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Annex IV

Horizon Europe

Work Programme 2026-2027

4. Health

DISCLAIMER

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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 second Horizon Europe strategic plan[1], covering years 2025 to 2027. It also aligns with the Commission's Political Guidelines for 2024-2029[2], 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 and cardiovascular health, through prevention, treatment, and management, supporting initiatives such as the "Healthier Together" EU Non-communicable Diseases Initiative and the future EU Cardiovascular Health (CVH) plan[3].
- 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 co-funded European Partnership on Transforming Health and Care Systems[4].
- 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)[5] Regulation.

1 https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/strategic-plan_en
2 https://commission.europa.eu/about/commission-2024-2029_en
3 https://data.consilium.europa.eu/doc/document/ST-15315-2024-INIT/en/pdf
4 https://cordis.europa.eu/project/id/101095654, https://www.thcspartnership.eu
5 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

- 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 the "Strategy for European Life Sciences"[6].

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 for 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 (PCP) 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 co-funded European Partnership on Rare Diseases[7] and the future co-funded European Partnership for Pandemic Preparedness[8], 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

6 https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/towards-strategy-european-life-sciences_en
7 https://cordis.europa.eu/project/id/101156595, https://erdera.org
8 https://beready4pandemics.eu

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[9], participation in the Health Cluster of Horizon Europe is open to third countries. Supporting the Global Gateway Strategy[10], projects involving international partners should aim to increase scientific knowledge and facilitate technology transfer among partner countries, addressing global health challenges and 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[11] 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 (2021-2027)[12] 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[13] 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,

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9 COM(2021) 252 final
10 JOIN(2021) 30 final
11 E.g. the EU4Health Programme, the Digital Europe Programme, the European Regional Development Fund (ERDF), including Interreg, the European Social Fund (ESF+), the Structural Reform Support Programme (SRSP), the Just Transition Fund (JTF), the European Maritime, Fisheries and Aquaculture Fund (EMFAF), the European Agricultural Fund for Rural Development (EAFRD), the European Defence Fund (EDF) or InvestEU.
12 https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en
13 https://digital-strategy.ec.europa.eu/en/activities/digital-programme

experimental development and feasibility studies, building on Research and Innovation stemming from Horizon Europe[14].

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 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[15, 16, 17, 18, 19, 20].

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

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14 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

15 https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf

16 The European Cancer Information System (ECIS - https://ecis.jrc.ec.europa.eu) and the European Network of Cancer Registries (ENCR - https://www.encr.eu)

17 European Commission Initiatives on Breast and Colorectal Cancer: https://healthcare-quality.jrc.ec.europa.eu

18 European Cancer Inequalities Registry: https://cancer-inequalities.jrc.ec.europa.eu

19 European Platform on Rare Disease Registration (EU RD Platform - https://eu-rd-platform.jrc.ec.europa.eu/_en) - for rare cancers

20 Health Promotion and Disease Prevention Knowledge Gateway Horizon Europe: https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway_en

website[21], the FAIR cookbook[22] and the guides for researchers on how to make your data FAIR[23].

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)[24], European Research Infrastructure Consortia (ERICs)[25] and the European Open Science Cloud[26]. 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)[27].

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 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[28] 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)[29]. CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data.

Applicants envisaging to develop, use and/or deploy AI based systems/techniques, should ensure that the proposed (Artificial Intelligence) AI systems/techniques are developed, used

21 https://www.go-fair.org/fair-principles
22 https://faircookbook.elixir-europe.org/content/home.html
23 https://www.openaire.eu/how-to-make-your-data-fair
24 https://ri-portfolio.esfri.eu
25 https://www.eric-forum.eu/the-eric-landscape
26 https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/our-digital-future/open-science/european-open-science-cloud-eosc_en
27 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
28 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536
29 https://euclinicaltrials.eu

and/or deployed in a safe, secure and responsible manner, with a clear identification of and preventative approach to risks and in accordance with the principles of the AI Act[30] and the Ethics Guidance on trustworthy AI[31]. Depending on the type of research being proposed (from basic to precompetitive) and as appropriate, AI-based systems or techniques should be, or be developed to become (implicitly or explicitly contributing to the following objectives):

- Technically robust, accurate and reproducible, and able to deal with and inform about possible failures, inaccuracies and errors, proportionate to the assessed risk posed by the AI-based system or technique.
- Socially robust, in that they duly consider the context and environment in which they operate.
- Reliable and function as intended, minimising unintentional and unexpected harm, preventing unacceptable harm and safeguarding the physical and mental integrity of humans.
- Able to provide a suitable explanation of its decision-making process, whenever an AI-based system can have a significant impact on people's lives.

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.

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30 https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai, https://eur-lex.europa.eu/eli/reg/2024/1689/oj

31 See Ethics Guidelines for Trustworthy AI, published by the European Commission's High Level Expert Group on Artificial Intelligence https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai and the Ethics by Design and Ethics of Use Approaches for Artificial Intelligence https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf

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:

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.

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Calls

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

HORIZON-HLTH-2026-01

Overview of this call[32]

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)[33]	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 Non-Communicable Diseases (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

[32] 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

[33] 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	45.00	Around 8.00	6
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 viral pathogens with epidemic potential	RIA	45.00	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: Understanding of sex and/or gender-specific mechanisms of cardiovascular diseases: determinants, risk factors and pathways	RIA	40.00	6.00 to 7.00	6
HORIZON-HLTH-2026-01-DISEASE-15: Scaling up innovation in cardiovascular health	CSA	2.00	Around 2.00	1
Destination - Ensuring equal access to innovative, sustainable, and high-quality healthcare				
HORIZON-HLTH-2026-01-CARE-01: Public procurement of innovative solutions for improving citizens' access to healthcare through integrated and personalised approaches	PPI	25.00	3.00 to 8.00	4
HORIZON-HLTH-2026-01-CARE-03: Identifying and addressing low-value care in health and care systems	RIA	45.00	Around 10.00	5
Destination - Developing and using new tools, technologies and digital solutions for a healthy				

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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		456.00		

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.

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Call - Partnerships in Health (2026/1)

HORIZON-HLTH-2026-02

Overview of this call[34]

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

Topics	Type of Action	Budgets (EUR million)		Expected EU contribution per project (EUR million)[35]	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.

[34] 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

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

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

Call - Partnerships in Health (2026/2)

HORIZON-HLTH-2026-03

Overview of this call[36]

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

Topics	Type of Action	Budgets (EUR million)		Expected EU contribution per project (EUR million)[37]	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		

[36] 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

[37] 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 - Partnerships in Health (2026/3)

HORIZON-HLTH-2026-04

Overview of this call[38]

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)[39]	Indicative number of projects expected to be funded

[38] 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

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

Opening: 10 Feb 2026 Deadline(s): 16 Apr 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		

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

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Overview of this call[40]

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

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[41]	Indicative number of projects expected to be funded
		2027		
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	40.00	6.00 to 8.00	5
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	42.00	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 [42]	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	45.00	Around 10.00	5

[40] 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

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

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

HORIZON-HLTH-2027-01-DISEASE-06: Development of monoclonal antibodies to prevent and treat infections from Flaviviridae	RIA	45.00	Around 10.00	5
HORIZON-HLTH-2027-01-DISEASE-07: Development of monoclonal antibodies to prevent and treat infections from Filo-, Nairo-, Phenui-, Picorna- and Toga Viridae	RIA	45.00	Around 10.00	5
HORIZON-HLTH-2027-01-DISEASE-08: Development of innovative antimicrobials against critical pathogens resistant to antimicrobials	RIA	45.00	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: Personalised approaches to reduce risks from Adverse Drug Reactions due to administration of multiple medications	RIA	45.00	8.00 to 10.00	5
Destination - Developing and using new tools, technologies and digital solutions for a healthy society				
HORIZON-HLTH-2027-01-TOOL-05: Pilot Actions for Follow-on Funding: Leveraging EU-funded Collaborative Research in Regenerative Medicine	IA	40.00	6.00 to 8.00	5
Destination - Maintaining an innovative, sustainable, and competitive EU health industry				
HORIZON-HLTH-2027-01-IND-01: Development of cell-free protein synthesis platforms for discovery and/or production of biologicals	RIA	35.00	6.00 to 8.00	5
Overall indicative budget		414.00		

General conditions relating to this call	
Admissibility conditions	The conditions are described in General Annex A.

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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 (Two stage - 2027)

HORIZON-HLTH-2027-02-two-stage

Overview of this call[43]

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

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[44]	Indicative number of projects expected to be funded
		2027		
Opening: 10 Feb 2027 Deadline(s): 13 Apr 2027 (First Stage), 22 Sep 2027 (Second Stage)				
Destination - Tackling diseases and reducing disease burden				

[43] 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

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

HORIZON-HLTH-2027-02-DISEASE-01-two-stage: Innovative healthcare interventions for non-communicable diseases	RIA	65.00	7.00 to 8.00	8
HORIZON-HLTH-2027-02-DISEASE-14-two-stage: Clinical trials for advancing innovative interventions for neurodegenerative diseases	RIA	40.00	Around 10.00	4
Destination - Developing and using new tools, technologies and digital solutions for a healthy society				
HORIZON-HLTH-2027-02-TOOL-01-two-stage: Development of predictive biomarkers of disease progression and treatment response by using AI methodologies for chronic non-communicable diseases	RIA	45.00	6.00 to 8.00	6
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	40.00	5.00 to 7.00	6
Overall indicative budget		190.00		

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	The rules are described in General Annex G.

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Agreements	

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

HORIZON-HLTH-2027-03

Overview of this call[45]

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

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[46]	Indicative number of projects expected to be funded
		2027		
Opening: 03 Jun 2027 Deadline(s): 22 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	45.00	7.00 to 10.00	5
HORIZON-HLTH-2027-03-TOOL-04: Virtual Human Twins (VHTs) for integrated clinical decision support in prevention and diagnosis	RIA	45.00	10.00 to 12.00	4
HORIZON-HLTH-2027-03-TOOL-08: Towards Artificial General Intelligence (AGI) for healthcare	CSA	3.00	Around 3.00	1
Overall indicative budget		93.00		

[45] 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

[46] 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.

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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[47].

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[48] 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[49], 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 Commission's Political Guidelines for 2024-2029[50], which call 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

47 https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/strategic-plan_en

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

49 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.

50 https://commission.europa.eu/about/commission-2024-2029_en

enrich emerging data resources such as the European Health Data Space (EHDS)[51] and European Open Science Cloud (EOSC)[52], and contribute to the European care strategy[53] and the digital transformation of health and care in the EU[54]. 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 part, 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; and 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 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 the Health Cluster and the 'Culture, Creativity and Inclusive Society' Cluster 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.

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51 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

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

53 Communication from the European Commission on the European care strategy, COM(2022) 440, 7.9.2022

54 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

- 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 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 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 Research and Training Programme of the European Atomic Energy Community (2021-2025) [55].

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 to deliver results that are directed at, tailored towards and contributing to all the following expected outcomes:

- Persons with disabilities are empowered and can enjoy their rights to live independently and be included in the community on an 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.
- 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[56] - 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 landscape of quality, accessible, person-centred and affordable, community- and family-based services comprising personal assistance, medical and social care and interventions by social

[55] 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

[56] 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).

workers, thereby facilitating everyday activities and providing choice to persons with disabilities and their families[57].

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 at least three of the following areas:

- Health related research addressing disabilities looking into finding the causes of the disease(s) leading to the disability and/or into developing innovative solutions. These solutions can include among others diagnoses, medicines, treatments, protocols, technologies, digital tools, low-tech solutions, etc. helping to improve the autonomy of persons with disabilities.

- 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.

- On prevention of disabilities through the life-course, different aspects that could have an impact on persons with disabilities may be addressed, such as gender, age, socio-economic background, ethnicity, detection of risks factors leading to a loss of autonomy, 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 activity/sports, screen-time dependency, smoking, drug use, alcohol use, stress, psychiatric and somatic diseases, loneliness and/or isolation, etc.

- Address the conditions for a successful transition from institutions to living in the community, including different tools to achieve it, such as needs assessments, service provision, budget and resources, management plans, monitoring, quality control, etc. Community support services to live independently may include personal assistance and/or disability inclusive and accessible community-based services -medical, technological, digital or other supportive initiatives- ensuring prevention of isolation or

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

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.

- Propose innovative solutions, care models and strategies for high quality person-centred, accessible and targeted social and healthcare services to support independent living, including if possible, 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 harmonise 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 involve their families, friends, colleagues, supporters and carers and other service providers. Policymakers and public authorities, social services, and civil society organisations, could also be considered.

The relevant European research infrastructures[58] in the area of health may be exploited for available digital tools and services for dataset creation, standardisation, data discovery, secure access, management, visualization, harmonization, analysis and other functions as appropriate.

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 topic HORIZON-CL2-2025-01-TRANSFO-09: “Good practices for increased autonomy of persons with disabilities, including physical, mental, intellectual and sensory disabilities” and 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[59] should provide details of their clinical studies in the dedicated annex using the template provided in the submission system.

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[58] The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

[59] 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-STAYHLTH-02: Behavioural interventions as primary prevention for Non-Communicable Diseases (NCDs) among young people

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project *Indicative budget*	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. 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 to deliver results that are directed at, tailored towards and contributing to 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.
- Health professionals and educators have access to strategies to mitigate risks of Non-Communicable Diseases (NCDs) 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 (RWD) [60] , existing health data infrastructure and digital tools, including Artificial Intelligence (AI), which can contribute to the sustained success of behavioural health interventions.

- Policymakers at local, regional, national 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 NCDs later in life, where "top NCDs" refers to the most prevalent NCDs. For the purpose of this call, NCDs explicitly exclude cancer, addiction/substance abuse, as they are covered by other topics.

Existing evidence-based 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 hardware and software for efficient self-monitoring (i.e. wearables and point-of-care devices for measuring various physiological parameters and other predictors and other biomarkers and the corresponding apps for easy readout and tracking, possibly also including gamification elements). Hardware and software should be interoperable in line with internationally accepted standards in order to avoid lock-in effects and assure scalability.

Proposals should also include most of the following aspects:

- 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 AI and RWD and biomarkers (e.g. genomic data, wearables, etc.) or existing relevant administrative dataset, will be integrated to enhance the scalability, personalisation, and effectiveness of interventions in the long-term.

- 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. randomised controlled trails, quasi-experimental designs, etc.), with clearly defined indicators of success of the intervention (e.g. biometric markers, psychosocial wellbeing metrics, physical activity change, etc.). Applicants should evaluate unintended consequences for all interventions.

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

- 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. As such, active involvement of key stakeholders throughout the study is strongly encouraged.

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.

The proposals should adhere to the FAIR[61] data principles, adopt data quality standards, data integration operating procedures and GDPR[62] compliant data sharing/access good practices developed by the European research infrastructures, where relevant.

Applicants should provide details of their clinical studies[63] 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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61 See definition of FAIR data in the introduction to this Work Programme part.

62 General Data Protection Regulation: https://commission.europa.eu/law/law-topic/data-protection_en, https://gdpr-info.eu

63 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[64].

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 Commission published a Strategic Research and Innovation Agenda on Health and Climate Change[65], 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 for 2024-2029[66], 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 recognises 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, fisheries and aquaculture, 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 Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and create

64 https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/strategic-plan_en

65 Reference to be provided once the strategy is published

66 https://commission.europa.eu/about/commission-2024-2029_en

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 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:

- Policymakers 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)

DRAFT

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 areas targeted[67], 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 broad focus area, 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

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

	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) [68].

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

- Citizens, patients, public authorities and policymakers 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, preparedness 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.

[68] 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

- Public authorities, organisations and the research community can rely on data collection and sharing according to FAIR[69] principles and leveraging of data availability and quality.

- Policymakers and public authorities develop evidence-based climate change and health policies and interventions that are nature positive, inclusive and responsive to diverse population needs.

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 and exacerbates existing health conditions and vulnerabilities.

Applicants should explicitly state in their proposal which of the following broad focus areas is targeted and the proposed work should address only this specific broad focus area:

i. Non-Communicable Diseases (NCDs) and/or 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.

ii. 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.

iii. 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:

[69] See definition of FAIR data in the introduction to this Work Programme part.

- Increase the understanding of correlations, causal pathways and mechanistic effects between climate change and disease/health outcomes, 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, generations 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) [70] and the European Open Science Cloud (EOSC)[71].

- 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, when relevant, geographical settings outside of urban areas, in overseas regions and in low- and middle-income countries (LMICs) [72] . Understand the role of inequalities and societal vulnerability in determining climate-related health impacts and adaptive capacity.

- Advance the knowledge on the climate, ecological 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.

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70 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

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

72 As defined by the World Bank, https://www.worldbank.org

- 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.

International cooperation, in particular with LMICs, is strongly encouraged.

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. 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[73].

Proposals should make sure that relevant activities, outcomes and outputs are shared with the European Climate and Health Observatory[74] through the cluster that will be formed after the approval of the proposals. Actions' results should also contribute to future European Climate Risk Assessments. When relevant proposals should build on the outcomes of the projects that are part of the European Climate-Health Cluster[75].

Proposals are encouraged to consider, where relevant, the data, expertise and services offered by European research infrastructures[76] in the environment, climate and health domain.

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

All proposals involving the development, use and/or deployment of AI based system/technique should ensure that the proposed AI system/technique is technical robust[77], safe and must describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability.

Applicants should provide details of their clinical studies[78] 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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73 https://research-and-innovation.ec.europa.eu/research-area/health/environment-climate-and-health_en
74 https://climate-adapt.eea.europa.eu/en/observatory
75 https://climate-health.eu
76 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu
77 See introduction to this Work Programme part.
78 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-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 *Indicative budget*	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. The total indicative budget for the topic is EUR 42.00 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).

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

- Researchers, policymakers, 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[79] data linking these exposures to disease and health outcomes.
- Researchers, governments, policymakers 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 nature-positive behaviours.

Scope: The exposome is the totality of exposures (and their interactions) experienced by an individual throughout their lifetime, including chemical, physical, biological, nutritional 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.

[79] See definition of FAIR data in the introduction to this Work Programme part.

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 should 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 and disrupted ecosystems. Proposals should include climate-relevant social determinants of health as part of their proposed activities.

More specifically, research actions under this topic should include all 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, social and occupational exposures) resulting from climate-related pressures and study their health implications 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 (RWD)[80].

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 (when relevant) and study existing and/or newly generated longitudinal cohorts that combine individual exposome data with the corresponding medical, omics and biological data.
- Identify exposome-relevant indicators and biomarkers for 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[81], age) and behavioural (e.g. public trust, risk perception)

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

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.

When handling data and indicators, sex-, gender-, race[82] and ethnicity-disaggregated data should be collected and analysed, incorporating intersectional factors where feasible and relevant.

International cooperation is encouraged, in particular with regions that are under-represented in human exposome research.

Projects should leverage the knowledge, data and tools already generated under past initiatives such as EHEN[83] and ongoing initiatives such as IHEN[84], ICOS ERIC[85] and EIRENE RI[86].

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. 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[87].

Proposals should make sure that relevant activities, outcomes and outputs are shared with the European Climate and Health Observatory[88] through the cluster that will be formed after the approval of the proposals.

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

All proposals involving the development, use and/or deployment of AI based system/technique should ensure that the proposed AI system/technique is technical robust[89], safe and must describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability.

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81 The use of the term 'racial origin' does not imply an acceptance of theories that attempt to determine the existence of separate human races.

82 The use of the term 'race' does not imply an acceptance of theories that attempt to determine the existence of separate human races.

83 https://www.humanexposome.eu

84 https://humanexposome.net

85 https://www.icos-cp.eu/about/organisation-governance/icos-eric

86 https://eirene.eu

87 https://research-and-innovation.ec.europa.eu/research-area/health/environment-climate-and-health_en

88 https://climate-adapt.eea.europa.eu/en/observatory

89 See introduction to this Work Programme part.

Applicants should provide details of their clinical studies[90] 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	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.
Indicative budget	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: 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.
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. Beneficiaries may provide financial support to third parties to ensure the deployment and impact of the project outcomes. The support to third parties can only be provided in the form of grants. The maximum amount to be granted to each third party is EUR 60 000. The specific conditions are described in General Annex H. PCP procurement costs are eligible.

[90] 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.

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

- Populations, public authorities and healthcare systems benefit from innovative solutions and technologies to increase surveillance and prevention and reduce climatic and environmental health risks.

- Policymakers 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, Pre-commercial 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, communities and individuals 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.

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 Research and Development (R&D). They will be able to respond to the call for tenders launched by consortia of procurers funded under this topic.

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, procedures and solutions for health risk management, prevention and resilience, enhancing strategies and interventions for health adaptation to climate change 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. Consortium composition could include diverse stakeholders such as hospitals, primary healthcare providers, domestic care services, municipalities, civil protection entities and government agencies. The focus can extend beyond climate variables to include other related environmental and ecological factors that interact with climate change and impact public health.

Proposals are encouraged to consider, where relevant, the data, expertise and services offered by European research infrastructures[91] in the environment, climate and health domain.

Continuous dialogue between demand and supply side is required for the success of PCPs, therefore the effective involvement of end users should be considered in the proposal. Furthermore, to stimulate dialogue with the supply side, procurers should organise an open market consultation before launching the procurement and should 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 i) procure the solution(s) as part of the PCP or ii) in a separate follow-up procurement after the PCP. In the first case, procurers can implement the project as a fast-track PCP (see section H of the General Annexes of this Work Programme for further details) and foresee the budget to purchase at least one solution during the PCP. In the second case, the procurers should include in the proposal a deliverable that prepares the follow-up procurement to purchase successful solution(s) after the PCP.

[91] The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

All proposals involving the development, use and/or deployment of AI based system/technique should ensure that the proposed AI system/technique is technical robust [92], safe and must describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability.

This topic is co-financed by the EU Mission on Adaptation to climate change[93] and supports the follow up to the 2023 Communication on the Missions[94]. Projects are encouraged to channel their activities through the Mission Implementation Platform[95] and the Mission's Community of Practice[96].

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).

92 See introduction to this Work Programme part.

93 https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/adaptation-climate-change_en

94 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023DC0457&qid=1693304388860

95 Initially established by MIP4Adapt (https://climate-adapt.eea.europa.eu/en/mission/the-mission/about-mip4adapt, https://fedarene.org/project/mip4adapt) and extended under the contract CINEA/2025/OP/0014.

96 https://climate-adapt.eea.europa.eu/en/mission/community-of-practice

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) [97].

[97] 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

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

- The healthcare sector is supported with new technological developments and frameworks for greening, decarbonising 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.
- Policymakers 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.
- Populations are empowered and equipped with knowledge, tools and resources to adopt health-protective behaviours and adapt to health-related climate risks.

Scope: The health sector accounts for nearly 5% of global greenhouse gas (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 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 some of the following activities:

- Develop and/or pilot effective, inclusive 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 interventions.

- Generate evidence on the health co-benefits of climate change mitigation and propose frameworks to quantify the magnitude of their 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 infrastructures, healthcare professionals and relevant supply chains and logistics.

- Explore and assess 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 GHG and pollutants (to air, water and soil) of healthcare practices and their supply chains. 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. 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[98].

International cooperation is encouraged.

Proposals should make sure that relevant activities, outcomes and outputs are shared with the European Climate and Health Observatory[99] through the cluster that will be formed after the approval of the proposals. When relevant proposals should build on the outcomes of the projects that are part of the European Climate-Health Cluster[100].

Proposals are encouraged to consider, where relevant, the data, expertise and services offered by European research infrastructures[101] in the environment and health domain.

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

All proposals involving the development, use and/or deployment of AI based system/technique must ensure that the proposed AI system/technique is technical robust[102], safe and must describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability.

Applicants should provide details of their clinical studies[103] 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	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.

98 https://research-and-innovation.ec.europa.eu/research-area/health/environment-climate-and-health_en
99 https://climate-adapt.eea.europa.eu/en/observatory
100 https://climate-health.eu
101 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu
102 See introduction to this Work Programme part.
103 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 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. 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) [104].

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

- An international multilateral initiative is established to facilitate coordination and synergy between different research and innovation funding organisations tackling climate change and health issues with adequate support of a secretariat that works

[104] 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

towards the definition of a governance model and forward-looking plan for the implementation of this initiative.

- The international community of research funders working in the climate-health nexus is well connected and supported to improve coordination of activities and alignment of priorities and increase the collective impact of funding streams.

- The research community, civil society groups and policymakers working in the climate-health nexus are well informed about the initiative's activities and benefit from the knowledge, tools and opportunities created during its implementation.

Scope: Climate-related health challenges are global and complex in nature, which calls for coordinated action bringing together different research disciplines, policy sectors, perspectives and approaches. This requires seamless communication and synergies between different Research and Innovation (R&I) funding instruments.

R&I is key to increasing our understanding of existing and emerging climate-related vulnerabilities experienced by populations and health systems alike, as well as to supporting the development and implementation of effective and sustainable interventions for prevention, adaptation and preparedness against climate-related health threats. They also play a crucial role in supporting the health sector's transition towards decarbonisation and long-term sustainability while ensuring that quality of care is maintained or improved.

R&I funding schemes and programmes will structure and accelerate the health response needed to meet the severity of the climate crisis in the decades to come. Achieving this requires building on a truly collaborative and impactful network of key players that optimally and efficiently structure and align their research programmes and funding streams.

The Commission, in collaboration with other funders and international organisations, will work on the development of a collaborative interface that brings together research funders from around the world working at the intersection of health and climate. This platform will establish opportunities for participating organisations to discuss challenges and priorities and share best practices, research strategies and implementation plans. The platform will also serve to identify areas of common interest for collaboration and to build a shared vision to support health and climate research globally.

Proposals under this topic should focus on the provision of administrative and technical support to the successful establishment and implementation of a multilateral initiative of research and innovation funders working in climate change and health.

More specifically, proposals are expected to focus on all the following activities:

- Support exchanges between relevant parties to define the structure and governance model of the multilateral initiative.

- Facilitate and support the drafting of the workplan for the first period of activities of the multilateral initiative.

- Provide administrative and organisational support to the board of the multilateral initiative, in close collaboration with the chairs of the initiative.
- Provide scientific and technical support in aspects relevant to the development and implementation of the multilateral initiative.
- Facilitate communication between members of the initiative as well as with external stakeholders and organisations, and support the organisation of necessary meetings and the preparation of supporting material.
- Support external communication activities such as the creation of a website, newsletters, social media outreach and any other relevant communication and dissemination materials to promote the multilateral initiative.

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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[105].

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[106]. 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 Guidelines for 2024-2029[107], such as the fight against non-communicable and communicable diseases, mental health, preparedness and response to and surveillance of health threats and epidemics, reduction of the number, and treatment, of Antimicrobial-Resistant (AMR) 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-

105 https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/strategic-plan_en

106 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

107 https://commission.europa.eu/about/commission-2024-2029_en

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) innovative therapies for AMR critical pathogens; and v) support to second phases of the co-funded European Partnership on Rare Diseases[108] and the future co-funded European Partnership for Pandemic Preparedness[109].

To increase the impact of EU investments under Horizon Europe, the 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 "Civil Security for Society", Artificial Intelligence (AI)-based tools and technologies under Cluster "Digital, Industry and Space", or antimicrobial resistance under Cluster "Food, Bioeconomy, Natural Resources, Agriculture and Environment".

The 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) [110], the EU's public health programme, as a means of capitalising on potential collaborations and maximising 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 World Health Organization (WHO) Global Action Plan for the Prevention and Control of non-

108 https://cordis.europa.eu/project/id/101156595, https://erdera.org
109 https://beready4pandemics.eu
110 https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en

communicable diseases[111,112] are attained, with an immediate impact on the related disease burden (Disability-Adjusted Life Years - DALYs)[113].

- 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[114,115].
- 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[116] 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

111 https://www.who.int/publications/i/item/9789241506236
112 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
113 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.
114 WHO global action plan on antimicrobial resistance, 2015
115 EU One Health Action Plan against AMR, 2017
116 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).

	selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 65.00 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: For the first stage, the thresholds for each criterion will be 4 (Excellence) and 4 (Impact). The overall threshold applying to the sum of the two individual scores will be set at a level that ensures the total requested budget of proposals admitted to stage 2 is as close as possible to three times the available budget, and not less than two and a half times the available budget. 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) [117].

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

[117] 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

burden". To that end, proposals under this topic should aim to deliver results that are directed at, 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 the following specific Non-Communicable Diseases (NCDs): 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.

- 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[118] 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: NCDs 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[119] clinical trial(s) to validate novel or refined healthcare interventions[120] for treatment and/or disease management solutions for patients suffering from the following specific NCDs: cardiovascular diseases, diabetes, chronic respiratory diseases or chronic kidney diseases [121] . Whenever relevant, existing co- and multimorbidities should be addressed in the trial design.

- Clinical trial(s) should be supported by completed proof-of-concept[122] of clinical safety and efficacy.

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118 See definition of FAIR data in the introduction to this Work Programme part.
119 For pharmacological interventions: phase 1 and/or phase 2 clinical trials.
120 Applicants may address any mono- or combinatorial pharmacological and/or non-pharmacological interventions.
121 Other diseases are not within the scope of this topic.
122 Comparative effectiveness studies are not within the scope of this topic.

- 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, genetic and epigenetic variations, 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 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. Hardware and software should be interoperable in line with internationally accepted standards. The use of virtual human twins[123] could also be considered, where relevant.

- Exploit existing data, health data infrastructures[124], biobanks, registries and/or cohorts, together with the generation of new data that should be managed in line with the FAIR principles and contribute to emerging research infrastructures established in the framework of the European Health Data Space (EHDS)[125], 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 (RWD)[126] analysis to enhance sustainability and scalability of novel interventions.

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

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

125 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

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

The participation of start-ups, micro, small and medium-sized enterprises (SMEs)[127] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

All proposals involving the development, use and/or deployment of AI-based systems or techniques should ensure that the proposed AI system or technique is technically robust[128] and safe and should describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability.

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

All projects funded under this topic are encouraged to participate in networking and joint activities, as appropriate[129] and explore potential synergies with projects funded under the EU4Health Programme (2021-2027)[130] in the area of NCDs.

Applicants invited to the second stage should provide details of their clinical studies[131] 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-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 45.00 million.

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

128 See introduction to this Work Programme part.

129 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.

130 https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en

131 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.

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

- Researchers and healthcare 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[132].
- 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.

[132] 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

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 the Gross Domestic Product (GDP)[133] and since then these figures worsened[134] 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[135]. 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), and could include the use of Artificial Intelligence (AI). When handling data and indicators, sex- and gender-disaggregated data should be collected and analysed, incorporating intersectional factors where feasible.

The applicants should address all the following aspects:

- 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).

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

- 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[136] 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 topic. Applicants envisaging to include longitudinal cohort studies are invited to indicate a sustainability plan on how those

133 https://health.ec.europa.eu/system/files/2020-02/2018_healthatglance_rep_en_0.pdf
134 https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/751416/EPRS_BRI(2023)751416_EN.pdf
135 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023DC0298
136 ICD11, Chapter 6: https://icd.who.int/browse/2025-01/mms/en#334423054

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 cohorts data 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[137], Euro-BioImaging[138]).

All projects funded under this topic should liaise with relevant European projects on mental health[139] and the future co-funded European partnership for Brain Health[140]. They are also encouraged to explore potential synergies with projects to be funded under the EU4Health Work Programme 2026 related to the harmful effects of using digital technologies on the mental health of children and young adults.

The participation of start-ups and/or micro, small and medium-sized enterprises (SMEs)[141] 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[142] data principles, adopt wherever relevant, data standards and data sharing/access good practices, and apply good practices for GDPR[143] compliant personal data protection.

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. The support and involvement of citizens and civil society should be considered.

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.

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137 https://www.ebrains.eu

138 https://www.eurobioimaging.eu

139 Projects funded under topics HORIZON-HLTH-2024-STAYHLTH-01-02-two-stage: "Towards a holistic support to children and adolescents' health and care provisions in an increasingly digital society" and HORIZON-HLTH-2022-STAYHLTH-01-01-two-stage: "Boosting mental health in Europe in times of change".

140 https://www.brainhealth-partnership.eu

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

142 See definition of FAIR data in the introduction to this Work Programme part.

143 General Data Protection Regulation: https://commission.europa.eu/law/law-topic/data-protection_en, https://gdpr-info.eu

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.

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 *Indicative budget*	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. 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 Research and Training Programme of the European Atomic Energy Community (2021-2025) [145].

[145] 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

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

- All players along the healthcare 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 healthcare 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 been 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.
- Increase 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[146] 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 hormonal and other biological factors, 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[147] data, leveraging existing European (research) infrastructures, including biobanks or cohorts' data[148] where relevant and contribute to emerging research infrastructures, established in the framework of the European Health Data Space (EHDS)[149] and the European Open Science Cloud (EOSC)[150].

Proposals should demonstrate complementarity with ongoing EU initiatives, including projects funded under relevant topics[151], 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[152]. They are also expected to engage early on with the European Medicines Agency

146 For pharmacological interventions: phase 1 and phase 2 clinical trials.
147 See definition of FAIR data in the introduction to this Work Programme part.
148 ORCHESTRA data portal: https://orchestra-cohort.eu/data-portal, Pathogens portal cohorts browser: https://www.pathogensportal.org/cohorts
149 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en
150 https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/our-digital-future/open-science/european-open-science-cloud-eosc_en
151 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 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2025-01-disease-07

(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.

If applicable, 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 minimise bias. Hardware and software should be interoperable in line with internationally accepted standard.

All proposals involving the development, use and/or deployment of AI-based systems or techniques should ensure that the proposed AI system or technique is technically robust[153] and safe and should describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability.

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.

Participation of start-ups, micro, small and medium-sized enterprises (SMEs)[154] is also encouraged to strengthen their scientific and technological foundations and enhance their innovation potential.

Applicants should provide details of their clinical studies[155] 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 viral pathogens with epidemic potential

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

152 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.

153 See introduction to this Work Programme part.

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

155 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 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.
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 viruses targeted[156], 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 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 at, 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, including better understanding of biological sex and social determinants that influence immune response, vaccine efficacy, safety, and uptake.

- Candidate vaccines are available for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

[156] Virus i to viii, as given in the scope of this topic.

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.

Applicants should explicitly state in their proposal which of the following viruses is targeted and the proposed work should exclusively pursue the development of existing prophylactic and therapeutic vaccine candidates targeting exclusively this specific virus:

i. Junin mammarenavirus
ii. Lassa mammarenavirus
iii. Andes virus,
iv. Hantaan virus
v. Sin Nombre virus
vi. Hendra virus
vii. Enterovirus D68
viii. Venezuelan equine encephalitis virus

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.

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- Production of batches of the most promising vaccine candidates according to the Good Manufacturing Practices (GMP)[157] standard in the EU or the European Economic Area (EEA)[158].

- 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) [159] 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 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[160].

Proposals should advance research by leveraging already existing and emerging state-of-the-art research infrastructures[161] such as those having contributed to the services developed under the ISIDORe project.

Applicants should provide details of their clinical studies[162] 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	The Commission estimates that an EU contribution of around EUR 10.00

157 https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp

158 https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:European_Economic_Area_(EEA)

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

160 https://isidore-project.eu

161 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

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

contribution per project	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.
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 viruses targeted[163], 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 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 at, 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 to treat patients for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

[163] Virus i to x, as given in the scope of this topic.

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.

Applicants should explicitly state in their proposal which of the following viruses is targeted and the proposed work should pursue the development of novel or existing broad spectrum antiviral candidates targeting exclusively this specific virus:

i. Junin mammarenavirus
ii. Lassa mammarenavirus
iii. Tick-borne encephalitis virus
iv. Japanese encephalitis virus
v. Andes virus
vi. Hantaan virus
vii. Sin Nombre virus
viii. Hendra virus
ix. Enterovirus D68
x. Venezuelian equine encephalitis virus

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.

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- 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 according to the Good Manufacturing Practices (GMP)[164] standard in the EU or the European Economic Area (EEA)[165] 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) [166] 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 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[167] such as those having contributed to the services developed under the ISIDORe project[168].

The projects funded under this topic should synergise with projects funded by the future co-funded European Partnership for Pandemic Preparedness[169].

Applicants should provide details of their clinical studies[170] 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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164 https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp

165 https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:European_Economic_Area_(EEA)

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

167 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

168 https://isidore-project.eu

169 https://beready4pandemics.eu

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

HORIZON-HLTH-2027-01-DISEASE-06: Development of monoclonal antibodies to prevent and treat infections from Flaviviridae

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 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 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.
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 Flaviviridae targeted[171], 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 Flaviviridae, 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

[171] Flaviviridae i to vi, as given in the scope of this topic.

burden". To that end, proposals under this topic should aim to deliver results that are directed at, 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 to treat patients 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.

Applicants should explicitly state in their proposal which of the following Flaviviridae is targeted and the proposed work should exclusively pursue the development of existing prophylactic and therapeutic monoclonal antibody candidates targeting exclusively this specific Flaviviridae:

i. Dengue Virus
ii. Tick-borne Encephalitis Virus
iii. Japanese Encephalitis Virus
iv. West Nile Fever Virus
v. Yellow Fever Virus
vi. Zika 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 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:

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- 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 according to the Good Manufacturing Practices (GMP)[172] standard in the EU or the European Economic Area (EEA)[173].

- 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) [174] 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 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[175] such as those having contributed to the services developed under the ISIDORe project[176].

Applicants should provide details of their clinical studies[177] 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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172 https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp

173 https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:European_Economic_Area_(EEA)

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

175 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

176 https://isidore-project.eu

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

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 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 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.
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 viruses targeted [178], 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 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

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

[178] Virus i to vi, as given in the scope of this topic.

burden". To that end, proposals under this topic should aim to deliver results that are directed at, 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 to treat patients 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.

Applicants should explicitly state in their proposal which of the following viruses is targeted and the proposed work should exclusively pursue the development of existing prophylactic and therapeutic monoclonal antibody candidates targeting exclusively this specific virus:

i. Ebola Virus
ii. Marburg Virus
iii. Crimean-Congo Hemorrhagic Fever Virus
iv. Rift Valley Fever Virus
v. Enterovirus D68
vi. 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 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.

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- 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 according to the Good Manufacturing Practices (GMP)[179] standard in the EU or the European Economic Area (EEA)[180].

- 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) [181] 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 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 [182] such as those having contributed to the services developed under the ISIDORe project[183].

Applicants should provide details of their clinical studies[184] 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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179 https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp

180 https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:European_Economic_Area_(EEA)

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

182 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

183 https://isidore-project.eu

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

HORIZON-HLTH-2027-01-DISEASE-08: Development of innovative antimicrobials against critical pathogens resistant to antimicrobials

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 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. 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.
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 critical pathogens targeted[185], 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 critical pathogen, 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

[185] Critical pathogen i to v, as given in the scope of this topic.

burden". To that end, proposals under this topic should aim to deliver results that are directed at, 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 to treat patients for antimicrobial resistant bacteria and fungi, increasing therapeutic options for clinical deployment in the fight against Antimicrobial Resistance (AMR).

Scope: The rapid rise of 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 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 World Health Organization (WHO) innovation criteria[186], namely: i) new chemical class, ii) new target, iii) new mode of action and iv) no evidence of cross-resistance.

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

Applicants should explicitly state in their proposal which of the following critical pathogens is targeted and the proposed work should exclusively pursue the development of existing therapeutic candidates targeting exclusively this specific critical pathogen:

i. Carbapenem resistant Acinetobacter baumanii (CRAB)
ii. Carbapenem-resistant Enterobacterales (CRE) and third-generation cephalosporin-resistant Enterobacterales (C3GRE)
iii. Carbapenem resistant Pseudomonas aeruginosa
iv. (Drug)-resistant Aspergillus fumigatus
v. (Drug)-resistant Candida spp

[186] https://www.who.int/publications/i/item/9789240093461

Proposals are expected to conduct advanced preclinical studies of antimicrobial candidates, prepare Good Manufacturing Practices (GMP)[187], 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 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 batches of the most promising antimicrobials candidates according to the GMP standard in the EU or the European Economic Area (EEA)[188].
- 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) [189] 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 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 future co-funded European Partnership on One Health Anti-Microbial Resistance (EUP OHAMR)[190].

Applicants should provide details of their clinical studies[191] 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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187 https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp
188 https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:European_Economic_Area_(EEA)
189 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361
190 https://www.jpiamr.eu/activities/one-health-amr

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 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) [192].

[191] 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.

[192] 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:

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

- Researchers, policymakers, healthcare- and non-healthcare-related stakeholders and authorities in low- and middle-income countries (LMICs)[193] and/or those in high-income countries (HICs) serving disadvantaged populations have access to improved insights and evidence on how to maximise collaboration and coordination with sectors and in settings beyond the healthcare system in the context of Non-Communicable Diseases (NCDs).

- Researchers, policymakers, healthcare- and non-healthcare-related stakeholders and authorities have an improved understanding how the proposed interventions draw on collaborative multisectoral engagement and utilise the different settings in which people are educated, work and live, to expand efforts to reduce risks, prevent, manage and control NCDs.

- Communities, relevant stakeholders from different sectors and authorities are fully engaged in implementing and taking up interventions that tackle the growing burden of NCDs through actions in sectors and settings outside the traditional health system and its facilities health-related outcomes, improve quality of life across the life course and extend healthy life expectancy.

Scope: The Commission is a member of the Global Alliance for Chronic Diseases (GACD)[194]. The GACD specifically addresses NCDs and supports implementation research[195] to improve health outcomes. This topic is launched in concertation with the other GACD members (international funding agencies) and aligned with the 11th GACD call.

Besides health-related determinants, the burden of NCDs is also driven by structural and social inequities, population ageing, the effects of globalisation on marketing and trade, diet and activity, commercial and economic determinants of health, rapid urbanisation and climate change, factors over which a conventional healthcare-oriented system has little sway. There is a need for a comprehensive approach, involving sectors outside of health, to meet the global targets that governments have agreed upon to protect people from chronic NCDs. Tackling chronic NCDs most effectively therefore requires engagement and coordinated policy development within and across many government departments, including education, workplace, environment, housing, transportation, agriculture, food industry and nutrition, leisure and culture.

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https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf

193 As defined by the World Bank, https://www.worldbank.org

194 https://www.gacd.org

195 https://iris.who.int/bitstream/handle/10665/91758/9789241506212_eng.pdf

The aim of this topic is to fund implementation research focused on strategies to tackle the growing burden of NCDs through actions in sectors and settings outside the traditional health system[196] and its facilities (with or without the involvement of the healthcare system) to attain equitable health-related outcomes or influence health determinants for people living in LMICs, and/or underserved populations in HICs.

Proposals can focus on more than one setting and/or include cross-sectoral approaches, involving both health and non-health settings to expand efforts to reduce risks, prevent, manage and control NCDs. Safety is a major concern in non-health settings, and proposals should ensure any risks and safety considerations are addressed.

The choice of intervention(s)[197] and provision of existing evidence of the intervention's effectiveness, cost-effectiveness, sustainability, scalability and potential for long-term health and other impacts should be justified (and in what context this evidence has been generated).

The majority of evidence-based interventions implemented outside of the health sector focus on prevention of NCDs: relatively few focus on strategies for management of these chronic conditions, and a limited number are implemented in LMIC contexts or underserved communities. Therefore, it may be important to undertake formative research as a part of the proposal to support readiness for implementation.

Applicants should explore the implementation of proposed intervention(s) for a selected study population(s) based in one or more LMICs, and/or underserved populations experiencing health disparities, including Indigenous populations, in HICs, considering the unique social, political, economic, and cultural context(s) in which the study will take place[198]. Applicants

[196] In this context, non-healthcare settings can include for instance: workplaces; schools, universities and other education venues (including pre-schools, nursery, etc.); faith-based communities, places of worship and traditional healers; recreation and sports clubs, fitness centres, swimming pools; prisons; communities (geographic and/or of identity) and families; community pharmacies; theatres, community spaces; retirement homes and care homes; homeless shelters; markets, malls, commercial settings; barbers, hairdressers and beauty salons; urban environments, parks, transportation (the list is not exhaustive).

[197] Research proposals might explore implementation, outcomes and impact of context relevant strategies to implement evidence-based interventions or initiatives including (though not limited to):i) Non-health sector policy introduction, to tackle relevant social and/or structural determinants of NCDs; ii) Strategies to expand screening for NCDs and their risk factors in community, school, workplace, faith-based settings (e.g. Human Papillomavirus - HPV screening, blood pressure monitoring, blood sugar testing); ii) Partnered strategies to prevent NCDs in the community (e.g. educational campaigns, changes to school or work environments, promotion/delivery of healthy food choice and diet, opportunities for increased physical activity, strategies to support tobacco cessation and alcohol cessation); iv) Cost effective, patient centred treatment and management of NCDs in the community (e.g. mental health support, community medicine purchasing clubs, self-management groups); v) Non-health sector policy introduction e.g. environmental policy or practices (e.g. improvements to transport systems, public infrastructure) and the potential co-benefits on health; vi) Digital interventions e.g. for patient or care giver support, such as use of Artificial Intelligence for Patient support or to promote prevention messages on Chronic Disease Risk Factors).

[198] Focus on populations facing extreme vulnerabilities, such as individuals or communities living in informal settlements, post-disaster settings, or in situations of homelessness is encouraged (though not required).

should justify why any adaptation will not compromise the known effectiveness of the selected intervention(s).

Proposals should address all the following implementation research activities[199]:

- Clearly describe the implementation research methodology, including the statistical design, and provide a rationale for the implementation strategy/ies to be explored (in light of the context), the community/population group(s) to benefit, the settings and sectors involved (and how these should be engaged), the current state of the art and how the proposal improves on this, and, if used, the theories, models and/or frameworks underpinning the research.

- Have an appropriate strategy for measuring implementation research outcomes and real-world effectiveness outcomes and indicators.

- Specifically address issues of equitable implementation to ensure interventions reach the populations that need them the most.

- Engage an appropriately expert and skilled research team which can ensure a suitable multidisciplinary approach and that demonstrates equitable partnership and shared leadership between HIC-LMIC, and/or non-Indigenous-Indigenous members of the project team and external stakeholders through a clear governance strategy.

- Provide a stakeholder engagement strategy with evidence of support/engagement from key stakeholders for delivering the intervention and a pathway to sustain the proposed intervention (if proven effective) after the funding from the GACD grant ends.

- Provide opportunities for implementation research capacity building for early career researchers and team members from lower resourced environments, such as LMICs or disadvantaged communities.

- Ensure meaningful involvement of early career team members, including at least one early career member as a co-investigator.

The study population may include the general population, people with one or more existing NCDs, those currently without NCDs, or a combination of both. Applicants may propose implementation research focused on interventions that are implemented at the individual, family, community (e.g. work or school), population, and/or structural level. With regard to NCDs, applicants are encouraged to explore any chronic non-communicable condition (or combination of conditions), including mental health disorders, autoimmune conditions,

[199] The following types of proposals are not in the scope of this topic: i) proposals with the primary aim of informing the development and/or selection of an intervention for a given context, where the implementation component will be explored in a future project (i.e. standalone feasibility projects);ii) epidemiological cohorts; iii) etiological work, mechanistic, or epidemiological research, unless an essential component of a focused study to develop implementation research approaches; iv) clinical trials, validation studies, or intervention efficacy studies for a new or established pharmacological agent or behavioural intervention.

musculoskeletal conditions, neurological disorders and sleep disorders and/or any risk factor (or combination of risk factors). Additionally, whenever relevant, applicants are also encouraged to take a life course approach, adapting interventions for particular life stages with the goal of promoting life-long health.

Proposals should use an appropriate implementation research design and frameworks[200], cluster Randomised Control Trials (cRCTs), before and after studies, and additional implementation science classifications of study designs (e.g. hybrid designs[201]), noting that applicants are not limited to any particular design.

Proposals are expected to generate evidence that is of direct relevance to policymakers, communities and practitioners. Projects will require a strategy to include the relevant policymakers, local authorities, as well as other stakeholders such as community groups, or other individuals or organisations involved in the implementation of the intervention, with co-creation from the development of the proposal through to the knowledge translation phase. Project partners should be engaged from the beginning to contribute to the sustainability of the intervention after the end of project. Proposals should demonstrate sustainability of the strategy, beyond the lifespan of the project.

Poverty, racism, gender inequality, ethnic discrimination, and other inequities are directly associated with reduced potential for equitable access to quality care. Proposals should consider relevant determinants of health (e.g. social, structural, commercial, economic) and discuss their potential impact on the effective implementation of the intervention(s). If there is a focus on a particular population (e.g. gender, race[202] and/or ethnicity), then the reason for this should be justified.

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

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, including internationally, as appropriate. These activities could, for example, involve the participation in joint workshops, the Annual Scientific Meetings of the GACD, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Therefore, proposals are expected to include a budget for such activities and may consider covering the costs of any other potential joint activities without

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200 Examples of frameworks include (this list is not exclusive): i) Consolidated Framework for Implementation Research (CFIR); ii) the context enhanced (RE-AIM) Reach, Effectiveness, Adoption, Implementation, Maintenance); iii) Practical Robust Implementation and Sustainability Model (PRISM) frameworks; iv) Framework for Developing and Evaluating Complex Interventions (MRC & NIHR).

201 https://pmc.ncbi.nlm.nih.gov/articles/PMC3731143 and https://pmc.ncbi.nlm.nih.gov/articles/PMC6779135

202 The use of the term 'race' does not imply an acceptance of theories that attempt to determine the existence of separate human races.

the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase.

Applicants should provide details of their clinical studies[203] 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-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 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

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

	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) [204].

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

- Researchers, healthcare practitioners and providers in low- and middle-income countries (LMICs) [205] and/or those in high-income countries (HICs) serving disadvantaged populations have access to improved insights and evidence on how to equitably promote the early prevention, risk reduction, and timely diagnosis of Non-Communicable Diseases (NCDs) in children and/or young people.

- Policymakers, public health managers and authorities, parents and their children, and young adults have access to evidence and recommendations for national programmes and policies to improve quality of life in children and/or young people and extend healthy life expectancy.

- Researchers, clinicians, policymakers, public health managers and authorities have an improved understanding how to effectively adapt and/or scale up interventions for prevention and management of chronic NCDs in children and/or young people at local, regional, and national levels.

- Communities, parents and their children, young adults, local stakeholders and authorities are fully engaged in implementing and taking up interventions that tackle NCDs in children and/or young people.

Scope: The Commission is a member of the Global Alliance for Chronic Diseases (GACD)[206]. The GACD specifically addresses NCDs and supports implementation research[207] to improve health outcomes. This topic is launched in concertation with the other GACD members (international funding agencies) and aligned with the 12th GACD call.

Chronic NCDs that begin in childhood have an impact on both quality of life and life expectancy. Onset of many NCDs diseases occurs at younger ages in LMICs, and this is further accompanied by a longer duration of disease and a higher rate of complications, including multimorbidity. The conditions in which people are born, grow and live (the social

204 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

205 As defined by the World Bank, https://www.worldbank.org

206 https://www.gacd.org

207 https://iris.who.int/bitstream/handle/10665/91758/9789241506212_eng.pdf

determinants of health) including access to good nutrition, education, housing, and healthcare are major contributors to health and ill health[208].

Up to 70% of preventable adult deaths from NCDs are linked to risk factors originating in childhood and adolescence[209], and interventions that can successfully control or prevent chronic disease in young people can dramatically improve health outcomes later in life. Childhood and adolescence are critical periods, when behaviours associated with NCD risk are adopted including tobacco use, alcohol use, substance abuse, unhealthy diets and sedentary lifestyles and children and young people are often targeted by commercial marketing of unhealthy products.

The aim of this topic is to fund implementation research, exploring strategies, evidence-based program and policy interventions across prevention, diagnosis, screening and management of chronic NCDs, centred on the critical life stages spanning early childhood to young adulthood (1-24 years of age) living in LMICs, and/or underserved populations in HICs.

In this regard, proposals focused on implementation research might explore implementation strategies on evidence-based interventions, adaptations of interventions and tailored interventions, or initiatives including (though not limited to) those focussed on one or more of the following:

- Policy evaluation to tackle childhood- and/or youth-relevant social, economic, political, structural or commercial determinants of chronic NCD conditions.
- Prevention of NCDs using children and/or young people targeted implementation strategies (e.g. educational strategies, vaccination strategies, promotion of behavioural and lifestyle changes).
- Screening and diagnosis of NCDs (or risk factors) in children and/or young people (in particular use of digital tools).
- Cost effective and patient-centred management of NCDs in children and/or young people (including access to medicines and equipment; integrated care pathways; continuity of care for adolescents with existing non-communicable diseases who "age out" of paediatrics, caregiver health and support, citizen science approaches).

Multiple interventions focus on prevention of NCDs in children and young people, yet relatively few have focussed on strategies for management of chronic conditions in these critical life stages, and a limited number of studies have been carried out to study implementation of these in LMIC contexts or with underserved communities. In this instance it would be anticipated that proposals may explore implementation strategies using the appropriate hybrid design study incorporating effectiveness and implementation research

208 https://www.taylorfrancis.com/chapters/oa-edit/10.4324/9781003306689-20/social-determinants-health-ncds-ruth-bell-jaime-miranda-jean-woo-michael-marmot

209 https://data.unicef.org/topic/child-health/noncommunicable-diseases/

outcomes. Therefore, it may be important to undertake formative research as a part of the proposal to support readiness for implementation.

The proposed implementation research should be focused on one or more evidence-based interventions (or complex interventions), providing existing evidence of the intervention's effectiveness, cost-effectiveness, sustainability, scalability and potential for long-term health and other impacts (and in what context this evidence has been generated).

Applicants should provide rationale and explore the implementation of proposed intervention(s) for a selected study population(s) based in one or more LMICs, and/or underserved populations experiencing health disparities, including Indigenous populations, in HICs, considering the unique social, political, economic, and cultural context(s) in which the study will take place[210]. Applicants should justify why any adaptation will not compromise the known effectiveness of the selected intervention(s).

Proposals should address all the following implementation research activities[211]:

- Clearly describe the implementation research methodology, including the statistical design.
- Have an appropriate strategy for measuring implementation research outcomes and real-world effectiveness outcomes and indicators.
- Specifically address issues of equitable implementation to ensure interventions reach the populations that need them the most.
- Engage an appropriately expert and skilled research team which can ensure a suitable multidisciplinary approach and that demonstrates equitable partnership and shared leadership between HIC-LMIC, and/or non-Indigenous-Indigenous members of the project team and external stakeholders through a clear governance strategy.
- Provide a stakeholder engagement strategy with evidence of support/engagement from key stakeholders for delivering the intervention and a pathway to sustain the proposed intervention (if proven effective) after the funding from the GACD grant ends.
- Provide opportunities for NCD-focused implementation research capacity building for early career researchers and team members from lower resourced environments, such as LMICs or disadvantaged communities.

[210] Focus on populations facing extreme vulnerabilities, such as individuals or communities living in informal settlements, post-disaster settings, or in situations of homelessness is encouraged (though not required).

[211] The following types of proposals are not in the scope of this topic: i) proposals with the primary aim of informing the development and/or selection of an intervention for a given context, where the implementation component will be explored in a future project (i.e. standalone feasibility projects); ii) epidemiological cohorts; iii) etiological work, mechanistic, or epidemiological research, unless an essential component of a focused study to develop implementation research approaches; iv) clinical trials, validation studies, or intervention efficacy studies for a new or established pharmacological agent or behavioural intervention.

- Ensure meaningful involvement of early career team members, including at least one early career member as a co-investigator.

The study population may include children and/or young people in the general population, with one or more existing NCDs, those currently without NCDs, or a combination of any of the above. Applicants may propose implementation research focused on interventions that are implemented at the individual, family, community (e.g. work or school), population, and/or structural level. With regard to NCDs, applicants are encouraged to explore any chronic non-communicable condition (or combination of conditions), including mental health disorders, autoimmune conditions, musculoskeletal conditions, neurological disorders and sleep disorders and/or any risk factor (or combination of risk factors). Additionally, whenever relevant, applicants are also encouraged to take a life course approach, adapting interventions for particular life stages with the goal of promoting life-long health.

Proposals should use an appropriate implementation research design and framework[212], before and after studies, and additional implementation science classifications of study designs (e.g. hybrid designs[213]), noting that applicants are not limited to any particular design.

Proposals would be expected to generate evidence that is of direct relevance to policymakers, communities and practitioners. Projects should identify and engage all key stakeholders necessary and relevant to the development, undertaking and knowledge translation phases of the project, including meaningful collaboration with young people themselves (and their families). Projects should also consider using co-development and co-design approaches, involving policymakers, local authorities, community groups, educators, healthcare providers, and other individuals or organisations necessary to the delivery and sustainability of the study outcomes. Project partners should be engaged from the beginning to contribute to the sustainability of the intervention after the end of project. Proposals should demonstrate sustainability of the strategy, beyond the lifespan of the project.

Poverty, racism, gender inequality, ethnic discrimination, and other inequities are directly associated with reduced potential for equitable access to quality care. Proposals should consider relevant determinants of health (e.g. social, structural, commercial, economic) and discuss their potential impact on the effective implementation of the intervention(s). If there is a focus on a particular population (e.g. gender, race[214] and/or ethnicity), then the reason for this should be justified.

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

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212 Examples of frameworks include (this list is not exclusive): i) Consolidated Framework for Implementation Research (CFIR); ii) the context enhanced (RE-AIM) Reach, Effectiveness, Adoption, Implementation, Maintenance); iii) Practical Robust Implementation and Sustainability Model (PRISM) frameworks; iv) Framework for Developing and Evaluating Complex Interventions (MRC & NIHR).

213 https://pmc.ncbi.nlm.nih.gov/articles/PMC3731143 and https://pmc.ncbi.nlm.nih.gov/articles/PMC6779135

214 The use of the term 'race' does not imply an acceptance of theories that attempt to determine the existence of separate human races.

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

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, including internationally, as appropriate. These activities could, for example, involve the participation in joint workshops, the Annual Scientific Meetings of the GACD, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Therefore, proposals are expected to include a budget for such activities 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.

Applicants should provide details of their clinical studies[215] 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-11: Understanding of sex and/or gender-specific mechanisms of cardiovascular diseases: determinants, risk factors and pathways

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 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 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).

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

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) [216].

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

- Researchers, developers of medical interventions, and healthcare professionals have a better understanding of biological sex and/or gender-specific health determinants, risk factors and pathways for cardiovascular diseases.
- Researchers, developers of medical interventions, and healthcare professionals have access and use sex and/or gender-specific or tailored risk models for better prevention, detection and diagnostic and treatment strategies.
- Healthcare systems benefit from novel sex and/or gender-specific strategies for prevention, detection, diagnosis and treatment options, resulting in reduced burden of cardiovascular diseases.

Scope: Cardiovascular diseases (CVDs) are the leading cause of premature deaths in the EU and account for 32% of all deaths in 2021 (over 1.7 million deaths)[217].

Biological sex and gender play a specific role both in the incidence and the prevalence of certain diseases, including CVDs. Sex and gender disparities in CVDs are influenced by biological, behavioural, and sociocultural factors, affecting symptoms, prevalence, treatment, and outcomes. Hormonal influences, genetic predispositions, and/or physiological differences

[216] 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

[217] European Union takes action for the cardiovascular health of its 440 million people - EACH: https://www.cardiovascular-alliance.eu/european-union-takes-action-for-the-cardiovascular-health-of-its-440-million-people

contribute to variations in how CVD presents and progresses in men and women. Risk factors such as diabetes, cholesterol, smoking, and age have different impacts across genders, highlighting the need for customised treatment strategies. Unique gender-specific conditions in women, such as menopause, pregnancy complications like preeclampsia and certain autoimmune diseases, also increase the risk for CVDs[218].

Mainstreaming a gender perspective into the research, prevention and control of CVDs is thus crucial to understanding and addressing the health risks and needs of women and men of all ages[219].

Although the significant progress has been done in investigating sex and/or gender-specific pathophysiological mechanisms of cardiovascular diseases, more research is needed to translate basic discoveries into the development of innovative prevention, detection, diagnosis, and treatment options.

Proposals should address most of the following aspects:

- Contribute to further the understanding on the structural, hormonal, and/or biological distinctions between sexes/genders to improve diagnostics and therapeutics for CVDs.
- Develop sex and/or gender-specific tailored risk models in a view of better prevention, detection and diagnostic, and treatment strategies.
- Identify and/or validate novel or existing sex and/or gender-specific health determinants, risk factors and pathways for cardiovascular disease(s) through the generation, integration and validation of data derived from relevant disciplines (e.g. molecular biology, behavioural science, nutrition, clinical, social and environmental epidemiology; exposure sciences; genetics and epigenetics, etc.).
- Make use of existing health data, including registries or cohorts, and/or assess the necessity to establish new ones, as well as, where relevant, exploit the knowledge gained from population-based biobanks. In case of the generation of new data, it should be managed in line with the FAIR[220] principles, when relevant.

Proposals are encouraged to consider, where relevant, the data, expertise and services offered by European research infrastructures[221] in the health domain.

The use and/or development of new technologies, including digital ones (e.g. (generative) Artificial Intelligence) that support research under this topic is encouraged. All proposals

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218 Gender Disparities in Cardiovascular Disease and Their Management: A Review - PMC: https://pmc.ncbi.nlm.nih.gov/articles/PMC11148660

219 Political declaration of the 3rd High-Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases : resolution adopted by the General Assembly: https://digitallibrary.un.org/record/1648984?v=pdf

220 See definition of FAIR data in the introduction to this Work Programme part.

221 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

involving the development, use and/or deployment of AI-based systems or techniques should ensure that the proposed AI system or technique is technically robust[222] and safe and should describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability.

Disease progression and overall health status at different life stages, as well as hormonal influences, genetic factors, etc. and psychosocial, socioeconomic, cultural and behavioural factors should be considered in the proposed research. Other intersecting factors such as racial[223] or ethnic origin, often amplify existing inequalities in health access and outcomes. Proposals should, where relevant, consider these to design effective and inclusive interventions.

In the context of gender-specific research, this topic requires the effective contribution of social sciences and humanities (SSH) disciplines and the involvement of SSH experts, institutions as well as the inclusion of relevant SSH expertise, in order to produce meaningful and significant effects enhancing the societal impact of the related research activities.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs) [224] 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. 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. All projects funded under this topic are also encouraged to explore complementarities and exploit potential synergies with the projects funded under topic HORIZON-CL6-2026-02-FARM2FORK-10: "Sustainable and healthy diets based on health status and socio-economic risk factors of ageing population", once information on the funded projects is available.

All projects funded under this topic are encouraged to explore potential synergies with projects to be funded under the EU4Health Work Programme 2026 related to the gender and CVDs.

Applicants envisaging to include clinical studies[225] should provide details of their clinical studies in the dedicated annex using the template provided in the submission system.

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222 See introduction to this Work Programme part.

223 The use of the term 'racial origin' does not imply an acceptance of theories that attempt to determine the existence of separate human races.

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

225 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-2026-02-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.
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: 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-

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	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. This is justified by the pooling of proposers' in-kind contributions and in-house activities and by the nature of activities to be performed: in addition of joint calls, highly integrative activities (EU clinical trial preparedness, training, patients' empowerment activities etc.) contributing to enhance the rare disease research and innovation ecosystem in Europe and beyond. • Beneficiaries may provide financial support to third parties (FSTP). The support to third parties can only be provided in the form of grants. As a co-funded European Partnership, providing financial support to third parties is a core activity of this action in order to achieve its objectives. Consequently, the EUR 60 000 threshold laid down in Article 207 of Financial Regulation (EU, Euratom) 2024/2509 does not apply. The maximum amount of FSTP that may be awarded to any single third party for the duration of the partnership is set at EUR 10.00 million. This ceiling is justified by the fact that FSTP is a primary activity of this action, by its expected duration of 7-10 years (exceeding a standard project lifespan), and by the extensive experience gained under predecessor partnerships. 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 one or several expected impacts of destination "Tackling diseases and reducing disease burden". It will complement the action launched under topic HORIZON-HLTH-2023-DISEASE-07-01: "European Partnership on Rare Diseases", by allowing additional partners (if relevant) to join the co-funded European Partnership on Rare Diseases in order to perform additional activities.

To that end, proposals under this topic are expected to build on the first phase of this partnership[226] and should aim to deliver results that are directed at, tailored towards and contributing to all 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 and cross-border FAIR[227] data access and analysis, including rare diseases registries, by integrating the EU, national/regional data and information infrastructures to improve translational research.
- People living with a rare disease, including those from underrepresented communities, benefit from a more timely, equitable access to innovative, sustainable and high-quality healthcare including novel diagnosis and treatments, 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. Non-Governmental Organisations, 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.

[226] Action "European Rare Diseases Research Alliance" (ERDERA) launched under topic HORIZON-HLTH-2023-DISEASE-07-01: "European Partnership on Rare Diseases".

[227] See definition of FAIR data in the introduction to this Work Programme part.

Scope: This topic targets an action under Article 24(2) HE Regulation aiming to add additional activities to existing grant agreements, together with additional partners (if relevant) that would deliver on those activities. The existing action, the "European Rare Diseases Research Alliance" (ERDERA) can only reasonably be enhanced and enlarged on the basis of the existing consortium[228], as the co-funded framework established cannot simply be replaced without significant disruption, given the top-quality, long-term expertise and wide coverage of the beneficiaries comprising this consortium.

The proposal should thus present the specific additional activities (including, if relevant, additional partners) 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), the "Council conclusions on the Future of the European Health Union: A Europe that cares, prepares and protects" (9900/24)[229] and support the objectives of the EU4Health Programme (2021-2027)[230].

This partnership should also contribute to achieving the objectives of the Pharmaceutical Strategy for Europe[231], in terms of fulfilling unmet medical needs and catalysing the clinical development of medicines for rare diseases (i.e. "orphan medicinal products") and ensuring that the benefits of research and innovation reach patients in the EU and the Associated Countries. Moreover, the partnership is expected to contribute and align with the objectives of the Directive 2911/24/EU on the application of patients' rights in cross-border healthcare[232] and of the European Health Data Space (EHDS)[233].

Thanks to its capacity to bring together different stakeholders (e.g. research funders, health authorities, healthcare institutions, innovators, policymakers), the partnership will strengthen the European Research Area and consolidate the European research and innovation ecosystem with a critical mass of resources, and implement a long-term Strategic Research and Innovation Agenda (SRIA)[234].

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 and clinical 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

228 Consortium which was awarded the grant under topic HORIZON-HLTH-2023-DISEASE-07-01: "European Partnership on Rare Diseases".
229 https://www.consilium.europa.eu/en/press/press-releases/2024/06/21/european-health-union-council-calls-on-commission-to-keep-health-as-a-priority
230 https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en
231 https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en
232 https://eur-lex.europa.eu/eli/dir/2011/24/oj/eng; in particular articles 12 and 13 respectively on European Reference Networks (ERNs) and rare diseases
233 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en
234 https://erdera.org/strategic-research-innovation-agenda-sria

research infrastructures[235] and resources, including networking, training and dissemination activities. To this end, the proposals are expected to build on the first phase of this partnership and should be structured along the following main objectives:

- Launch joint transnational calls for RD research and innovation actions, aligned with SRIA priorities, to fund patient-need-driven research across Europe, ensuring effective cross-border collaboration and scalability, while demonstrating short, medium and long-term impact and value creation through financial support to third parties and a rigorous monitoring strategy of research outputs.

- Further establish, strengthen and develop the different components of a European Clinical Research Network (CRN) to boost clinical trial readiness and capacity to readily implement well-coordinated multi-national clinical studies on rare diseases, building on the European Reference Networks (ERNs). The partnership is expected to showcase the CRN's contribution to the cost-effective therapeutic development and decrease in diagnostic timelines linked with improvement in health outcomes ensuring durable collaboration among research, clinical, and regulatory actors.

- Advance and consolidate the capacity building of the RD data ecosystem by supporting interoperable and/or federated cross-border access and analysis of FAIR research and healthcare data, including rare disease registries, ensuring ongoing their usability more efficient translational and clinical research, including regulatory science. The relevant European research infrastructures in the area of health should be exploited for available services, expertise and digital tools for the management and analyses of FAIR health data, as appropriate.

- Integrate basic, pre-clinical, clinical and implementation research to streamline the Research and Innovation (R&I) continuum and minimise redundancies, ensuring lasting impact on the quality of life of the people living with a rare disease while strengthening systemic efficiency and cost-effectiveness. To that end, the partnership should mobilise a significant investment to spur innovation, by aligning regional, national and European R&I priorities and improving EU competitiveness in R&I.

- Support research and innovation across key intervention areas (prevention, diagnosis, treatment), and promote the sustainable uptake of existing health innovations in clinical practice through coordinated training, implementation research, and active stakeholder engagement.

- Contribute to and align with the International Rare Disease Research Consortium (IRDiRC)[236] to reinforce Europe's global leadership, ensure policy coherence, and

[235] The relevant European research infrastructures in the area of health should be exploited for available services, expertise and digital tools for dataset creation, standardisation, data discovery, secure access, management, visualisation, harmonisation, analysis and other functions as appropriate. The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

sustain long-term strategic alignment beyond the lifetime of the partnership. To that end, an optimised assessment of the European contribution to IRDiRC would be beneficial to ensure complementarity and avoid overlaps.

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

HORIZON-HLTH-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
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.
Award criteria	The criteria are described in General Annex D. The following exceptions

[236] https://irdirc.org

	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: 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. This is justified by the pooling of proposers' in-kind contributions and in-house activities and by the nature of activities to be performed: in addition of joint calls, sustain and further develop the EU-wide networks and infrastructures for clinical research, and in particular a network of ever-warm clinical trial sites. • Beneficiaries may provide financial support to third parties (FSTP). The support to third parties can only be provided in the form of grants. As a co-funded European Partnership, providing financial support to third parties is a core activity of this action in order to achieve its objectives. Consequently, the EUR 60 000 threshold laid down in Article 207 of Financial Regulation (EU, Euratom) 2024/2509 does not apply. The maximum amount of FSTP that may be awarded to any single third party for the duration of the partnership is set at EUR 3.00 million. This ceiling is justified by the fact that FSTP is a primary activity of this action, by its expected duration of 7-10 years (exceeding a standard project lifespan), and by the extensive experience gained

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	under predecessor partnerships. 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 "Tackling diseases and reducing disease burden". It will complement the action launched under topic HORIZON-HLTH-2024-DISEASE-12-01: "European partnership for pandemic preparedness", by allowing additional partners (if relevant) to join the co-funded European Partnership for Pandemic Preparedness in order to perform additional activities, such as the close coordination with the Clinical Trial Coordination Mechanism (CT-CM)[237]. The partnership should be firmly anchored within the framework of the European Health Union package[238] and ensure synergies with the European Health Emergency Preparedness and Response Authority (HERA) and other relevant Commission services. The Partnership's activities are expected to be key enablers of the EU Global Health Strategy[239].

Proposals under this topic are expected to build on the first phase of this Partnership[240], and should aim to deliver results that are directed at, tailored towards and contributing to all 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.

237 https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupId=104872&fromMeetings=true&meetingId=59543

238 1

239 2

240 Action "Be Ready Now - European Partnership for Pandemic Preparedness" (BE READY NOW) launched under topic HORIZON-HLTH-2024-DISEASE-12-01: "European partnership for pandemic preparedness".

- 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.

- 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, adopting a One Health approach.

- 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: This topic 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 "Be Ready Now - European Partnership for Pandemic Preparedness" (BE READY NOW) can only reasonably be enhanced and enlarged on the basis of the existing consortium[241], as the co-funded framework established cannot simply be replaced without significant disruption, given the top-quality, long-term expertise and wide coverage of the beneficiaries comprising this consortium

The partnership should contribute to the actions proposed in the Joint Communication on the European Preparedness Union Strategy (JOIN(2025) 130 final[242]) 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"[243]. Synergies with EU programmes such as EU4Health Programme (2021-2027)[244] or the Digital Europe Programme[245] are encouraged.

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241 Consortium which was awarded the grant under topic HORIZON-HLTH-2024-DISEASE-12-01: "European partnership for pandemic preparedness".

242 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025JC0130

243 https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/towards-strategy-european-life-sciences_en

244 https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0522

The co-funded Partnership for Pandemic Preparedness should enable improved coordination and cooperation on national and European levels (and contributing globally), building on the Strategic Research and Innovation Agenda (SRIA)[246] 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. As a continuation of an existing action, the proposal should present the additional activities (including additional partners) to be covered by the award primarily in terms of grant agreement revisions.

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, ecological 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 CT-CM, 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.

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.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs)[247] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

The relevant European research infrastructures[248] in the area of health should be exploited for available services, expertise and digital tools for dataset creation, standardisation, data discovery, secure access, management, visualization, harmonization, analysis and other functions as appropriate.

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245 https://digital-strategy.ec.europa.eu/en/activities/digital-programme

246 https://beready4pandemics.eu/sria

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

248 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

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 support and involvement of citizens and civil society should be considered.

The partnership will consolidate a suitable health research data ecosystem aligned with the European Health Data Space (EHDS)[249], and the European Open Science Cloud (EOSC)[250] supporting the harmonisation and standardisation as well as the federated access of FAIR[251] 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.

HORIZON-HLTH-2027-02-DISEASE-14-two-stage: Clinical trials for advancing innovative interventions for neurodegenerative diseases

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

249 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

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

251 See definition of FAIR data in the introduction to this Work Programme part.

	additionally be used).
Award criteria	The criteria are described in General Annex D. The following exceptions apply: For the first stage, the thresholds for each criterion will be 4 (Excellence) and 4 (Impact). The overall threshold applying to the sum of the two individual scores will be set at a level that ensures the total requested budget of proposals admitted to stage 2 is as close as possible to four times the available budget, and not less than three and a half times the available budget. For the second stage, 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 at, tailored towards and contributing to all the following expected outcomes:

- The scientific and clinical communities make effective use of state-of-the-art knowledge, data, technologies, tools, methods, best practices, and trainings to underpin and complement the development of innovative interventions aimed at more effective treatments for neurodegenerative diseases.
- The scientific and clinical communities benefit from the exchange of data, knowledge and best practices, thereby strengthening their collaboration in the EU, the Associated Countries and beyond.
- The 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[252] principles, thereby encouraging further use of the data.
- Policymakers, funders, scientific and clinical communities, patient organisations, regulators, and other relevant bodies are informed of the research advances made 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: Neurodegenerative diseases are a high burden for patients, caregivers, health systems and society. Given the limitations with current therapeutic solutions, including that they primarily address symptoms rather than underlying causes and can have serious side effects,

[252] See definition of FAIR data in the introduction to this Work Programme part.

together with the increasing prevalence of neurodegenerative diseases in an aging population, there is a huge need to develop more innovative, safer and more effective therapeutic solutions for these diseases. To further enhance their safety and effectiveness, the therapeutic solution based on an active substance should be combined/complemented with another multidisciplinary approach (e.g. lifestyle changes, cognitive training, rehabilitation therapies). Together this innovative intervention should lead to an improved quality of life and reduce the societal impact of these diseases.

Rare neurodegenerative diseases are excluded[253].

Proposals should address most of the following aspects:

- Perform rigorous early-stage [254] clinical trials into the safety and efficacy of the innovative interventions and their mode of administration, ensuring adequate cohorts/sample sizes with adequate representation of the patient population, including in terms of age, sex and ethnicity.

- Through the clinical trials and to the extent possible of additional studies, gain further insight into the potentially novel mechanism(s) of action of the innovative therapies and complementary approaches. This could entail analyses of imaging (e.g. MRI, ultrasound, nuclear imaging), as well as physiological, molecular, biochemical or omics signatures revealing potential perturbations prior to the intervention and recovery/improvement thereafter, and it could lead to the development of surrogate endpoints. This insight should open the path to more personalised interventions and approaches.

- Use and/or develop technologies, including digital ones (e.g. (generative) Artificial Intelligence - AI[255], wearable technologies) to help implement and monitor the long-term efficacy of the intervention(s), as well as manage the disorder 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.

- Exploit existing data, biobanks, registries and/or cohorts, together with the generation of new data that should be managed in line with the FAIR principles.

- Engage all relevant stakeholders (especially patients and patients' representatives for the disease, caregivers, clinicians, counsellors, regulators, etc.) to design end-user optimised interventions, applying gender-sensitive and intersectional approaches.

253 Rare diseases, as defined by the European Union Regulation on Orphan Medicinal Products (1999), being a disease that affects not more than 1 person per 2000 in the European population (https://www.orpha.net/).

254 For pharmacological-based interventions: phase 1 and/or phase 2 clinical trials.

255 Generative AI is a type of AI technology that can generate various forms of new content such as text, images, sounds, and even code, such as for programming or gene sequencing (https://ec.europa.eu/newsroom/dae/redirection/document/101621).

- Advance research by leveraging already existing and emerging state-of-the-art research infrastructures (e.g. EuroBioImaging[256], European Genomic Data Infrastructure[257], ECRIN[258], EATRIS[259], EBRAINS[260], BBMRI[261], etc.), as well as results stemming from EU-supported research projects, where applicable[262].

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

The participation of start-ups, micro, small and medium-sized enterprises (SMEs)[263] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

Funded projects should liaise with the future co-funded European Partnership for Brain Health[264] (covered by topic HORIZON-HLTH-2025-02-DISEASE-01: "European Partnership for Brain Health") once launched.

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.

All proposals involving the development, use and/or deployment of AI-based systems or techniques should ensure that the proposed AI system or technique is technically robust[265] and safe and should describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. Therefore, proposals should include a budget for the attendance to regular joint meetings and may consider 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.

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256 https://www.eurobioimaging.eu
257 https://gdi.onemilliongenomes.eu
258 https://ecrin.org
259 https://eatris.eu
260 https://www.ebrains.eu
261 https://www.bbmri-eric.eu
262 Consult databases e.g. CORDIS (https://cordis.europa.eu) & the JPND Research Database (https://neurodegenerationresearch.eu/search-our-database).
263 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361
264 https://www.brainhealth-partnership.eu
265 See introduction to this Work Programme part.

Applicants should provide details of their clinical studies[266] 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-15: Scaling up innovation in cardiovascular health

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 2.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 2.00 million.
Type of Action	Coordination and Support Actions
Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, legal entities established in the United States of America may exceptionally participate as a beneficiary or affiliated entity, and are eligible to receive Union funding. Coordinators of projects must be legal entities established in an EU Member State or Associated Country. 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

[266] Please note that the definition of clinical studies (see introduction to this work programmeWork 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) [267].

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

- Healthcare providers, policymakers and researchers benefit from an improved knowledge base and collaboration on the key challenges and gaps on cardiovascular health research and a conceptual framework to develop a roadmap for research and innovation is established.

- Health systems gain improved and standardised evidence to better prevent, diagnose or treat cardiovascular diseases (CVDs) and associated comorbidities, based on the research results on prediction, early detection, screening practices and diagnostic methods and tools, including via personalised and digital approaches.

- Medical and non-medical health professionals and technology developers have an increased knowledge, awareness and capacity to uptake and deliver effective and innovative approaches for risk prediction, early detection, screening and health management strategies, such as Virtual Human Twins (VHT)[268] or Artificial Intelligence (AI)-based applications. This involves supporting, strategic foresight, improving health literacy and cross-sectoral knowledge exchange and collaboration to drive innovation in personalised prevention and cardiovascular risk prediction.

- Healthcare providers and policymakers have an improved knowledge base to inform future strategies for early detection and prevention of CVDs, with specific attention to women and vulnerable groups, through research on personalised risk prediction approaches that consider multiple and interacting risk factors (e.g. genetic predisposition, environmental pollutants, diet, lifestyle habits, multimorbidity, gender).

Scope: CVDs are the main cause of death in the EU, with over 1.6 million deaths annually, costing about EUR 282 billion, or 11% of the healthcare budget. With projections showing a rise in CVD prevalence and mortality by 2050 due to an aging population, the Commission is

[267] 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

[268] See the European Virtual Human Twins Initiative: https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins

preparing a comprehensive EU Cardiovascular Health (CVH) plan[269] to support Member States in their efforts to reduce the burden of CVDs. The proposal is expected to support prevention, early detection, including via digital and personalised approaches.

Applicants should take stock of research and innovation results to identify gaps and set up a plan for a Strategic Research and Innovation Agenda (SRIA) on CVDs, with the final aim of leveraging research and innovation results to improve risk prediction, early detection and screening practices for CVDs and associated comorbidities, especially obesity and diabetes, across the European Union and Associated Countries. This initiative addresses the pressing need to translate existing innovations and promising research results into implementable protocols that enhance prevention, diagnosis, and health outcomes for diverse populations. By fostering collaboration and integrating digital tools and methods, proposals will support the future EU CVH plan, building and aligning with future and ongoing activities, including the European VHT Initiative, the 1+Million Genomes Initiative[270], and actions funded under the EU4Health Programme (2021-2027)[271] and the Digital Europe Programme[272].

Proposals should include all the following activities:

- Conduct a comprehensive review at national, EU, and international levels of existing cardiovascular research and innovative healthcare solutions, potentially linked with associated comorbidities, to identify gaps and areas where future integration into health systems can have the greatest impact. The mapping should build upon existing EU-level reviews and pay particular attention to sex- and gender-related gaps, including under-representation in studies and differences in risk, diagnosis, and treatment. Such insights shall inform subsequent policy actions and implementation initiatives under other funding programmes.

- Create a detailed report outlining the barriers to effective personalised prediction, screening and prevention in cardiovascular health, providing recommendations to overcome these challenges.

- Develop a SRIA on CVDs and associated comorbidities aiming to improve personalised prevention, prediction and screening and to inform research funders and stakeholders, including relevant EU and national initiatives. The agenda will include stakeholder validation and adoption pathways. Support the development of personalised prevention and care pathways and the role of digital interventions, based on genomics, VHTs and AI-driven methods in line with the European Health Data Space (EHDS)[273] Regulation, to enhance precision in early detection and health management. Where applicable, the

269 https://data.consilium.europa.eu/doc/document/ST-15315-2024-INIT/en/pdf
270 https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes
271 https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en
272 https://digital-strategy.ec.europa.eu/en/activities/digital-programme
273 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

mapping of existing practices such as biomarkers for diagnosis, monitoring in patients, and stratification of patient groups should be considered.

- Integrate sex and gender-related variables, age, racial [274] or ethnic origin, socio-economic, lifestyle and behavioural factors, genetic predisposition into research design, data collection and analysis, to ensure inclusive and generalisable findings enhancing the effectiveness of screening, diagnostic, and prevention strategies across diverse population groups.

- Organise high-impact, targeted events with clear objectives to promote a multi-sectorial approach, fostering collaboration among healthcare providers, researchers, civil society, patients' organisations, and policymakers

- Work with health experts to develop the capacities for implementing standardised screening protocols and methods.

- Develop a comprehensive dissemination strategy and stakeholder engagement plan to share findings and promote the results, utilising online platforms and social media to reach a broad audience. Complement with long-term engagement mechanisms such as policy briefings or partnerships with EU-level dissemination networks.

The applicants should ensure adequate involvement across the project lifespan of all relevant stakeholders and value chain actors including industry, healthcare professionals, scientists, patients' associations to ensure performance and sustainability and maximise the final impact.

This topic requires the effective contribution of social sciences and humanities (SSH) disciplines and the involvement of SSH experts and institutions, in order to meaningfully enhance the societal impact of the related research activities.

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[274] The use of the term 'racial origin' does not imply an acceptance of theories that attempt to determine the existence of separate human races.

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[275].

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-centred 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

[275] https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/strategic-plan_en

destination will contribute to, among other things, the European Care Strategy[276], the digital transformation of health and care in the EU[277], the European Pillar of Social Rights[278] [279], the EU strategy on adaptation to climate[280], the Pharmaceutical Strategy for Europe[281], the European Health Data Space (EHDS)[282], the Strategy for European Life Sciences[283] and the European Green Deal. They align with the Commission's Political Guidelines for 2024-2029[284], 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[285].

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 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 "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 "Digital, Industry and Space" focusing on the digitalisation of the health sector, including the use of Artificial Intelligence (AI).

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276 Communication from the European Commission on the European care strategy, COM(2022) 440, 7.9.2022

277 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

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

279 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

280 https://climate.ec.europa.eu/eu-action/adaptation-climate-change/eu-adaptation-strategy_e

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

282 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

283 https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/towards-strategy-european-life-sciences_en

284 https://commission.europa.eu/about/commission-2024-2029_en

285 Missing link!

The 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) [286], the EU's public health programme, as a means of capitalising on potential collaborations and maximising impact.

Expected impacts:

Proposals for topics under this destination should set out a credible pathway to contributing to ensuring access to innovative, sustainable and high-quality 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):

[286] https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en

HORIZON-HLTH-2026-01-CARE-01: Public procurement of innovative solutions for improving citizens' access to healthcare through integrated and personalised approaches

Call: Cluster 1 - Health (Single stage - 2026)	
Specific conditions	
Expected EU contribution per project *Indicative budget*	The Commission estimates that an EU contribution of between EUR 3.00 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. 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: 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.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: Beneficiaries may provide financial support to third parties to ensure the deployment and impact of the project outcomes. The support to third parties can only be provided in the form of grants. The maximum amount to be granted to each third party is EUR 60 000. The specific conditions are described in General Annex H. PPI procurement costs are eligible.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination "Ensuring equal access to innovative, sustainable, and high-quality healthcare". To that end, proposals under this topic should aim to deliver results that are directed at, tailored towards and contributing to several of the following expected outcomes:

- Patients and their carers, health authorities and health professionals will benefit from the deployment of innovative solutions, designed around actual clinical needs, that facilitate identification, integration and/or coordination of care, allowing for personalised, more accessible and higher quality of health and care.

- Patients will benefit from personalised approaches, 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 diagnosis, care delivery and coordination, with multi-disciplinary approaches and closer patient engagement, thanks to new technologies.

- Health systems will improve their accessibility, coordination mechanisms, effectiveness and resilience, thanks to innovative solutions, with a better use of resources, thus stimulating organisational innovation, cultural transformation within hospitals, and European-level collaboration.

Scope: Public Procurement of Innovative Solutions (PPI)[287] can boost the wider market uptake of high impact innovations in health systems, while enhancing the tools available to providers and improving access to healthcare for citizens. This supports enhancement of social rights [288] and the European 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 European industry and small and medium-sized enterprises (SMEs)[289]. Joint/collaborative demand-driven 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 or diagnostics for personalised medicine. This topic does not provide direct funding to developers, industry or research organisations to perform research and development. They will be able to respond to the call for tenders launched by consortia of procurers funded under this topic.

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, when relevant, to the principles of integrated care[290] or personalised medicine[291].

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287 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 should 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 should focus on one concrete need identified as a common challenge that requires the deployment of innovative solutions. Projects that aim to implement a PPI should contain a preparation and execution stage.

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

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

290 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

Examples of target groups that could be covered by this action are: patients at risk of vulnerability such as children and older/frail people with complex needs for health and 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 or cancer; 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, clearly describe the application of the principles of integrated care and personalised medicine in the deployed solutions, when relevant. 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 Artificial Intelligence (AI) elements, to facilitate delivery of integrated care across hospitals, primary care, Long-Term Care (LTC) facilities and home settings, or technologies that improve routine diagnosis and lead to personalised medicine approach with the health and care setting.

The actions will target first 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 deployment plans, explaining how the procurement of the innovative solutions will contribute to the expected outcomes and improve current practice. 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/regional policy frameworks and policies, 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 healthcare 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. When relevant, linkage with ongoing work at national level for the implementation of the European Health Data

[291] https://health.ec.europa.eu/medicinal-products/personalised-medicine_en

Space (EHDS)[292] is encouraged. Proposals are encouraged to consider, where relevant, the data, expertise and services offered by European research infrastructures[293] in the health domain.

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 ongoing EU-funded projects and initiatives, for example the Joint Actions JADECARE[294] and Xt-EHR[295], and the three co-funded European Partnerships on Transforming Health and Care Systems[296], on Personalised Medicine[297] and on Rare Diseases[298], 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 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

292 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

293 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

294 https://www.jadecare.eu

295 https://www.xt-ehr.eu

296 https://cordis.europa.eu/project/id/101095654, https://www.thcspartnership.eu

297 https://cordis.europa.eu/project/id/101137129, https://www.eppermed.eu

298 https://cordis.europa.eu/project/id/101156595, https://erdera.org

	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 "Ensuring equal access to innovative, sustainable, and high-quality healthcare". To that end, proposals under this topic should aim to deliver results that are directed at, tailored towards and contributing to all the following expected outcomes:

- Patients benefit from decreased incidence of Adverse Drug Reactions (ADRs) caused by the administration of multiple medications (three or more medicinal products[299]) 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 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 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 reactions. 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[300]. 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.

299 https://www.ema.europa.eu/en/glossary-terms/medicinal-product

300 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

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. Furthermore, it is also possible that aside from the ADRs specific to individual drugs taken in combination, new ADRs can emerge as results from the drug combinations themselves.

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, imaging biomarkers, drug-drug/drug-gene/drug-food interactions, therapeutic dose reduction and pharmaco-exposomics, nutrition and beverage interference, smoking, vaping, 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 (EMA), in view of possible adoption of deprescribing or adjusted-prescribing guidelines by relevant authorities at EU and national levels.

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

- Joint EMA/Heads of Medicines Agencies (HMA)/EC Workshop recommendations on pharmacogenomics in medicines regulation and on implementation into clinical practice[301].

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

- Pharmaceutical development of medicines for use in the older population, Scientific guideline from the EMA[302].

- Guidelines from the Clinical Pharmacogenetics Implementation Consortium ('CPIC guidelines')[303].

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

- Leverage the role of pharmacogenomics, pharmacokinetics and pharmacodynamics in predicting and preventing adverse drug reactions in situations of multiple medications (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 co-funded European Partnership for Personalised Medicine[304], the co-funded European Partnership on Transforming Health and Care System[305] etc. while avoiding any potential overlaps.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs)[306] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

All proposals involving the development, use and/or deployment of AI-based systems or techniques should ensure that the proposed AI system or technique is technically robust[307] and

302 https://www.ema.europa.eu/en/pharmaceutical-development-medicines-use-older-population-scientific-guideline
303 https://cpicpgx.org/guidelines
304 https://cordis.europa.eu/project/id/101137129, https://www.eppermed.eu
305 https://cordis.europa.eu/project/id/101095654, https://www.thcspartnership.eu
306 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361
307 See introduction to this Work Programme part

safe and should describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability.

Applicants should provide details of their clinical studies[308] 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 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.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination "Ensuring equal access to innovative, sustainable, and high-quality healthcare". To that end, proposals under this topic should aim

[308] 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.

to deliver results that are directed at, tailored towards and contributing to all the following expected outcomes:

- Healthcare providers and policymakers make use of evidence-based indicators and methodologies to identify low-value care[309] 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.

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[310] 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[311] by the Expert Group on Health Systems Performance Assessment (HSPA)[312] establishes the methodological basis and metrics to identify, measure and reduce low-value care.

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309 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."*

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

311 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

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

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. Proposals should engage citizens and civil society organisations in the development of their actions to ensure acceptability of solutions. 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[313] include clinical studies[314] 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. Proposed activities may also facilitate or implement collaboration among registries (disease registries such as cancer registries, primary healthcare visits registries, prescription and drug purchase registries, reimbursement and medical devices registries, screening databases, socio-economic and census databases, etc.) across regions or countries, to enable or improve the assessment and comparison of different levels of care and their value to patients. 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 co-funded European Partnership on Transforming Health and Care Systems [315] or any other relevant European or global initiatives). Additionally, proposals may include or support international comparisons of low-value care practices and strategies for their reduction across countries, if and where deemed valuable.

Research actions should address all 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 evidence-based methodologies that enable the pursuit of improved efficiency and quality of care.

313 Some proposals may not need to conduct clinical studies to achieve the objectives.

314 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.

315 https://cordis.europa.eu/project/id/101095654, https://www.thcspartnership.eu

- 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/or pilot innovative strategies for effective reduction of low-value care in specific settings across the care pathway. 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 initiatives (e.g. the Expert Group on Health Systems Performance Assessment, the co-funded European Partnership on Transforming Health and Care Systems, relevant projects or Joint Actions funded under the EU4Health Programme (2021-2027)[316] and under EU Research & Innovation Framework Programmes, etc.) or other international initiatives (e.g. the 2017 OECD report mentioned above) in this area.

All proposals involving the development, use and/or deployment of AI-based systems or techniques should ensure that the proposed AI system or technique is technically robust[317] and safe and should describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability.

Applicants should provide details of their clinical studies[318] in the dedicated annex using the template provided in the submission system. As proposals under this topic may[319] include clinical studies, for those proposals that 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)

316 https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en
317 See introduction to this Work Programme part.
318 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.
319 Some proposals may not need to conduct clinical studies to achieve the objectives.

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.
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.
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: 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	The rules are described in General Annex G. The following exceptions

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financial set-up of the Grant Agreements	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. As a co-funded European Partnership, providing financial support to third parties (FSTP) is a core activity of this action in order to achieve its objectives. Consequently, the EUR 60 000 threshold laid down in Article 207 of Financial Regulation (EU, Euratom) 2024/2509 does not apply. The maximum amount of FSTP that may be awarded to any single third party for the duration of the partnership is set at EUR 10.00 million. This ceiling is justified by the fact that FSTP is a primary activity of this action, by its expected duration of 7-10 years (exceeding a standard project lifespan), and by the extensive experience gained under predecessor partnerships. 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 "Ensuring equal access to innovative, sustainable, and high-quality healthcare". It will complement the action launched under topic HORIZON-HLTH-2023-CARE-08-01: "European Partnership on Personalised Medicine", by allowing new partners to join the co-funded European 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 to deliver results that are directed at, tailored towards and contributing to all 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 topic 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 for Personalised Medicine" (EP PerMed) can only reasonably be enhanced and enlarged on the basis of the existing consortium[320], as the co-funded framework established cannot 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 topic should consist of several of the following:

- Organisation of activities or tools according to their expertise and interests, e.g.:

[320] Consortium which was awarded the grant under topic HORIZON-HLTH-2023-CARE-08-01: "European Partnership on Personalised Medicine".

  - 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.

- Contribution 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 (Work Package 5 - WP5), summer schools (WP3/4).
- Contribution to the development and dissemination of strategic documents in additional geographical areas, for example the Strategic Research and Innovation Agenda (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 topic 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.

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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[321].

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 for 2024-2029[322], 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 Machine-Learning/Artificial Intelligence (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 - RWD[323]), 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

321 https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/strategic-plan_en

322 https://commission.europa.eu/about/commission-2024-2029_en

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

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"[324] the "Artificial Intelligence Strategy"[325] and the "Strategy for European Life Sciences"[326] and focuses 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 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 "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:

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324 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

325 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

326 https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/towards-strategy-european-life-sciences_en

- 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 better patient outcome and wellbeing, in particular through increasingly shared health resources (interoperable data, infrastructure, expertise, citizen/patient driven co-creation)[327].

- 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 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.

Legal entities established in China are not eligible to participate in Innovation Actions in any capacity. 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-TOOL-01-two-stage: Development of predictive biomarkers of disease progression and treatment response by using AI methodologies for chronic 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 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.

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

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: For the first stage, the thresholds for each criterion will be 4 (Excellence) and 4 (Impact). The overall threshold applying to the sum of the two individual scores will be set at a level that ensures the total requested budget of proposals admitted to stage 2 is as close as possible to four times the available budget, and not less than three and a half times the available budget. For the second stage, 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 to deliver results that are directed at, tailored towards and contributing to all 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.
- Key stakeholders have access to trustworthy Artificial Intelligence (AI) tools to guide the development 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 personalised healthcare.

Scope: Biomarkers[328] 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 characterised by broad inter-and intra-patient heterogeneity. The established biomarkers have limitations in their use as prognostic and predictive indicators, 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 established AI methodologies able to combine data of clinically used and candidate biomarkers, with available data from relevant clinical studies, longitudinal and Real-World Data (RWD)[329]. This topic is expected to support collaborative projects paving the way for future innovations in personalised 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. This should include stratification by biological sex, and where feasible, integration of gender-related variables and sociodemographic determinants that may modulate disease trajectories or treatment efficacy.

- Adapt and apply of established AI methods rather than developing novel ones from scratch, to deliver novel 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

328 See definition as in the Strategic Research and Innovation Agenda of the Innovative Health Initiative Joint Undertaking: http://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/IHI_SRIA_ApprovedJan22.pdf

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

applicants should provide information in their proposal that the appropriate high-quality clinical data are readily available, and when necessary generate small-scale new data for the AI optimisation needs. 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 justify why the development of the 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 AI trustworthiness[330] and develop the adequate performance metrics to assess their accuracy, reliability, reproducibility, including the assessment of possible inherent bias. Moreover, proposals should consider the development of user-friendly and fit-for-purpose visualisation and decision-support tools to guide clinicians in evaluating the clinical plausibility of the biomarkers under study across diverse patient groups.

- Establish a biomarker validation platform to assess the clinical utility of the predictive biomarkers identified. To this end, the applicants should implement clinical validation studies in independent disease cohorts, RWD and exploratory clinical studies, as appropriate, 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/EFTA and/or Associated Countries.

- Develop a comprehensive exploitation plan for the valorisation 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. Participation of small and medium-sized enterprises (SMEs)[331] is encouraged with the aim to strengthen the scientific and technological basis of SMEs and valorise their health innovations.

It is imperative that applicants should adhere to GDPR[332] compliant personal data protection and implement the appropriate measures.

330 See, introduction to this Work Programme part and the relevant guidelines: https://digital-strategy.ec.europa.eu

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

332 General Data Protection Regulation: https://commission.europa.eu/law/law-topic/data-protection_en, https://gdpr-info.eu

Proposals are encouraged, where relevant, to exploit the available data services, expertise and digital tools offered by the relevant European research infrastructures [333] and/or data infrastructures in the area of health funded under the Digital Europe Programme[334].

All proposals selected for funding under this topic will be strongly encouraged to participate in networking and joint activities (e.g. participation in joint workshops, development of best practices, or joint communication activities), which may also involve networking with projects funded under Horizon Europe, or other EU programmes (e.g. the Digital Europe Programme[335]). The proposals should allocate a sufficient budget for networking and joint activities, without the prerequisite to detail such activities at the proposal stage.

Applicants should provide details of their clinical studies[336] 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 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).

333 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

334 https://digital-strategy.ec.europa.eu/en/activities/digital-programme

335 https://digital-strategy.ec.europa.eu/en/activities/digital-programme

336 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.

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 to deliver results that are directed at, tailored towards and contributing 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 regenerative 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. For printing complex tissues and especially entire organs an in-vitro approach followed by transplantation is the preferred way. "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 in certain instances (e.g. tissue repair) 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

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may facilitate repair and/or regeneration of defective complex tissues or internal organs. For such approaches meticulous engineering of the bio-printing equipment is necessary, involving sophisticated micro-surgical instrumentation and medical imaging platforms. To achieve the desired function and to mimic the natural cues in native tissues for in-vitro printed bio-constructs, the use of additional stimuli is needed, whereas in-situ approaches normally rely on the body as natural bioreactor providing the necessary extracellular cues. Recently, combinations of in-situ bio-printing with real-time stimuli have been investigated, even for the repair of internal organs. However, there remain bottlenecks that need to be overcome, like the integration with existing imaging modalities and surgical procedures or the long-time stability and functionality of the created bio-constructs.

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 vascularisation and faster repair of the defect in the body.
- Scale-up the chosen bio-printing technology to a Good Manufacturing Practices (GMP)[337] 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 or endoscope 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 (ATMPs) should 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.

Proposals under this topic may address any therapeutic area, i.e. any disease, dysfunction or defect. Sex differences at the cellular level should be taken into consideration.

Preclinical stage and clinical development are eligible. The involvement of small and medium-sized enterprises (SMEs)[338] is encouraged.

337 https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp

Applicants should provide details of their clinical studies[339] 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

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

339 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) [340].

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 to deliver results that are directed at, tailored towards and contributing to several of the following expected outcomes:

- Researchers are in possession of improved human-relevant New Approach Methodologies (NAMs) 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 and personalised treatment strategies across diverse life stages.

- 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, other 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 better 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 support the ongoing paradigm shift in biomedical research and safety assessment of chemical compounds by fully integrating NAMs across the entire research and regulatory spectrum, from basic discovery phase to clinical application, and regulatory testing of medicinal products and medical devices, and/or industrial and environmental chemicals.

NAMs include a wide range of innovative and human-relevant technologies such as in-vitro or human ex-vivo 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 modelling.

[340] 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 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. There is a need to address this situation 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.

Proposals should bring together stakeholders from academia, health-related infrastructures, SMEs[341], industry, and regulators to develop new NAMs platforms or improve existing ones that could be used for biomedical applications and/or regulatory testing. For biomedical applications, these platforms should enhance disease modelling precision, especially in areas where current animal models are of limited human relevance, and where NAMs could effectively complement or replace animal studies. For proposals addressing regulatory use, in particular the safety assessment of chemicals, other medicinal products and medical devices, the intended context(s) of use should be clearly defined, with validation strategies and methodologies aligned with current OECD and/or European Medicines Agency (EMA) guidance. Early, proactive, and sustained engagement with regulators should also be demonstrated.

Proposals should develop or optimise scalable and reproducible platforms based on one or more of the following:

- Advanced in-vitro assays.
- iPSC-based models, organoid or complex OoC systems derived from patients and/or healthy donors.
- Human tissues that closely replicate physiological and pathological conditions.

In order to enable real-time monitoring of physiological responses, proposals should consider integration of embedded sensors. They should also address biological diversity, reflecting variations in genetics, phenotype, age, immune status, and microbiome across the population.

Moreover, proposals 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.
- Virtual twin technology to simulate disease progression, responses to interventions, and support the optimisation of clinical trials.

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

To maximise scientific impact, interoperability, and reuse, all data generated should comply with FAIR[342] principles. Proposals should describe how data will be curated, standardised, and shared within or linked to the European Health Data Space (EHDS) [343] or other repositories, and/or relevant ESFRI[344] research infrastructures.

Applicants should provide details of their clinical studies[345] 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-04: Virtual Human Twins (VHTs) for integrated clinical decision support in prevention and diagnosis

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 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 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.

342 See definition of FAIR data in the introduction to this Work Programme part.

343 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

344 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

345 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.

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 to deliver results that are directed at, tailored towards and contributing to all the following expected outcomes:

- Healthcare professionals have access to multi-scale[346], multi-organ models of individual patients that aim to improve prevention and diagnosis in high disease burden areas.
- Health professionals benefit from enhanced knowledge of complex diseases and co-morbidities by recourse to multi-scale, multi-organ models.
- Patients with diverse characteristics (e.g. of any gender or age group) benefit from improved, integrated and personalised prevention and diagnostics tools.
- Health professionals and patients benefit from the use of "Virtual Human Twin" (VHT) models which enable integration of other preventive and diagnostic tools and modalities.

Scope: VHTs are digital representations and in-silico models of an individual's health and disease state at different levels of anatomy. Multi-scale, multi-organ VHT solutions have a potential for tailored prevention and diagnosis, particularly in areas of high disease burden, and can significantly benefit citizens' health and the efficiency of EU health systems.

Proposals should take into account the work of projects funded under topic HORIZON-HLTH-2023-TOOL-05-03: "Integrated, multi-scale computational models of patient patho-physiology ('virtual twins') for personalised disease management", 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.

The proposals should address all 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; examples include 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.

[346] 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 (e.g. biobanks, environmental data, others) and modelling assets (e.g. those of the EDITH CSA[347] and the Platform for Advanced VHT Models[348]), 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 biophysics-based modelling, artificial intelligence (AI) that should be interpretable or allow explainability of outcomes, generative AI and in-silico modelling, agent-based and network physiology approaches. Evaluation, selection and extension of these should be documented during the design phase. Availability and integration of the multi-modal data should 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 the solutions deliver clinically meaningful decision support, addressing use case requirements. Document lessons-learned for broader application. Gather evidence via health economic and/or feasibility studies in real-world healthcare settings confirming cost-effectiveness vis-à-vis current practice (e.g. cost-effectiveness analysis). Produce an exploitation plan on regulatory compliance[349] and intellectual property.

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 software development including responsible AI development [350] should be followed (e.g. risk assessment and management, requirements definition process).

Participation of small and medium-sized enterprises (SMEs)[351] is encouraged.

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347 See the "European Virtual Human Twin" Coordination and Support Action EDITH, funded under the Digital Europe Programme: https://www.edith-csa.eu

348 Funded under the Digital Europe Programme, procedure identifier EC-CNECT/LUX/2024/OP/0014: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/tender-details/16cc3c6a-844a-42d4-9746-dcc7444b8001-CN

349 For example with Regulation (EU) 2017/745 on medical devices: http://data.europa.eu/eli/reg/2017/745/oj, Regulation (EU) 2017/746 on in vitro diagnostic medical devices: http://data.europa.eu/eli/reg/2017/746/2025-01-10, Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence: http://data.europa.eu/eli/reg/2024/1689/oj

350 All proposals involving the development, use and/or deployment of AI-based systems or techniques should ensure that the proposed AI system or technique is technically robust and safe and should describe how they will uphold the principles of human agency and oversight, fairness, diversity, non-discrimination, societal and environmental well-being, transparency and accountability; see introduction to this Work Programme part.

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

Proposals should contribute to the objectives of the European VHT Initiative[352] and to the Platform for Advanced VHT Models, with project assets made available on the Platform and interoperable with its technical specifications[353]; relevant consortia members should join its User Community. Budget should be reserved for these activities. Projects are expected to collaborate with other EU-funded projects on VHTs[354] and align with relevant EU initiatives funded under Horizon Europe, the Digital Europe Programme [355] and the EU4Health Programme (2021-2027)[356], e.g. European Cancer Imaging Initiative[357], 1+Million Genomes Initiative [358], Intensive Care Unit Data Space [359], co-funded European Partnership for Personalised Medicine[360], and projects on advancing AI in health where relevant.

This topic requires the effective contribution of social sciences and humanities (SSH) disciplines and 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[361] 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: Pilot Actions for Follow-on Funding: Leveraging EU-funded Collaborative Research in Regenerative Medicine

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 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. The total indicative budget for the topic is EUR 40.00 million.
Type of Action	Innovation Actions
Eligibility	The conditions are described in General Annex B. The following

352 https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins
353 No contact with the developer of the Platform is required at proposal stage.
354 Including the projects funded under topic HORIZON-HLTH-2023-TOOL-05-03: "Integrated, multi-scale computational models of patient patho-physiology ('virtual twins') for personalised disease management"
355 https://digital-strategy.ec.europa.eu/en/activities/digital-programme
356 https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en
357 https://digital-strategy.ec.europa.eu/en/policies/cancer-imaging
358 https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes
359 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/digital-2023-cloud-ai-04-icu-data
360 https://cordis.europa.eu/project/id/101137129, https://www.eppermed.eu
361 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: The proposals must be based on results generated within a prior multi-beneficiary project funded under Horizon 2020 or Horizon Europe Framework Programme. This project must have been completed maximum 3 years before the submission deadline. Applicants must explicitly state in their proposal the prior multi-beneficiary project concerned. Projects funded under Marie Sklodowska-Curie Actions are not considered eligible. 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) [362].

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 to deliver results that are directed at, tailored towards and contributing to all the following expected outcomes:

- The overall competitiveness of the EU biotechnology sector is strengthened through the further development of closer-to-deployment health innovations.

[362] 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 EU benefits from greater impact of the EU's Research and Innovation (R&I) Framework Programmes through successful leveraging of previous EU funding in the field of regenerative medicine.

- EU innovators secure further funding to finalise the last stages of development.

- Patients benefit faster from solutions that improve their health and wellbeing.

Scope: R&I is essential for economic growth and boosting the competitiveness of the EU's life sciences sector. Through the Horizon 2020 and Horizon Europe Framework Programmes, the EU has supported projects that significantly impact our health by fostering scientific discoveries and developing new solutions. Transformational health innovations, such as mRNA vaccines, highlight the importance of collaboration among businesses, research institutions, and healthcare providers. Furthermore, sustained funding throughout the entire value chain is crucial for maximising impact and ensuring more products reach patients faster. The main aim of this topic is to pilot a follow-on funding mechanism, supporting the stepwise development of biotech innovations through collaboration, resulting from previously supported EU R&I actions in the field of health. Given the importance of biotechnology as a critical technology, this topic aims to ensure that promising research results are efficiently taken further along the value chain, speeding the time to market or patient through stepwise funding and increasing the EU's competitiveness. The chosen area of focus is regenerative medicine as it has the potential to heal or replace tissues and organs damaged by age, disease, or trauma, as well as to normalise congenital defects. Proposals should focus on prototyping, demonstrating and validating health innovations from TRL 5, moving beyond early-stage research to clinical development, testing, or eventual large-scale manufacturing. The funded Innovation Actions (IAs) should build on previously funded EU research applicable to the field of regenerative medicine and should have clear exploitation potential and/or socio-economic benefits for the patients.

Applicants are expected to:

- Demonstrate in their proposal that the health product, therapy or service, has been successfully validated at preclinical level in the prior EU funded project and provide justification of the innovation potential with qualitative and quantitative data (e.g. publications, patent/trademark/design applications, spin-out/start-up track record, regulatory procedures, venture capital pitches, funds raised etc).

- Justify the proposed composition of the consortium and explain how this differs from the previous grant, and demonstrate how the health product, therapy or service to be developed further qualifies as regenerative medicine.

- Demonstrate adequate protection of the idea or Intellectual Property Rights or ensure freedom to operate until full deployment.

- Have a clear vision on the intended pathway to patients and/or route to market, including regulatory compliance. This includes defining specific milestones together with concrete

and verifiable Key Performance Indicators (KPIs) to assess progress towards the market or healthcare settings.

- Identify the target patient group(s) (how many patients to be treated during the project and the potential patient population that could benefit) and product development milestones including a financial plan (for each milestone).

In the case of innovations with commercial potential, proposals should present the investor and market readiness towards commercialisation and deployment (market research, value proposition, business case and business model, prospects for growth, intellectual property protection, competitor analysis etc.) as well as aspects of regulation, certification and standardisation and reimbursement.

In the case of innovations with evidenced limited commercial potential but high patient benefit, proposals should contain a deployment and sustainability plan including aspects related to regulations, certification and standardisation and patient access through healthcare providers.

Proposals should take into account sex, gender, age and other relevant socio-demographic variables to ensure the scientific robustness, clinical value and applicability of the targeted regenerative medicine innovation.

Applicants should provide details of their clinical studies[363] 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-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	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.
Indicative budget	The total indicative budget for the topic is EUR 3.00 million.
Type of Action	Coordination and Support Actions
Eligibility	The conditions are described in General Annex B. The following

[363] 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, 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. 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) [364].

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 to deliver results that are directed at, tailored towards and contributing to all the following expected outcomes:

- Member States and relevant stakeholders identify priority areas where New Approach Methodologies (NAMs) and infrastructures are most needed and expected to have the highest short- to medium-term impact.
- Member States and other stakeholders jointly support the validation and qualification of a limited set of NAMs that are intended to be accepted and implemented in regulatory testing of medicinal products and medical devices.

[364] 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

- Member States and other stakeholders develop common education and training programmes based on best practices identified in European and non-European countries to better inform researchers and regulators on NAMs and on the application of the 3Rs principles[365].

- Member States and other stakeholders implement a harmonised NAM openness and awareness programme that improves open access to NAMs protocols and results of animal experiments. It also provides guidance to harmonise the awareness of NAMs for ethical committee members, reviewers, and regulators, based on best practices in the participating Member States. The programme should propose concrete actions to increase the confidence of regulators in NAMs including a better understanding of the potential and limitations of NAMs.

Scope: This topic aims at coordinating and implementing the new European Research Area (ERA) policy action on "accelerating New Approach Methodologies (NAMs) to advance biomedical research and testing of medicinal products and medical devices", which is part of the ERA Policy Agenda 2025-2027[366].

The ERA action should establish an EU-wide forum that brings together relevant ministries, regulatory agencies, research funding organisations, academia, industry (pharmaceutical and medical technology), Contract Research Organisations (CROs), small and medium-sized enterprises (SMEs) [367], and startups to harmonise policies and strategies for NAMs development and implementation.

The selected proposal should be coordinated by any active participant to the ERA action. It should contribute to the implementation of the four thematic Working Groups (WGs) of the ERA action:

WG1: Development of NAMs and common infrastructures. This WG identifies opportunities for NAMs development and support to infrastructures in specific disease or biological areas and in safety, quality, and efficacy assessment endpoints for medicinal products and medical devices. The WG provides insight and suggests priorities to governments and industry for the further coordinated efforts to leverage promising development of NAMs, taking into consideration the complementarity of scientific strengths, funding priorities and available expertise in the different Member States and regions.

WG2: Validation, acceptance, and uptake of NAMs. The WG defines optimal criteria for NAMs to facilitate their uptake in the contexts of basic and applied biomedical research, and their acceptance for the regulatory assessment of medicinal products and medical devices in defined contexts of use. It proposes priorities for the validation and qualification of NAMs. Member States and pharma/MedTech industry take the decision to jointly support the

365 Replacement, Reduction, Refinement: https://nc3rs.org.uk/who-we-are/3rs

366 Proposal for a Council Recommendation on the European Research Area Policy Agenda 2025-2027: https://european-research-area.ec.europa.eu/documents/proposal-council-recommendation-european-research-area-policy-agenda-2025-2027

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

validation/qualification of certain NAMs that are sufficiently mature for acceptance and uptake in regulatory testing of medicinal products and medical devices.

WG3: Education and training. The WG maps existing education and training programmes on NAMs and the 3Rs principles and assesses their quality and outreach. Based on this exercise, the WG makes suggestions to Member States for jointly developing education and training modules on NAMs and the application of the 3Rs principles in close partnership with education directors at knowledge institutes.

WG4: Openness and awareness. The WG develops common policies to improve the openness and quality of research, including open access to available protocols on NAMs, and facilitating the publication of results from NAMs and animal experiments, even if these are negative or neutral (or historic, if feasible and appropriate), to avoid unnecessary duplication of animal testing or development of non-valid NAMs. It considers strategies for sharing best practices to make sure that different ethical committees, funding assessment committees, reviewers, and regulators have a similar level of awareness regarding the latest scientific advancements in available NAMs. It proposes actions to enhance the confidence of regulators in validated and qualified NAMs. The WG also identifies opportunities for raising awareness among civil society and patients regarding the biomedical research, drug discovery and development process.

HORIZON-HLTH-2027-03-TOOL-08: Towards Artificial General Intelligence (AGI) for healthcare

Call: Cluster 1 - Health (Single stage - 2027/2)	
Specific conditions	
Expected EU contribution per project	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.
Indicative budget	The total indicative budget for the topic is EUR 3.00 million.
Type of Action	Coordination and Support Actions
Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: 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) [368].

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 to deliver results that are directed at, tailored towards and contributing to all the following expected outcomes:

- Researchers and innovators benefit from an improved understanding of how to develop and use the next generation of frontier Artificial Intelligence (AI) models for healthcare, including how to leverage AI Factories and how to combine and expand the capabilities of existing foundation models towards inclusive and personalised medicine.
- Researchers and innovators benefit from an improved understanding of how to leverage highly heterogeneous and multimodal health data spanning a range of anatomical scales (i.e. the micro to the macro level).
- Multidisciplinary stakeholders have access to a collaboratively created roadmap for developing the next generation of frontier AI models for healthcare, towards Artificial General Intelligence (AGI) for healthcare.

Scope: The AI Continent Action Plan[369] identifies the health sector, encompassing life sciences, medical devices and healthcare delivery, as one of the key strategic sectors. The action will contribute to making European life sciences[370] and healthcare more impactful and productive by fostering the full integration of advanced AI in the health sector and biomedical research, along the objectives of the AI in Science strategy[371] and Apply AI strategy[372].

368 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

369 https://digital-strategy.ec.europa.eu/en/library/ai-continent-action-plan

370 https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/towards-strategy-european-life-sciences_en

371 https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/artificial-intelligence-ai-science_en

Healthcare typically involves the combining of multimodal data, ranging from electronic health records through imaging and laboratory to molecular and omics data. This information combination is performed by specialists and is often challenging towards optimised patient care. In Europe, the growing amount of accessible multimodal health data, including via the forthcoming European Health Data Space (EHDS)[373], combined with the increasing availability of high-performance computing facilities (e.g. AI Factories), presents a unique opportunity to develop the next generation of frontier AI models for healthcare. This action anticipates and operationalises the use of such federated infrastructures for research and innovation. Moreover, regulations such as the EHDS regulation and AI Act[374] steer the direction into building an ecosystem fostering ethical and safe innovation on AI in healthcare.

AI models are becoming increasingly complex and able to tackle increasingly challenging tasks. The next generation of frontier AI models are expected to make strides towards AGI, a type of AI capable of tackling highly complex and diverse tasks with proficiency comparable to that of humans. This topic will lay the foundation for the development of the next generation of frontier AI models, paving the way for new, advanced AI-powered solutions to increase efficiency and efficacy in the health sector towards improved patient outcomes. It will leverage results, methodologies, data etc. of other relevant EU-funded projects.

Proposals should include all the following activities, primarily coordination and support but also with elements of research and innovation, while ensuring multidisciplinary approaches and a broad representation of stakeholders in the consortium (e.g. healthcare professionals, patients, biomedical scientists, AI developers, data engineers, ethics experts):

- Community building: build a large-scale and diverse pan-European community of stakeholders with the multidisciplinary expertise united as required to develop the next generation of frontier AI models for healthcare, towards AGI for healthcare, with a view to leveraging as a community the potential of AI Factories. Where relevant, this should build on and strengthen existing EU-funded communities and networks, and could pave the way for a formalised long-term collaboration under one of the available EU instruments.

- Roadmap creation: review previous research to identify the most promising AI models and model development approaches. In addition, risk assess and review evidence on safety and efficacy of existing AI models with reference to the AI Act, related regulatory provisions (including any jurisprudence) and ethical considerations, so that frontier AI model development can proceed on a well-informed basis. Finally, create a roadmap for developing the next generation of frontier AI models.

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372 https://digital-strategy.ec.europa.eu/en/consultations/commission-launches-public-consultation-and-call-evidence-apply-ai-strategy

373 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

374 https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai, https://eur-lex.europa.eu/eli/reg/2024/1689/oj

- Dataset identification, curation, expansion and use: i) identification: identify the most suitable existing datasets for the development of frontier AI models for healthcare, ii) curation: identify how to validate the datasets, ensure dataset interoperability, and convert datasets into formats suitable for frontier AI model development, iii) expansion: identify additional datasets and/or annotations required for frontier AI model development, especially to ensure that datasets are representative and iv) use: identify methods and required infrastructure to allow use and further expansion of the datasets in alignment with and through the EHDS.

- Frontier AI model preparatory research: develop approaches for training and evaluating frontier AI models (e.g. approaches to combine foundation models for life sciences and healthcare delivery in order to develop more advanced and multidisciplinary models towards personalised medicine), and then pilot these approaches to develop proof of concepts. This preparatory research should pave the way for more advanced research in future actions. The approaches should leverage European AI Factories and ensure the development of trustworthy models in a data privacy preserving manner. Proof of concept evaluation should cover all trustworthy AI aspects: model accuracy, robustness, fairness, explainability and ability to generalise.

This action should take into account the results of other relevant projects on AI in health, in particular in the two GenAI4EU topics HORIZON-HLTH-2025-01-CARE-01: "End user-driven application of Generative Artificial Intelligence models in healthcare (GenAI4EU)" and HORIZON-HLTH-2025-01-TOOL-03: "Leveraging multimodal data to advance Generative Artificial Intelligence applicability in biomedical research (GenAI4EU)", and leverage the AI Factories and specialised health data infrastructures funded under the Digital Europe Programme[375], biobanks, relevant ERICs[376], as well as the data resources accessible through the EHDS infrastructure starting in 2029, funded under EU4Health Programme (2021-2027)[377]. In addition, a key requirement is the need to ensure trust in frontier AI models for healthcare.

DRAFT

375 https://digital-strategy.ec.europa.eu/en/activities/digital-programme
376 European Research Infrastructure Consortia: https://www.eric-forum.eu/the-eric-landscap
377 https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en

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[378]. 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 Commission's Political Guidelines for 2024-2029[379], and building on the recommendations of the reports by Mario Draghi[380] and Enrico Letta[381], as well as the "Strategy for European Life Sciences"[382], 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

378 https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/strategic-plan_en

379 https://commission.europa.eu/about/commission-2024-2029_en

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

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

382 https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/towards-strategy-european-life-sciences_en

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 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 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)[383].

- 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

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

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.

Legal entities established in China are not eligible to participate in Innovation Actions in any capacity. 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-2027-01-IND-01: Development of 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 35.00 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 at, tailored towards and contributing 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 enhanced or decentralised 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 standardisation 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 personalised 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, potentially also 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 for 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 characterise 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 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 optimise existing CFPS platforms for the production of the targeted biomolecule to a Good Manufacturing Practices (GMP)[384] conform process, producing clinical-grade material that can be tested in clinical trials.

The demonstration of the superiority of the developed CFPS platform as compared to the current state-of-the art production system for a specific therapeutic peptide or protein would be an asset and participation of start-ups, micro, small and medium-sized enterprises (SMEs)[385] is encouraged.

Applicants envisaging to include clinical studies[386] 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.

384 https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp
385 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361
386 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 40.00 million.
Type of Action	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: For the first stage, the thresholds for each criterion will be 4 (Excellence) and 4 (Impact). The overall threshold applying to the sum of the two individual scores will be set at a level that ensures the total requested budget of proposals admitted to stage 2 is as close as possible to four times the available budget, and not less than three and a half times the available budget. 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) [387].

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

[387] 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

results that are directed at, tailored towards and contributing 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, miniaturisation, 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.

The World Health Organization (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 challenges like: Miniaturisation, 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, environmental footprint 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 Machine-Learning/Artificial Intelligence (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 optimised should 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 should 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 optimisation 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 optimised 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) optimised PoC diagnostic medical device(s) as a preferred information source for their clinical validation; subsequent conformity assessment in agreement with requisite EU's In-Vitro Medical Device (IVDR) or Medical Device (MDR) regulatory requirements.

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 cases where decisions can have life-saving character.

Applicants invited to the second stage and envisaging to include clinical studies[388] 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

[388] 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.

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) [389].

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

- Policymakers and regulators will get accelerated access to improved evidence driven 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

[389] 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

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 needs to be updated. This concerns *inter alia* i) more precise delineation of specific requirements (e.g. closing existing gaps concerning sufficiency of clinical evidence) and ii) the consideration of novel biomedical approaches, data and digital solutions (e.g. artificial intelligence - AI, virtual human twin, new approach methodologies as well as methods that cut through these domains) which model and predict relevant biological 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.

Proposals can 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, proposals should address either, or a combination of the following: i) the improvement of existing methodologies and their fitness to specific types or classes of health technologies, including methodology for regulatory assessment and ii) 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.

Proposals 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. Proposals 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.

Applicant consortia should reflect a broad representation of stakeholders, notably clinical societies, academia, notified bodies, industry, patients and regulators and 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 AI-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 the use and aggregation of already existing data, including clinical ones, from similar types or groups of technologies (e.g. retrospective information in registries, data collections, including Real-World Data (RWD)[390] from using technologies that have characteristics that are relevant for innovative technologies).

    - 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 by focusing the generation and assessment of clinical data on health technologies for which those data are indispensable (the actual conduct of clinical studies is not in scope).

- Data and analyses that examine to which extent the above-mentioned 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[391] and IVDR[392], the proposed SoHO-Regulation[393], and AI Act[394] among others.

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

391 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/eli/reg/2017/745/oj

392 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices: https://eur-lex.europa.eu/eli/reg/2017/746/oj

Proposals are encouraged to consider, where relevant, the data, expertise and services offered by European research infrastructures especially those active in the health domain, such as EATRIS ERIC[395], and also the findings of previous EU-projects (e.g.: CORE-MD[396]).

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393 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: https://eur-lex.europa.eu/eli/reg/2024/1938/oj

394 https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai, https://eur-lex.europa.eu/eli/reg/2024/1689/oj

395 European Infrastructure for Translational Medicine: https://www.eatris.eu

396 Improved methods for clinical investigation and evaluation of high-risk medical devices: https://www.core-md.eu

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 198 (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 the following expected outcomes:

- Healthcare 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 198 (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 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 future co-funded European Partnership for Pandemic Preparedness[397] 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, small and medium-sized enterprises (SMEs) [398] 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 4 (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 reaches tens of millions of Euros[399].

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

397 https://beready4pandemics.eu

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

399 Gouglas, D. et al.: Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimisation study. Lancet Global Health Vol. 6 (12) E1386-E1396. DOI: https://doi.org/10.1016/S2214-109X(18)30346-2, https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30346-2/fulltext

Indicative timetable: Fourth Quarter of 2026

Indicative budget: EUR 40.00 million from the 2026 budget

2. European registry for human pluripotent stem cell lines

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 evaluation committee will be composed fully by representatives of EU institutions.

Legal and financial set-up of 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)[400].

The funding rate will be 100%.

Subcontracting is not restricted to a limited part of the action.

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 timetable: Fourth Quarter of 2026

[400] 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

Indicative budget: EUR 1.50 million from the 2026 budget

3. Presidency event - Ireland. Bridging Worlds - Climate Change and Health through the lens of the One Health Agenda - Research, Innovation and Problem Solving

This action will cover the organisation of a conference by the Irish Presidency, focusing on the impacts of climate change on Health and the research needs within the wider context of the One Health agenda.

The impacts of climate change present significant threats to public health, including extreme heat, antimicrobial resistance, zoonotic transfer of pathogens, shifting diseases vectors, and food and water availability and quality.

In recent years, the importance of adopting a One Health approach has become increasingly evident, particularly in Research and Innovation. These efforts are vital to safeguard human, animal, and plant health, alongside their shared environments and economic competitiveness.

The conference should be informed by key EU initiatives such as:

- The Commission's Scientific Advice Mechanism (SAM) opinion on One Health[401] supporting an integrated approach and emphasising the importance of interdisciplinary and cross-sectoral collaboration, including in research and innovation.
- Actions and initiatives focusing on optimising the health of people, animals, and ecosystems, including the European Climate and Health Observatory[402] and the EU Global Health Strategy[403].
- The Strategic Research and Innovation Agenda (SRIA) on Health and Climate change, reflecting key concepts in One Health such as inter- and transdisciplinary research, or the role of vectors in the climate related spread of infectious diseases.

This conference will champion the One Health agenda as the foundational framework for building climate-resilient health systems across Europe. By fostering cross-disciplinary collaboration the complex health threats posed by climate change can effectively be addressed and mitigated, moving from reactive responses to proactive prevention and sustainable adaptation.

The conference will create an opportunity for policymakers, national health ministries, research institutions, experts, academics public health agencies, environmental organisations, agricultural sector representative and civil society to share innovative research and solutions to solve climate change-related health risks.

401 One Health governance in the European Union - Scientific Advice Mechanism: https://scientificadvice.eu/advice/one-health-governance-in-the-european-union

402 European Climate and Health Observatory: https://climate-adapt.eea.europa.eu/en/observatory

403 EU Global Health Strategy: Better Health for All in a Changing World - European Commission: https://health.ec.europa.eu/publications/eu-global-health-strategy-better-health-all-changing-world_en

The conference should aim to address the following goals:

- Highlighting and promoting innovative research and evidence-based solutions from across EU Member States being developed under One Health agenda, focusing on:
    - Climate Change Impacts on Health and Ecosystems: i) emerging and re-emerging zoonotic diseases, antimicrobial resistance and climate change, ii) food and water security challenges in a changing climate and their health implications, iii) supporting healthcare provision during the green transition.
    - Advancing Research and Innovation for Climate-Resilient One Health Systems: i) cutting-edge data surveillance and early warning systems for climate-sensitive health threats, ii) sustainable agriculture and food systems for health and climate mitigation.
    - Policy, Governance, and Implementation: i) integration of One Health polices and datasets into national and European climate adaptation strategies and health policies, ii) guidance that has been developed -or is under development- to strengthen interdisciplinarity in research and innovation, along with mechanisms to assess the effectiveness of One Health implementation, iii) public engagement, communication, and education for One Health and climate action.
- Facilitating knowledge sharing and networking across a wide range of disciplines together to and spark inspiration on climate and health challenges.
- Building on the Strategy for European Life Sciences aiming to strengthen life sciences research and innovation in Europe, supporting wide ranging green transitions.
- Building on the Strategic Research Agenda on health and climate change, identifying research gaps and data infrastructure requirements relevant to progressing climate and health under a One Health agenda.

This event would result in a proceedings paper to underpin a call for action to foster inter- and transdisciplinary collaboration in research and innovation at the intersection between climate and health and the One Health Agenda so as to help inform relevant policies being developed at both EU and Member State level.

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 evaluation committee will be composed fully by representatives of EU institutions.

Legal and financial set-up of 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)[404].

The funding rate will be 100%.

Subcontracting is not restricted to a limited part of the action.

Legal entities:

Department of Health, Government of Ireland, 50 - 58, Block 1, Miesian Plaza, Baggot Street Lower, Dublin 2, D02 XW14

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 timetable: First Quarter of 2026

Indicative budget: EUR 0.30 million from the 2026 budget

4. Presidency event - Lithuania. Title of the event

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 evaluation committee will be composed fully by representatives of EU institutions.

Legal and financial set-up of 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

[404] 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

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)[405].

The funding rate will be 100%.

Subcontracting is not restricted to a limited part of the action.

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 timetable: Third Quarter of 2026

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 198 (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 the following expected outcomes:

- Healthcare 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.

405 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

- 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 198 (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 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 future co-funded European Partnership for Pandemic Preparedness[406] 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, small and medium-sized enterprises (SMEs)[407] 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 4 (Implementation). The cumulative threshold will be 12.

Legal and financial set-up of the Grant Agreements:

The funding rate will be 70%.

406 https://beready4pandemics.eu
407 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361

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 reaches tens of millions of Euros[408].

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 timetable: Fourth Quarter of 2027

Indicative budget: EUR 35.00 million from the 2027 budget

6. Presidency event - Greece. Title of the event

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 evaluation committee will be composed fully by representatives of EU institutions.

Legal and financial set-up of 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

[408] Gouglas, D. et al.: Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimisation study. Lancet Global Health Vol. 6 (12) E1386-E1396. DOI: https://doi.org/10.1016/S2214-109X(18)30346-2, https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30346-2/fulltext

Research and Training Programme of the European Atomic Energy Community (2021-2025)[409].

The funding rate will be 100%.

Subcontracting is not restricted to a limited part of the action.

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 timetable: First Quarter of 2027

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 timetable: 2026 and 2027

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

[409] 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

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; advice 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 timetable: 2026 and 2027

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:

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In case of a public health emergency[410] (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 [411] 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[412] 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 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 [413] 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.

410 Should there be no Public Health Emergency in 2026 or 2027, the indicative budget may be reallocated.
411 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2371&qid=1673372768554
412 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;".
413 See definition of FAIR data in the introduction to this Work Programme part.

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 timetable: Will depend on the Public Health Emergency

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

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 timetable: 2026 and 2027

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

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5. Subscription to the Human Frontier Science Program Organization

An annual subscription to the international Human Frontier Science Program Organization (HFSPO)[414] 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[415].

Type of Action: Subscription action

Indicative timetable: 2026 and 2027

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

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

415 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[416] [417]

	Budget line(s)	2026 Budget (EUR million)	2027 Budget (EUR million)
Calls			
HORIZON-HLTH-2026-01		456.00	
	from 01.020210	*456.00*	
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			404.00[418]
	from 01.020210		*404.00*
HORIZON-HLTH-2027-02-two-stage			190.00
	from 01.020210		*190.00*

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416 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.

417 The contribution from Cluster 1 for year 2026 is EUR 126.70 million for the Missions work programme part and EUR 23.31 million for the New European Bauhaus Facility and Horizontal Activities work programme part.
The contribution from Cluster 1 for year 2027 is EUR 124.60 million for the Missions work programme part and EUR 22.23 million for the New European Bauhaus Facility and Horizontal Activities work programme part.

418 To which EUR 10.00 million from the 'Climate, Energy and Mobility' budget will be added making a total of EUR 414.00 million for this call.

HORIZON-HLTH-2027-03			93.00
	from 01.020210		*93.00*
Other actions			
Grant awarded without a call for proposals according to Financial Regulation Article 198(e)		42.10	35.30
	from 01.020210	*42.10*	*35.30*
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		1.00	1.00
	from 01.020210	*1.00*	*1.00*
Subscription action		7.04	7.04
	from 01.020210	*7.04*	*7.04*
Estimated total budget		594.24	829.44

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