HNN 3.0
HEALTH-NCP-NET

Health NCP Net

InfoDay Cluster 1 “Health”
Q&A on Calls 2025

www.healthncp.net

HNN3.0 (The Cluster 1 Health consortium of NCPs for Horizon Europe) has received funding from the European Union’s Horizon EUROPE research and innovation programme under Grant Agreement number 101057279

INTRODUCTION AND BACKGROUND

On May 22rd, 2025, a virtual Horizon Europe Info Day was organized for the health cluster by the European Commission. This Info Day aimed to inform (potential) applicants about topics included in the Cluster 1 'Health' work programme of 2025.

The European Commission has published the slides and videos of the topic presentations and the questions and answers (Q&A) online.

This document prepared by NCPs will give you the links to all topic presentations and Q&A sessions including the exact time in the video where the questions are answered.

The aim of this document is to help Health NCPs provide their applicants with the best possible advice and support and to assist applicants in preparing a high-quality application.
This document is provided for information only. It has been written as part of the HNN 3.0 project, a Coordination and Support Action funded by the European Commission, with the goal to improve and support the professionalization of the services rendered by Cluster 1 – Health NCPs across Europe, helping for a simpler access to different health related Horizon Europe calls, lowering the entry barriers for newcomers and raising the average quality of the submitted proposals.

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Destination 1 - Staying healthy in a rapidly changing society

Watch Presentation of Destination 1 Topics; Unlisted Topics did not receive related questions.

HORIZON-HLTH-2025-03-STAYHLTH-01: Improving the quality of life of persons with intellectual disabilities and their families	Time [h:min:sec] in the recording when the question is asked
Is it compulsory to deliver technologies and digital solutions?	1:49:45
What is the definition of disabilities that is considered in this topic?	1:50:48
How is this topic linked to the political priorities of the Commission?	1:52:18
Can the project improve the quality of life (for example through empowering) without focusing on health?	1:54:11
Is dementia (for example Alzheimer's disease) covered by the topic?	1:55:15
Is it possible to include patients with no intellectual disabilities in a minor part of the proposal? (e.g. disorders where some [patients] have intellectual disabilities and some don't)	1:56:40

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

Watch Presentation of Destination 2 Topics; Unlisted Topics did not receive related questions.

General Questions	Time [h:min:sec] in the recording when the question is asked
"To consider the use of experimental methods not using live animals" this means that we should avoid in vivo methods? And in vitro would be sufficient?	9:35
Can proposals only be submitted to one of the topics per destination? Or is it also possible to submit thematically more open to a destination?	10:47
In projects on pollution would it be possible to also include micro/nanoplastics as environmental contaminants with a specific WP within the planned activities?	13:48
What type of involvement from SSH is expected in these topics, any specific discipline or perspective? The call does not specify.	27:25

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HORIZON-HLTH-2025-03-ENVHLTH-01-two-stage: The impact of pollution on the development and progression of brain diseases and disorders	**Time [h:min:sec] in the recording when the question is asked**
Topic on brain health and pollution: will proposals with a multi-pollutant approach score higher than those looking at singular pollutants?	3:48
Call focusing for chemical pollution, exclusively? Would e.g. light, noise pollution be out-of-scope?	4:55
Can proposals focus on integrating and analysing existing datasets and cohorts? Or better to prioritize data generation over data reuse?	8:09
Does ADHD has the same importance/ weight in comparison to Alzheimer or Parkinsons for example? do specific diseases score higher?	17:02
Can we focus on one brain disease? Or do we need to consider multiple?	18:29
Is the call related only to neurological diseases, or could psychiatric diseases be suitable as well?	19:41
What policy needs does this call answer to?	21:34
Can proposals budget more than the suggested 6-7 million EUR?	23:12
How much are neurotoxic chemicals in the focus of this call? Which exposome are in the focus of the call?	24:08
In call there is no TRL indicated. Is it expected that we use mature techs for the studies or there is margin to develop new techs?	26:28

HLTH-2025-03-ENVHLTH-02-two-stage: Advancing knowledge on the impacts of micro- and nanoplastics on human health	**Time [h:min:sec] in the recording when the question is asked**
Are environmental impacts of microplastics in scope of this topic? Or only those relating to health...? What if they are related?	6:54
Can we include studies around behaviour even if this is not listed in the activities? For example, stakeholder or public engagement elements…	12:41
How much should proposals contribute to policy support (ex: development of standards, regulatory frameworks) vs advancing basic scientific knowledge	15:17

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Destination 3. Tackling diseases and reducing disease burden

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HORIZON-HLTH-2025-01-DISEASE-01: Testing safety and efficacy of phage therapy for the treatment of antibiotic-resistant bacterial infections	Time [h:min:sec] in the recording when the question is asked
Do you expect that a phage product is already in place to move onto trials, or can the phage product be developed during the project?	47:21
This topic has clinical focus, how much phage research is encouraged as outcome and involvement of phage researcher/clinician?	1:02:22
Does the requirement to have the RCT protocol delivery date by Month 12 mean that the regulatory authorities must have approved it by month 12?	1:05:56
What is the participation scheme for the HORIZON-HLTH-2025-02-DISEASE-01 topic? Would joining it enable future involvement in this partnership's calls?	1:10:05
Is prevention of infection (e.g. decolonization) in scope?	1:15:43
Are pathogens 'rated' so that projects targeting bacteria being multi-drug resistant to one or more last-resort antibiotics are more likely to get funded?	1:20:02
The call indicates a total b. 45 million (for n. 3 projects), with €15 million allocated by EU per project. Is any co-funding from applicants required	1:23:18

HORIZON-HLTH-2025-03-DISEASE-02-two-stage: Advancing innovative interventions for mental, behavioural and neurodevelopmental disorders	Time [h:min:sec] in the recording when the question is asked
What does 'active substances' mean? A mainly pharmacological intervention as treatment? Can it be paired with non-pharmacological methods?	35:42
How important is the pharmacological component? In other words, can the proposal focus primarily on cognitive behavioral therapy?	41:35
What is meant by "novel intervention"?	50:50

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Is it strongly recommended to include components like genetics and neuroimaging, or can other non-biological predictors be sufficient?	1:00:47
For this can we focus on AI based innovation as prospective solution?	1:04:40
Can we focus on non-pharmaceutical therapeutic solutions primarily (i.e. CBTs), instead of pharmaceutical approaches?	1:14:34
To what extent to you consider molecular, biochemical or omics signatures as well as biomarkers a crucial element to the call?	1:25:48

HORIZON-HLTH-2025-01-DISEASE-03: Development of antibodies and antibody-derived proteins for the prevention and treatment of infectious diseases with epidemic potential	**Time [h:min:sec] in the recording when the question is asked**
Do you reward to include partners from more countries than only the 3 necessary and represent by that more European regions (e.g. Eastern Europe)?	49:30
Can you explain in which way we should integrate the Isidore project in our proposal? Do we have to get in contact with them?	57:25

HORIZON-HLTH-2025-01-DISEASE-04: Leveraging artificial intelligence for pandemic preparedness and response	**Time [h:min:sec] in the recording when the question is asked**
Can we use this call also for vaccine development acceleration (e.g. epitope and immunogenicity prediction)?	37:44
Is drug development based on AI technology within the scope for this topic?	40:44
Topic 4 mentions "Scout, assemble and prepare appropriate FAIR datasets (e.g. COVID-19, Influenza)" - are there any type of expectations for specific datasets	45:40
Is there any list of infectious diseases to be in scope other than COVID-19, influenza?	50:06
For epidemiologic prediction and response, only? Vaccine develop acceleration e.g. epitope and immunogenicity prediction, out-of-scope?	53:45

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Are prophylactic vaccines included? or it is only "therapeutics" vaccines? It would be great to give examples, to avoid mistakes!	1:03:15
How should projects include the issue of getting health data from member states, by relying on other EU initiatives like EHDS?	1:08:40
Is the proposal reviewed by multidisciplinary experts, eg. health/epidemiology and AI experts?	1:26:58

HORIZON-HLTH-2025-01-DISEASE-06: Implementation research addressing strategies to strengthen health systems for equitable high-quality care and health outcomes in the context of non-communicable diseases (GACD)	**Time [h:min:sec] in the recording when the question is asked**
Will collaborators in India be eligible to apply for funding?	46:43
Could you please give an overview of the GACD call on Implemebtation Research on Health System Strengthening for NCDs	55:28
Is it necessary that the exact evidence-based intervention the implementation of which is studied is pre-decided already in the proposal?	1:19:06
Is there any preferred geographical balance, spread, or total number of LMICs to include? E.g. 2 from the same global region? Or 6 global?	1:22:25

HORIZON-HLTH-2025-01-DISEASE-07: Tackling high-burden for patients and under-researched medical conditions	**Time [h:min:sec] in the recording when the question is asked**
From the scoping study linked to the topic, the burden of post covid-19 (table 4.5), would be eligible? Could you confirm this?	43:08
How best to involve patient organisations? Could you help connect us to organisations outside DK/SE?	56:15
Are gynecological cancers included in "gynecological diseases", or is it just "chronic" gynecological diseases?	59:00
Is axiale spondyloarthritis in scope even though the discussion paper say “Arthritis(no back)”?	1:17:15

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

Watch Presentation of Destination 4 Topics; Unlisted Topics did not receive related questions.

HORIZON-HLTH-2025-01-CARE-01: End user-driven application of Generative Artificial Intelligence models in healthcare (GenAI4EU)	Time [h:min:sec] in the recording when the question is asked
What is the focus here – to develop on GenAI solution that can be applied across multiple use cases or several tailored GenAI solutions for different use cases?	4:06
This topic is a Research and Innovation Action, but in the text, Applicants should provide evidence of a high maturity technology for the use cases. What level of TRL is expected? 4:54	4:38
Should there be a common AI concept for all use cases or can there be multiple solutions?	5:13
Could you clarify the expected role of HTA bodies in relation to GenAI technologies?	5:50
What level of involvement do you anticipate from AI factories in this project?	6:22
Is the AI research expected to start at low TRL or the focus is on deployment of high TRL solutions into practice?	6:52
Should the Generative AI solution be based on a European-made Foundation model or for example could be based on a GPT of open AI?	7:14
How is the virtual assistant defined for the purpose of the call?	7:42
Applicants should demonstrate high technology maturity for the use cases. Is this prior to testing or as an outcome of the project activities?	8:24
Does different medical fields mean different medical areas like cardiology and oncology, or different disciplines in one medical area like surgery and drug treatment?	8:54
In the Work Programme, there are examples of health Imaging like MR, CT. Do we understand correctly that under these Imaging techniques are also included electrocardiogram?	9:22
How broad or how specific shall the use cases be? Can you give examples?	9:43
Are private companies welcome to participate in the course?	10:24
Most of the topics are to be centred in LLMs. Is this topic also considering other types of generative AI like synthetic bio signal generation?	11:26
Is the focus of the call on development of lower TRL AI for example starting TRL3 or the deployment into products and clinical practice?	11:51

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

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HORIZON-HLTH-2025-01-TOOL-01: Enhancing cell therapies with genomic techniques	Time [h:min:sec] in the recording when the question is asked
Is CT mandatory or CTA is sufficient?	23:19 and 34:20
Is it obligatory to have a digital tool for aided design?	28:16
What are the main differences in terms of outcomes between Topics 1 and 3 ?	30 :42
Are digital tools for efficient design mandatory (are simulation or in-silico tools also possible ?)	34:20
Is proposal starting at AI guided discovery and genetic circuit design phase eligible or is a high TRL required ?	36:34
Are CROs eligible to take part in a consortium to support CTA enabling studies?	39:55
Is autologous cell-based therapy possible in this Topic?	45:57
If no clinical trial is planned, shall we have to complete the CT template?	48:57
Are research on cell therapy at the discovery stage eligible?	47:30
Are researches on synthetic cells eligible ?	49:52

HORIZON-HLTH-2025-01-TOOL-02: Advancing cell secretome-based therapies	Time [h:min:sec] in the recording when the question is asked
Is 46% of the total budget acceptable to subcontract to a CRO for phase 1 and 2 CT?	21 :42
Is a secretome-based therapy used on transplant organs, (thus) not directly on the patient, e.g. ex-vivo therapy, eligible?	41:10
Phase 2 CT must be completed in the end of the project; what is expected as "further" step activity mentioned in the project?	43:33
Will there be a 50 pages proposal on a lump sum cost?	50:25
Shall the mechanisms be fully understood (by the end of the project) or is research on the understanding of the mechanism also eligible?	52:15

HORIZON-HLTH-2025-01-TOOL-03: Leveraging multimodal data to advance Generative Artificial Intelligence applicability in biomedical research (GenAI4EU)	Time [h:min:sec] in the recording when the question is asked

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Is a final market-ready solution expected or appreciated or the Topic focuses only on Proof-of-concept?	19 :48
The Topic mentions biomedical research, health research, healthcare research which is large and broad topic : how close to the clinic should the proposal be?	32 :40
Should the IA factories be part of the consortium or external from it?	33:38
Is clinical diagnostic tool eligible or basic biomed/lab research?	35:10
Is a common IA concept expected for all use-cases or is it possible to have multiple solutions for multiple use-cases?	35:41
Is there still TRL eligibility aspects as (it was) in an old draft version of the Work Programme?	40:38
Would Medical Devices regulation to be considered in this Topic?	44:30
Shall we develop only one Gen-AI for several use-cases of or several tailored Gen-AI models for several different use-cases are expected?	51:05
Given the healthcare focus of Topic TOOL-01, would biomedical research using multimodal molecular and cellular data fit to the Topic TOOL-03 scope?	53:00

HORIZON-HLTH-2025-01-TOOL-05: Boosting the translation of biotech research into innovative health therapies	**Time [h:min:sec] in the recording when the question is asked**
Is the topic also open to prophylactic vaccines?	19 :15
Is it allowed to have a Start-Up SME coordinator a proposal dedicated to boosting biotech?	22:25
How are ATMP eligible whereas blood derived products and human origin products are not eligible? Many ATMP are derived from human origin substances.	24:12
Is it required to have regulatory authorisation at the submission stage or acceptable to get it during the project implementation?	23:35
Are some preclinical activities eligible? Within the 4-years duration are phases 1 and/or 2 of CT prioritised?	29:00
Are therapeutics for difficult to treat cancer eligible (eligible disease area)?	29:57
How is "large" population defined ? Is there a defined threshold?	37:56
How will proposal "for high prevalence" be favored? According to prevalence of the indication? Moreover, what is the latest possible start date of the project?	38:55
Shall the regulatory approval for the CT need to be on the same trial (indication) targeted in the proposal or can it be for another indication not covered by the original proposal?	49:25

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Destination 6. Maintaining an innovative, sustainable and globally competitive health industry

Watch Presentation of Destination 6 Topics; Unlisted Topics did not receive related questions.

HORIZON-HLTH-2025-01-IND-01: Optimizing the manufacturing of Advanced Therapy Medicinal Products (ATMPs)	Time [h:min:sec] in the recording when the question is asked
Is decentralizing and existing ATMP process from one GMP center to others aligned with the expectations of the call?	1:01:02
Can two different established products within the same ATMP category be included in one application?	1:03:10
Does the project have to create a center of excellence?	1:08:31
Should the project focus on a specific product or can it target general manufacturing platforms for a category of ATMPs?	1:09:30
Does the established use require a product to be approved or marketed, or can it include prior clinical use like early trials or compassionate use?	1:10:20
Is it acceptable to consider established use in terms of technology platforms, such as CAR T or genetically modified human stem cells, not strictly tied to a single product?	1:14:31
Is the development and/or the application of AI a mandatory requirement?	1:15:59
Is it necessary to integrate the new developed manufacturing progress into a clinical study during the project duration?	1:18:05
Is it expected to validate the clinical utility of a manufactured ATMPs or only validate the process itself against the status quo?	1:19:22
Can AI automation and process analytics in GMP-like settings be included, even if not fully validated in project start?	1:28:55
What is the definition of a center of excellence? Is it the higher education establishment that publishes in Cell and Nature?	1:29:54
Does topic 01 aim to involve more companies in ATMP manufacturing or tech development or to support new technologies within existing ones?	1:30:38
Academic teams often work on platforms optimization for future pipeline products. Will this be evaluated positively or excluded as not concrete enough?	1:33:33
Can an established product A as manufacturing process be used for a product B with the same platform such as CAR T but for a different indication?	1:34:14
Topic 01 calls for exploring the potential of platform technologies. Is this a necessary step before drafting a proposal, for instance to find suitable partners?	1:35:30

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HORIZON-HLTH-2025-01-IND-02: Digitalisation of conformity assessment procedures of medical devices and in vitro diagnostic medical devices	**Time [h:min:sec] in the recording when the question is asked**
The proposal addresses both medical device and in vitro diagnostic medical device or is each one eligible? And it refers to footnote number 218 which says that both.	1:11:56
Does the call also cover the monitoring of the notified bodies?	1:16:52
Would it be possible to include two partners but from the same country under this call?	1;20:46

HORIZON-HLTH-2025-01-IND-03-two-stage: Facilitating the conduct of multinational clinical studies of orphan devices and/or of highly innovative ("breakthrough") devices	**Time [h:min:sec] in the recording when the question is asked**
Does this call enable highly innovative devices that are not related to orphan devices? This relates to the mention of and/or highly innovative.	59:25
Can this call fund a clinical study using an already CE marked device for a given application but to apply for a novel CE IVD marked application?	1:00:17
In case of an EU-wide clinical trial, all partners must have fully accepted the ethical approval of the trial?	1:01:57
Are phase 2 trial or study eligible? If so, how can we refer to our phase 1 study anonymously?	1:04:26
Are novel therapies for the neurodegenerative disease such as Alzheimer disease or Parkinson's disease eligible?	1:05:25
What is the definition of a breakthrough or highly innovative device? Where can we find this definition?	1:06:18
Is breakthrough software as a medical device eligible?	1:07:45
Can or must SMEs receive funding?	1:08:03
The topic aims to improve the market position of EU companies. Does this rule out US company involvement or comparison of US and EU devices?	1:13:04
Can a phase 3 study be considered in the scope of the topic?	1:17:35
The topic has a focus on clinical studies on safety performance and clinical benefit. Should we keep it between TRLs level 3 to 6 or can the activity extend to TRL7?	1:21:58
Is there a preferred role for cooperation with national or international regulators?	1:23:39
What would be a valid indication of orphan devices in rare cohorts of patients?	1:26:10
Should the justification of a breakthrough device be based on European regulatory criteria only?	1:27:19
What is expected in terms of good practices related to the design, conduct, sample handling or data analysis?	1:31:56
For a breakthrough device multicentered trial, does ethical approval have to be in place in stage 1 of the submission at all sites?	1:36:12

The concept and development process of this document belongs to the HNN3.0 network and is based on official information provided by European Commission experts during the HE 2024 Info Days.

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