

# Health NCP Net

InfoDay Cluster 1 "Health" Q&A on Calls 2024

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#### INTRODUCTION AND BACKGROUND

On June 1<sup>st</sup>, 2023, a virtual <u>Horizon Europe Info Day</u> 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 2024.

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

Presentations of Destination 1 Topics - Part 1 | Part 2; Watch the whole Q&A on Destination 1

**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

	Question	<b>Link</b> to answer
1.	Should projects address health & physical activity & nutrition etc.? Or is the focus on one area/ prevention of specific pathology possible?	12:14
2.	Keeping the holistic approach, may primary focus be on a specific prevention area (e.g. obesity, addiction, mental health)?	12.14
3.	Are the tools and interventions developed by the projects expected to be digital (at least in part)?	<u>17:26</u>
	Proposals should be dedicated to all children and youths, from 5/6 years old till 25 years old, or focus on specific age targets?	<u>19:28</u>
5.	Is there a possibility for African countries to participate?	<u>20:08</u>

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

	Question	<b>Link</b> to answer
1.	Does "background" information also include multiple data from habits/lifestyle such as diet, exercise etc.?	20:52
2.	Is the use of large data sets and AI mandatory to address the topic?	<u>21:26</u>
3.	Is also sport considered as a priority? Sport associations could be involved, right?	<u>21:59</u>

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

Watch Presentation of Destination 2 Topics; Watch the whole Q&A on Destination 2

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

	Question	<b>Link</b> to answer
1.	For the sub-topic on air pollution is it mandatory to consider emerging pollutants?	<u>5:15</u>
2.	Do proposals need to include vulnerable population groups?	<u>6:10</u>
3.	The call mentions the requirement to form a cluster. What does this imply at the proposal stage?	<u>6:56</u>
4.	Does JRC involvement somehow need to be addressed in the proposal?	<u>8:23</u>
5.	Should the proposal present a plan on how to submit the data in IPCHEM in terms of format and categories of data collected?	<u>9:10</u>
6.	What does the 2 stage evaluation procedure entail? Is there a max number of proposals that can pass to the second stage?	<u>10:36</u>
7.	Is it expected to focus the proposals on more than one sub-aspect of pollution addressed?	<u>11:38</u>
8.	Can the proposals focus only on single exposure routes?	<u>13:13</u>
9.	Should all the exposure routes mentioned in the text call be considered?	<u>14:12</u>

10. At least one means that it is really enough to cover one aspect or is it better	
to touch the other aspects as well?	
11. Is the development of sensors under the scope of the call?	<u>17:04</u>
12. How many US partners are allowed to participate?	<u>18:00</u>
13. Air pollution: how much of indoor vs outdoor pollution is considered?	<u>18:50</u>
14. Any legal entity established in the United States of America is eligible to	
receive Union funding. Which type of partnership is the commission	<u>19:40</u>
expecting?	

### Destination 3. Tackling diseases and reducing disease burden

Watch Presentation of Destination 3 Topics; Watch the whole Q&A on Destination 3

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

	Question	<b>Link</b> to answer
1.	Are substance dependent individuals, e.g. opioid addicts, within the scope of this call?	<u>17:54</u>
2.	Preference for interventions with a high public health relevance, are childhood cancers considered as a high public health relevance as they are rare?	<u>23:50</u>
3.	Are exploitation activities, for example plans for possible market exploitation, welcome in this proposal?	<u>26:20</u>
4.	A clinical study comparing a new intervention with the usual clinical practice would be considered as comparative effectiveness research?	32:52
5.	Is there a temporal limit for the project lifetime, for example, 3 years or 5 years?	38:34

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

Question	<b>Link</b> to answer
N/A	N/A

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

	Question	<b>Link</b> to answer
1.	Could you please confirm that for topic 03-13, the conditions of the topic allow participants from the US are eligible for funding?	<u>22:24</u>
2.	Can you provide examples of evidence supporting the regulatory acceptance of biomarkers?	<u>27:15</u>
3.	Is certain type of validation expected, like replication across population or technical validation of measurements?	<u>31:28</u>
4.	Validation of fluid-derived biomarkers for brain disorders, could it be applied to the brain metastasis categorization and treatment definition?	<u>39:45</u>

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

	Question	<b>Link</b> to answer
1.	Can developing a technology-based intervention for autism be the main object of a proposal in this call?	<u>10:50</u>
2.	Can you give an example for the kind of social science and humanities involvement contribution you would expect in this project/topic?	<u>12:58</u>
3.	The topic describes SME participation as encouraged, can an SME be a coordinator or can an SME to be one of the beneficiaries?	<u>16:35</u>
4.	Can we address a disease that does not appear in the list published in the reference scoping study?	<u>19:04</u>
5.	Would cancer be in scope of this topic?	<u>20:37</u>
6.	Can you please confirm that clinical studies attachment is not required at stage 1, only stage 2?	<u>25:25</u>
7.	For the bullet point of the scope "when applicable", does it mean it should be a minor part of the proposal?	<u>28:44</u>
8.	Is international participation competitive edge within this topic?	<u>30:12</u>
9.	With respect to infrastructure, what is expected in the proposal currently under development, for example, EHDS (European health data space)	<u>34:05</u>
10	. Are we limited to the conditions listed conditions under research in the scoping paper or can other conditions be proposed?	<u>36:45</u>

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

Question	<b>Link</b> to answer
N/A	N/A

## **HORIZON-HLTH-2024-DISEASE-08-20:** Pandemic preparedness and response: Host-pathogen interactions of infectious diseases with epidemic potential

	Question	<b>Link</b> to answer
1.	Is work on vaccine candidate etc. mandatory or sufficient to identify possible targets?	<u>9:00</u>
2.	Should all listed viruses be included in a project or can applicants choose from the list?	<u>14:00</u>
3.	Can Brazilian entities be funded in case their participation is deemed important to bring case studies and number of patients?	<u>15:00</u>

# <u>Destination 4. Ensuring access to innovative, sustainable and high-quality</u> health care

Watch Presentation of Destination 4 Topics; Watch the whole Q&A on Destination 4

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

	Question	<b>Link</b> to answer
1.	Is it enough to examine only people with disabilities based on the different perspectives mentioned in the call?	<u>4:12</u>
2.	Can (applicants) focus on one type of vulnerable group such as migrants (regular or irregular) or do they have to cover all vulnerable groups?	<u>5:17</u>
3.	Is it advisable to contact the initiatives and projects mentioned in the call such as, for example, the transformation of health and care systems cofund, and ask for a letter of commitment?	<u>6:37</u>
4.	Does it have to be one of the (vulnerable) groups mentioned?	<u>8:21</u>
5.	Does the range '4 to 6 million' (euros) mean that 4 million is the minimum and 6 million is the maximum?	<u>9:43</u>
6.	Would it be possible for partners from African countries to participate?	<u>10:46</u>
7.	The data sources for health projects are usually with a long agreement process. What is your advice?	<u>11:46</u>
8.	Does access to health and care include e-health?	<u>14:22</u>
9.	Do you consider data sources from hospitals / health facilities from old projects as a must for a proposal, as a better advantage or connection to an old project?	<u>16:59</u>
10	. What about specialist education for doctors to fill the gaps?	<u>18:25</u>
	. Would access to health and care services include access to therapeutical drug monitoring - advanced therapy that may help to improve treatment?	<u>19:36</u>
12	. If letters of intent are appropriate, do they belong in the 1 <sup>st</sup> or 2 <sup>nd</sup> stage?	<u>20:00</u>

# <u>Destination 5. Unlocking the full potential of new tools, technologies and digital solutions for a healthy society</u>

Watch Presentation of Destination 5 Topics; Watch the whole Q&A on Destination 5

#### **General Questions**

	Question	<b>Link</b> to answer
1.	Involvement of JRC (Joint Research Centre), should it be performed at the proposal stage?	<u>11:00</u>
2.	Are both Destination 5 calls restricted to particular disease area/ tissue type?	<u>20:43</u>

## **HORIZON-HLTH-2024-TOOL-05-06-two-stage:** Innovative non-animal human-based tools and strategies for biomedical research

	Question	<b>Link</b> to answer
1.	Should the proposal focus be on reduction of number of animals use in any area of research?	<u>7:25</u>
2.	Could tools that address rare diseases (RD) be a focus area within a project?	<u>8:15</u>
3.	Should the developed tools and strategies be compared to current animal models in the project?	<u>15:24</u>
4.	Which animals are considered as "animals" under the scope of this call topic? In particular, Zebra fish and Drosophila.	<u>16:21</u>
5.	Is it possible to study a field where animal models are not currently used because not relevant? (i.e. personalized medicine applications)	<u>18:22</u>
6.	Will it be mandatory to propose a computational model? What if the envisioned tool will be an organoid?	<u>19:50</u>

#### HORIZON-HLTH-2024-TOOL-11-02: Bio-printing of living cells for regenerative medicine

	Question	<b>Link</b> to answer
1.	The availability of larger scale bioprinted tissues (call text)- does this imply that tissue of larger surface/mass has to be printed?	<u>12:15</u>
2.	Should the outcome of the project be freely available bioprinted tissue?	<u>17:15</u>
3.	Are pre-clinical and clinical studies eligible to be included?	<u>20:27</u>

# <u>Destination 6. Maintaining an innovative, sustainable and globally competitive health industry</u>

Watch Presentation of Destination 6 Topics; Watch the whole Q&A on Destination 6

HORIZON-HLTH-2024-IND-06-08: Developing EU methodological frameworks for clinical/performance evaluation and post-market clinical/performance follow-up of medical devices and in vitro diagnostic medical devices (IVDs)

	Question	<b>Link</b> to answer
1.	Are methods that are only viable for a subset of devices sufficient or does the call only address generalizable approaches?	<u>13:13</u>
2.	Is it planned to align medical device classification between the EU and US? Should this be addressed for the topic?	<u>16:16</u>
3.	The topic is intended for competent charities and notified bodies as primary participants so they have a common framework to assess projects. Correct?	<u>17:53</u>
4.	Medical device in a combined product ATMP (regenerative medicine) is eligible for the scope?	20:00

**HORIZON-HLTH-2024-IND-06-09:** Gaining experience and confidence in New Approach Methodologies (NAM) for regulatory safety and efficacy testing – coordinated training and experience exchange for regulators

Question	<b>Link</b> to answer
N/A	N/A

### **Cross cutting issues**

See Slides on <u>Clinical Studies</u>, <u>Social Science and Humanities</u>, <u>Gender Equality Provisions</u>, <u>Lump Sum Funding</u> and <u>watch Presentation</u> on lump sum funding; <u>Watch the whole Q&A</u> on Cross cutting issues

#### **General Questions**

Question	<b>Link</b> to answer
1. Lump sum funding: When getting audited - do we need same records as before?	<u>55:42</u>
2. Lump-sum funding: who decides whether the work package is completed?	<u>57:07</u>
3. Blind evaluation: how to describe previous projects and work, if one is not allowed to name the organisations?	<u>58:03</u>
4. Blind evaluation: how to describe cohorts in the 1 <sup>st</sup> stage of proposals without giving information about partners involved?	<u>59:04</u>
5. Lump-sum funding: how is the approximation checked?	<u>59:50</u>
6. Project management: how do we split work program management along the reporting periods?	<u>1:01:15</u>
7. SSH involvement: What are such disciplines typical in health projects?	<u>1:02.30</u>
8. Lump-sum funding: How is the lump-sum funding applied to projects with associated partners, who are not receiving EU funding but contribute to work packages?	<u>1:03:18</u>
9. Lump-sum funding: Why do you not ask for detailed lump sum budgets during grant negotiation only from those consortia that receive the grant?	1:04:28
10. Lump-sum funding: Is there any pre-financing in lump-sum projects?	<u>1:05:33</u>
11. Blind evaluation: When the activity is very innovative and atypical, the blind application is hart to maintain or keep blind, since only one company is doing this. How can we do it in this case?	<u>1:06:22</u>
12. International cooperation: Are US partners eligible for the funding?	1:07:41
13. Blind evaluation: Currently the blind evaluation is applied in stage 1 only. Is there a long-term plan to have fully blind evaluation in the future?	1:08:22
14. Lump-sum funding: Should the project officer be informed about changes in budget lines?	<u>1:09:07</u>
15. Lump-sum funding: Does lump-sum funding apply to national agencies and partners involved in European Partnerships or to individual project consortia that apply to a call or both?	<u>1:10:17</u>
16. Gender balance: How is the female / male ratio considered? Is the prevalence of female scholars appreciated or discouraged?	<u>1:10:53</u>
17. Gender balance: When is the gender equality plan needed - at proposal submission or grant agreement preparation stage?	1:12:12
18. How to be a member of health cluster?	<u>1:13:20</u>

19. Lump-sum funding: Will the payments be based on activities finalized or work packages finalized?	<u>1:14:47</u>
20. International cooperation: Is Canada allowed to participate in the non-animal models topic and can it receive funding?	<u>1:15:56</u>
21. International cooperation: Are there 2024 topics where co-funding for non- EU countries is foreseen?	<u>1:16:57</u>
22. Blind evaluation: Do applicants need to change their project acronym, if it refers to a previous project?	<u>1:21:44</u>
23. International cooperation: Is it an advantage to include partners from India when addressing the topic HORIZON-HLTH-2024-DISEASE-03-13-two-stage: Validation of fluid-derived biomarkers for the prediction and prevention of brain disorders?	1:22:20
24. International cooperation: Opportunities for Canadian partners to participate in HE: some more explanations.	<u>1:23:25</u>
25. Lump-sum funding: How will the pre-financing be determined? Also, with the pre-financed amount be deduced from the first period payment.	<u>1:24:53</u>
26. In two stage calls – does the first-stage application undergo formal expert- review/peer review or these initial applications reviewed by a more general panel?	<u>1:27:15</u>

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.