability, on-demand launch of production, ability to rapidly switch products, simplified purification to facilitated standardization and quality control. CFPS needs less energy resources, the manufacturing footprint is less complex and smaller than in cell cultivation and it enables production of proteins that have toxic effects on cells. In addition, CFPS has the potential as an enabling technology for personalized medicines and is amenable to decentralised manufacturing. CFPS has gained even more interest in the recent past owing to advances in synthetic biology and thanks to the arousal of machine-learning/artificial intelligence (ML/AI). The use of generative deep learning and artificial intelligence has high potential in the *de-novo* design of biomolecules with specific properties of therapeutic and/or preventive nature. CFPS offers here great opportunities to increase the throughput in screening of the *de-novo* created biomolecules.

The application of synthetic biology combined with generative AI and cell-free biosynthesis open up new avenues for the design, discovery and manufacture of therapeutics not only against infectious diseases, but also non-communicable diseases and equally vaccines.

The proposed work should address at least two of the following elements:

- Address the bottlenecks that currently hamper the large-scale deployment of CFPS, i.e. the lack of a quality-by-design approach, the need to fully characterize the underlying cell lysates and their critical quality attributes and the need for better understanding of the correlations between specific cell lysate properties and CFPS process parameters,

specific product quality attributes (such as protein folding), and CFPS platform performance.

- Use synthetic biology techniques in combination with ML/AI- tools for the design of *de-novo* biomolecules with specific desired properties (antimicrobial, immunogenic, angiogenic, etc.) and develop suitable cell-free systems for the high-throughput screening of the designed biomolecules.

- Develop novel or optimize existing CFPS platforms for the production of the targeted biomolecule to a GMP-conform process producing clinical-grade material that can be tested in clinical trials.

Applicants envisaging to include clinical studies[156] should provide details of their clinical studies in the dedicated annex using the template provided in the submission system.

HORIZON-HLTH-2027-02-IND-02-two-stage: Portable and versatile Point-of-care diagnostics

Call: Cluster 1 - Health (Two stage - 2027)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 5.00 and 7.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget *Type of Action*	The total indicative budget for the topic is EUR 50.00 million. 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:

[156] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 4 (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: 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) [157].

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination "Maintaining an innovative, sustainable, and competitive EU health industry". To that end, proposals under this topic should aim to deliver results that are directed towards and contribute to all the following expected outcomes:

- Healthcare professionals dispose of diagnostic tools at the point of care that accelerate therapeutic decision making
- Patients benefit from fast and accurate diagnosis leading to improved health outcomes
- Thanks to more efficient diagnosis, health systems will get better evidence for disease control and prevention strategies.

Scope: Point-of-care (POC) medical testing has made great technical progress (e.g. improved extraction, microfluidics, miniaturization, and data processing techniques) with POC test accuracies nearly matching those of lab-based tests. POC tests may thus be an alternative to laboratory testing methods, enabling faster diagnostic results and therapeutic decision making. However, POC testing is not always achieving a completely accurate diagnosis and one of the major issues with POC diagnostics is the occurrence of false results during testing, another one is the often-cumbersome sample preparation. Hence there is a need for POC diagnostics that are more sensitive, selective and easy-to-use allowing for improved clinical practice.

WHO has defined a set of criteria for POC diagnostics in primary care which, in the advent of digital technologies, has been completed with two additional features and is represented by the acronym REASSURED: Real-time connectivity, Ease of specimen collection and environmental friendliness, Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free (or equipment-modest) and Deliverable to end users. To these criteria adds the feature of "sample-to-answer" (sometimes also called "sample-to-result") and more

[157] 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

challenges like: Miniaturization, power supply, versatility (nature and origin of the human sample), biocompatibility of the used materials and their suitability for mass production, readiness for high-throughput testing, quality control, regulatory compliance and, last but not least, cost, which is of particular concern in resource-limited settings. All these challenges are not only valid for POC diagnostics developed for infectious diseases, they equally apply to those that are designed to detect non-communicable diseases as well as their continuous monitoring on patients. Mobile technologies are playing an important role, especially since around 70% of the globally 7.4 billion cell phone users live in developing countries, which are the areas in direct need of advanced and more accessible POC diagnostics (lower density of relevant health infrastructure, e.g. hospitals and laboratory medicine testing facilities). Mobile phones have not only been proposed and tested for data acquisition and readout of assays, images and other results but also for sample processing (e.g. for heating step), as have been ML/AI-powered algorithms that are integrated in the diagnostic devices to analyse complex biological data and detect patterns that might be missed by human analysis.

The selection of the PoC device to be developed or optimized must be based on an objectively conducted clinical needs assessment, which includes – next to clinicians' perspectives – the complete care pathway and system-level needs. Moreover, a value-based concept is to be applied in the choice and development of the PoC device, taking into account its Health Technology Assessment (HTA) by the relevant HTA bodies, in order to facilitate their decisions for adoption.

Proposals should be driven by a clear clinical need, integrate a value-based concept and include all the following activities:

- the optimization of (the) targeted POC diagnostic device(s) that take(s) the above-mentioned criteria, challenges and aspects into consideration;
- the elaboration of a comparative study clearly demonstrating the added value and improved performance of the optimized POC diagnostic device(s) as compared to the current state of the art for the targeted diagnostic application;
- the conduct of clinical studies of (the) optimized POC diagnostic medical device(s) as a preferred information source for their clinical validation; subsequent conformity assessment in agreement with requisite regulatory requirements of the EU's IVDR or MDR.

In general, priority should be given to approaches that are suitable for resource-limited settings. In case of targeting infectious diseases, priority should be given to approaches enabling the distinction between viral, bacterial or fungal infections. In case of targeting non-communicable diseases, priority should be given to approaches that are used in emergency rooms where decisions can have life-saving character.

Applicants invited to the second stage and envisaging to include clinical studies[158] should provide details of their clinical studies in the dedicated annex using the template provided in the submission system.

HORIZON-HLTH-2026-01-IND-03: Regulatory science to support translational development of patient-centred health technologies

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 4.00 and 6.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
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 4 (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: 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

[158] Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

	Research and Training Programme of the European Atomic Energy Community (2021-2025) [159].

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination "Maintaining an innovative, sustainable, and competitive EU health industry". To that end, proposals under this topic should aim to deliver results that are directed towards and contribute to the following expected outcomes:

- Policymakers and regulators will get access to improved methodologies to evaluate the impact and efficiency of novel health technologies, facilitating decision-making for their use in humans and uptake in clinical practice.
- Patients and the health systems will benefit from the more targeted and efficient uptake of safe and effective health innovations in clinical practice, supporting more personalised approaches and improved care and public health.

Scope: The development, uptake and impact of health technologies typically results from a long product development process that is based on a 'life cycle approach' which typically involves several iterations of defined stages, i.e. from development, assessment to post-market surveillance and post-market clinical follow-up.

While health technologies are governed by comprehensive legal frameworks aiming to ensure that health technologies are safe and effective, the regulatory science underlying these legal frameworks need to be updated. This concerns *inter alia* a) more precise delineation of specific requirements (e.g. closing existing gaps concerning sufficiency of clinical evidence) and b) the consideration of novel biomedical approaches, data and digital solutions (e.g. artificial intelligence, virtual human twin, new approach methodologies as well as methods that cut through these domains) which model and predict relevant biological, anatomical physiological parameters and exploit relevant end-points and novel (bio)markers for clinical diagnostic and prognostic predictions. Such update of the regulatory science of health technologies should aim at supporting an effective adoption and uptake into routine use by health systems and end-users (healthcare providers, citizens), while maintaining guardrails to ensure that innovative health technologies are backed up by evidence of sufficient quality and relevance to the human situation.

The proposed work shall cover all types of health technologies, aiming to define improved and novel sources of evidence with proven relevance for regulatory decision-making with a focus on safety and performance throughout their lifecycle, i.e. throughout the continuous process of clinical evaluation. To this end, the work should address either, or a combination of the following: a) the improvement of existing methodologies and their fitness to specific types or classes of health technologies, including methodology for regulatory assessment and b)

[159] 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

explore and examine to which extent novel information sources as indicated above can be considered as evidence that is satisfactory in view of regulatory needs concerning safety and performance.

The work should support the update and refinement of regulatory science on health technologies and contribute actionable information that can be used for improved or novel regulatory policies, rules, guidance documents and other tools with a view to ensuring that European patients and healthcare professionals have access to safe and effective innovative health technologies. The work should ultimately contribute to a regulatory environment that makes use of the full spectrum of novel biomedical and bio-digital approaches for clinical investigation and evaluation, while promoting a patient-centred approach to health technology innovation, facilitating the timely entry to market of performant and effective innovations and support their uptake in the health systems and clinical workflows without compromising patient safety.

The proposed work should address one or more of the following elements:

- Data and analyses on how existing approaches in regulatory science can be refined and improved in view of closing existing gaps of clarity, sufficiency of clinical evidence, generated on the basis of clinical studies and clinical investigations.

- Data and analyses on whether and to which extent novel information sources from biomedicine including new approach methods and digital and artificial intelligence-enabled models and approaches can contribute to the clinical evaluation of innovative health technologies, e.g.:

    - by providing information on relevant biophysical, anatomical, physiological and other disease-relevant aspects;

    - by supporting information integration through exploiting existing data from similar types or groups of technologies (e.g. retrospective information in registries, data collections, including real-world data from using technologies that have characteristics that are relevant for innovative technologies);

    - by complementing clinical data obtained from studies involving appropriate patient populations;

    - by supporting improved planning and design of first-in-man clinical studies, with a view of enhancing the effectiveness and the safety of such studies and rationalising the use of resources of all involved actors (clinical researchers, industry, regulatory bodies and authorities) by focusing the generation and assessment of clinical data on health technologies for which those data are indispensable.

- Data and analyses that examine to which extent above points can support the development and uptake of innovative technologies for unmet medical needs and for special patient populations (e.g. paediatric and rare conditions) via dedicated regulatory

pathways and/or within a structured framework enabling their development and testing in a real-world environment under regulatory supervision ("regulatory sandbox").

The activities should cover and draw on all the relevant healthcare innovation related frameworks other than pharmaceutical products, i.e. medical devices, in-vitro diagnostics, AI, and substances of human origin (SoHO).

The starting point is a good understanding of the innovative technology and of its inherent risks, so that appropriate safety and quality requirements can be applied for monitoring the outcome in the relevant healthcare setting. As the number of hybrid or combinations of health technologies increases and technology integration becomes rather the norm than an exception in health innovation, the current segregated, technology-specific, frameworks may not provide a clear path forward for the health technology that is targeted. To that end, when considering an innovation, it is important to consider all relevant legislative frameworks including MDR[160] and IVDR[161], the proposed SoHO-Regulation[162], and AI Act among others.

Applicants envisaging to include clinical studies[163] should provide details of their clinical studies in the dedicated annex using the template provided in the submission system.

160 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

161 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

162 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

163 Please note that the definition of clinical studies (see introduction to this work programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

Other Actions not subject to calls for proposals

Grants to identified beneficiaries

1. Contribution to the Coalition for Epidemics Preparedness Initiative (CEPI)

This is a grant awarded without a call for proposals (Article 195 (e) of the EU Financial Regulation). CEPI is a global initiative focused on vaccine development for pathogens causing epidemic threats. It has played a crucial role in the Union's response to COVID-19. This funding will enable CEPI to issue competitive calls to develop medical countermeasures for diseases with epidemic potential. The grants will support research on new vaccines to prevent future epidemics.

Expected Outcome:

Proposals should set out a credible pathway to contributing to one or several expected impacts of destination: “Tackling diseases and reducing disease burden”. Project Results under this action are expected to contribute to all of the following expected outcomes:

- Health care providers have access to newly developed medical countermeasures against prioritised pathogens with epidemic potential.
- Citizens benefit from improvements in prevention and containment of epidemics.
- Research funders, policymakers and the research community will have better tools for achieving Sustainable Development Goals[1] related to communicable diseases
- and solutions to achieve the Sustainable Development Goal 3.3[2].

Scope:

This grant will be awarded without a call for proposals according to Article 195 (e) of the EU Financial Regulation and Article 24(3)(b) of the Horizon Europe Regulation to the legal entities identified below as CEPI has been a key partner for implementing the common Union response to the COVID-19 epidemic.

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international non-profit association established under Norwegian Law. Its objective is to finance and coordinate the development of new vaccines to prevent and contain infectious diseases that have epidemic potential. The Horizon Europe funding will be used to enhance and expand CEPI’s activities. This action will also contribute to the implementation of the Union’s strategy for international cooperation in research and innovation and the EU’s development policy.

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

- Vaccine research and development for emerging pathogens to stop future epidemics.
- Development of adaptable vaccine technologies.

- Collaboration with stakeholders in epidemic preparedness.

This action is expected to engage with other relevant initiatives, such as the forthcoming Partnership for Pandemic Preparedness and the European Vaccine Hub.

With the grant from the European Union, CEPI will be able to award one or several grants to third parties through competitive calls for proposals. The call(s) will be issued to fund advanced pre-clinical as well as clinical research on new vaccines for the prevention of emerging and re-emerging infectious diseases. For this purpose this action is also expected to engage with HERA. The expected recipients of the grant(s) issued by CEPI include research institutes, universities, SMEs as well as large companies, all active in research and innovation on new and improved vaccines.

Award criteria:

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

Legal and financial set-up of the Grant Agreements:

The funding rate will be 70%.

Financial support provided by CEPI to third parties is one of the primary activities of this action in order to be able to achieve its objectives as CEPI does not have the capacity to develop new medical countermeasures itself. The maximum amount to be granted to a third party is EUR 35 million. This is justified by the high cost of development for new vaccines, that reach tens of millions of Euros[3].

Legal entities:

Coalition for Epidemic Preparedness Innovations, Marcus Thranes gate 2, 0473 Oslo, Norway

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 198(e) - Programme co-fund action

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes

Indicative budget: EUR 40.00 million from the 2026 budget

2. European registry for human pluripotent stem cell lines

Please fill in.

Legal entities:

Fraunhofer Gesellschaft zur Förderung der angewandten Forschung e.V., Hansastrasse 27C, 80686, Muenchen, Germany

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 198(e) - Coordination and support action

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes

Indicative budget: EUR 1.50 million from the 2026 budget

3. Presidency event - Ireland. Title of the event

Please fill in.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 198(e) - Coordination and support action

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes

Indicative budget: EUR 0.30 million from the 2026 budget

4. Presidency event - Lithuania. Title of the event

Please fill in.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 198(e) - Coordination and support action

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes

Indicative budget: EUR 0.30 million from the 2026 budget

5. Contribution to the Coalition for Epidemics Preparedness Initiative (CEPI)

This is a grant awarded without a call for proposals (Article 195 (e) of the EU Financial Regulation). CEPI is a global initiative focused on vaccine development for pathogens causing epidemic threats. It has played a crucial role in the Union's response to COVID-19. This funding will enable CEPI to issue competitive calls to develop medical countermeasures for diseases with epidemic potential. The grants will support research on new vaccines to prevent future epidemics.

Expected Outcome:

Proposals should set out a credible pathway to contributing to one or several expected impacts of destination: "Tackling diseases and reducing disease burden". Project Results under this action are expected to contribute to all of the following expected outcomes:

- Health care providers have access to newly developed medical countermeasures against prioritised pathogens with epidemic potential.
- Citizens benefit from improvements in prevention and containment of epidemics.
- Research funders, policymakers and the research community will have better tools for achieving Sustainable Development Goals[1] related to communicable diseases
- and solutions to achieve the Sustainable Development Goal 3.3[2].

Scope:

This grant will be awarded without a call for proposals according to Article 195 (e) of the EU Financial Regulation and Article 24(3)(b) of the Horizon Europe Regulation to the legal entities identified below as CEPI has been a key partner for implementing the common Union response to the COVID-19 epidemic.

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international non-profit association established under Norwegian Law. Its objective is to finance and coordinate the development of new vaccines to prevent and contain infectious diseases that have epidemic potential. The Horizon Europe funding will be used to enhance and expand CEPI's activities. This action will also contribute to the implementation of the Union's strategy for international cooperation in research and innovation and the EU's development policy.

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

- Vaccine research and development for emerging pathogens to stop future epidemics.
- Development of adaptable vaccine technologies.
- Collaboration with stakeholders in epidemic preparedness.

This action is expected to engage with other relevant initiatives, such as the forthcoming Partnership for Pandemic Preparedness and the European Vaccine Hub.

With the grant from the European Union, CEPI will be able to award one or several grants to third parties through competitive calls for proposals. The call(s) will be issued to fund advanced pre-clinical as well as clinical research on new vaccines for the prevention of emerging and re-emerging infectious diseases. For this purpose this action is also expected to engage with HERA. The expected recipients of the grant(s) issued by CEPI include research institutes, universities, SMEs as well as large companies, all active in research and innovation on new and improved vaccines.

Award criteria:

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

Legal and financial set-up of the Grant Agreements:

The funding rate will be 70%.

Financial support provided by CEPI to third parties is one of the primary activities of this action in order to be able to achieve its objectives as CEPI does not have the capacity to develop new medical countermeasures itself. The maximum amount to be granted to a third party is EUR 35 million. This is justified by the high cost of development for new vaccines, that reach tens of millions of Euros[3].

Legal entities:

Coalition for Epidemic Preparedness Innovations, Marcus Thranes gate 2, 0473 Oslo, Norway

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 198(e) - Programme co-fund action

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes

Indicative budget: EUR 40.00 million from the 2027 budget

6. Presidency event - Greece. Title of the event

Please fill in.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 198(e) - Coordination and support action

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes

Indicative budget: EUR 0.30 million from the 2027 budget

Other Instruments

1. External expertise

This action will support the use of appointed independent experts for the monitoring of running actions (grant agreement, grant decision, public procurement actions, financial instruments) funded under Horizon Europe and previous Framework Programmes for Research and Innovation, for ethics checks, for the evaluation of large actions annual work plans, as well as for compliance checks regarding the Gender Equality Plan eligibility criterion. A special allowance of EUR 450/day will be paid to the experts appointed in their personal capacity who act independently and in the public interest.

Form of Funding: Other budget implementation instruments

Type of Action: Expert contract action

Indicative budget: EUR 2.00 million from the 2026 budget and EUR 2.00 million from the 2027 budget

2. External expertise in relation to EU research and innovation policy issues

This action will support the provision of independent expertise in support of the assessment, design, implementation, evaluation and valorisation of EU research and innovation policies in the areas currently in scope of the Health Cluster.

Individual experts will work on tasks such as, but not limited to: portfolio analysis of projects funded under Horizon Europe or previous European research and innovation programmes; analysis of the contribution of research results (at national, EU and/or international level) to EU policy objectives and emerging issues, including policy recommendations; analysis of the state-of-the-art at European and international level; participation in studies, conferences, events, symposia, etc, including the drafting of papers and reports on their conclusions; assistance for setting-up a research and innovation strategy for selected domains; policy recommendations and options assisting Commission services in elaborating evidence-based and scientifically sound policy proposals; assistance in the evaluation of calls for expression of interest; advice on the valorisation, communication, dissemination and exploitation of research results; identification of innovative solutions as well as potential gaps and synergies to be addressed by EU research and innovation policy; advise on promising technologies covered by European and nationally funded projects and on ways to stimulate synergies, etc.

In addition to individual experts, this action could provide for Commission expert groups.

A special allowance of maximum EUR 450/day will be paid to the experts appointed in their personal capacity who act independently and in the public interest.

Form of Funding: Other budget implementation instruments

Type of Action: Expert contract action

Indicative budget: EUR 0.10 million from the 2026 budget and EUR 0.10 million from the 2027 budget

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

Expected Outcome:

Proposals should set out a credible pathway to contributing to one or several expected impacts of destination: "Tackling diseases and reducing disease burden".

Project results are expected to contribute to the following expected outcome: Allow the Union to respond to Public Health Emergencies.

Scope:

In case of a public health emergency[164] (such as a Public Health Emergency of International Concern (PHEIC) according to the World Health Organization, a public health emergency under Regulation (EU) 2022/2371 [165] or under applicable national frameworks and regulations), funding will be mobilised for:

- The award of grants without a call for proposals according to Article 198 (b) of the EU Financial Regulation[166] in exceptional and duly substantiated emergencies. At that time, the Funding & Tenders Portal will open a dedicated section where proposals can be submitted. This will be communicated to the National Contact Points. The invitation to apply for funding will be open to all eligible entities or be limited to targeted entities, taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances; and/or

- The award of additional funding for ongoing grant agreements funded through EU Framework Programmes for Research and Innovation to cover additional activities specifically linked to the public health emergency, in exceptional and duly substantiated emergencies. Providing such additional funding to ongoing EU Framework Programmes for Research and Innovation grants that can support pertinent short- and mid-term research efforts to confront the public health emergency will save valuable time and

164 Should there be no Public Health Emergency in 2023, 2024 or 2025, the indicative budget may be reallocated.

165 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2371&qid=1673372768554

166 Article 198 (b) of the Financial Regulation 2018/1046 "Grants may be awarded without a call for proposals only in the following cases: […] (b) in other exceptional and duly substantiated emergencies;".

allow addressing the situation with the appropriate urgency. Restricted calls for expression of interest or proposals will develop such additional activities or add additional partners to existing EU Framework Programmes for Research and Innovation actions.

It is expected that quality-controlled data are shared in accordance with the FAIR [167] principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

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

The beneficiaries must comply with the public emergency related provisions listed in the General Annexes concerning the project implementation under - Intellectual Property Rights (IPR), background and results, access rights and rights of use (article 16 and Annex 5) for the duration of the Public Health Emergency; and under Communication, dissemination, open science and visibility (article 17 and Annex 5) during the entire duration of the action and for four years after the end of the action.

The following derogations to the evaluation procedure described in General Annexes D and F apply to open invitations to submit applications:

In order to ensure a balanced portfolio covering responses to different aspects of the public health emergency, grants will be awarded to applications not only in order of ranking, but also to those projects that enhance the quality of the project portfolio through synergies between projects and avoidance of overlaps, provided that the applications attain all thresholds.

The action may also include justified derogations from the standard limits to financial support to third parties. Where applicable, the relevant grant agreement options will be applied.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant awarded without call for proposals according to Financial Regulation Article 198 (b)

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes

Indicative budget: EUR 1.00 million from the 2026 budget and EUR 1.00 million from the 2027 budget

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

4. Studies, conferences, events and outreach activities

A number of specific contracts will be signed in order to: (i) support the dissemination and exploitation of project results; (ii) contribute to the definition of future challenge priorities; (iii) undertake citizen surveys such as Eurobarometers; (iv) carry out specific evaluations of programme parts; (v) support future European Research Area (ERA) policy actions; and (vi) organise conferences, events and outreach activities.

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

Form of Funding: Procurement

Type of Action: Public procurement

Indicative budget: EUR 12.00 million from the 2026 budget and EUR 10.00 million from the 2027 budget

5. Subscription to the Human Frontier Science Program Organization

An annual subscription to the international Human Frontier Science Program Organization (HFSPO)[168] will allow researchers from EU non-G7 Member States to fully benefit from the Human Frontier Science Program (HFSP), enable initiatives to help the affected scientific community in and from areas recently severely ravaged by conflict and/or war on European ground and contribute to the implementation of the Global Approach to Research and Innovation, Europe's strategy for international cooperation in a changing world[169].

Type of Action: Subscription action

Indicative timetable: First Quarter of 2026

Indicative budget: EUR 7.04 million from the 2026 budget and EUR 7.04 million from the 2027 budget

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

169 Communication from the Commission on the Global Approach to Research and Innovation. Europe's strategy for international cooperation in a changing world, COM(2021) 252, 18.5.2021 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2021%3A252%3AFIN).

Budget[170]

	Budget line(s)	2026 Budget (EUR million)	2027 Budget (EUR million)
Calls			
HORIZON-HLTH-2026-01		524.00	
	from 01.020210	*524.00*	
HORIZON-HLTH-2026-02		30.00	63.00
	from 01.020210	*30.00*	*63.00*
HORIZON-HLTH-2026-03		40.00	33.00
	from 01.020210	*40.00*	*33.00*
HORIZON-HLTH-2026-04		15.00	
	from 01.020210	*15.00*	
HORIZON-HLTH-2027-01			502.00[171]
	from 01.020210		*502.00*
HORIZON-HLTH-2027-02			130.00
	from 01.020210		*130.00*
HORIZON-HLTH-2027-03			50.00
	from 01.020210		*50.00*

[170] The budget figures given in this table are rounded to two decimal places.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for 2026 and 2027.

[171] To which EUR 10.00 million from the 'Climate, Energy and Mobility' budget will be added making a total of EUR 512.00 million for this call.

Contribution from this part to call HORIZON-MISS-2026-03 under Part 12 of the work programme		114.15	
	from 01.020210	*114.15*	
Contribution from this part to call HORIZON-MISS-2027-02 under Part 12 of the work programme			130.44
	from 01.020210		*130.44*
Other actions			
Grant awarded without a call for proposals according to Financial Regulation Article 198(e)		42.10	40.30
	from 01.020210	*42.10*	*40.30*
Expert contract action		2.10	2.10
	from 01.020210	*2.10*	*2.10*
Grant awarded without a call for proposals according to Financial Regulation Article 198		1.00	1.00
	from 01.020210	*1.00*	*1.00*
Public procurement		12.00	10.00
	from 01.020210	*12.00*	*10.00*
Subscription action		7.04	7.04
	from 01.020210	*7.04*	*7.04*
Estimated total budget		787.39	968.88