Health NCP meeting - Q&A

13 December 2022

DESTINATION 1

HORIZON-HLTH-2023-STAYHLTH-01-01: The Silver Deal - Person-centred health and care in European regions

The topic looks very wide in terms of scope activities, why is this dealt with as an R&I action? Could you clarify?

Indeed it could also have been an Innovation Action, nevertheless, we were strongly encouraged by feedback from other NCP's that more research is needed. We try to give enough space to what is implementation, deployment and collaboration across regions, that's why we wanted to enhance the importance to have this interregional cooperation which is going more into an innovation action. On the other hand there's also enough space for research, testing and evidence based care models. During H2020, we funded a lot of R&I actions, projects that are specifically aiming to support elderly people through sensors, devices, frailty prevention, etc. We counted over 80 actions and projects. At least in CNNCT.

There is still lack of uptake and we want to further promote big actions that do not aim at developing a device or 1 solution, but preferably several solutions and bringing them (more) to use. For example, on providing coordinating care models & pathways on several different solutions. Bigger action aiming to take forward what already has been done.

The Active and Assisted Living Programme has been discontinued.

We want to forward actions that were developed already but further down into deployment & implementation. We considered to make out an innovation action of this, but we wanted to take on board new pathways and care models that could potentially need some researching.

How high TLR level?

Given that there are so many solutions that are already created in the last decade, we would want to see higher TLR. It's not specifically indicated in the call.

Can I ask you if you have in mind an age range for the elderly population?

At all, because we are talking about an age friendly working environment. We have not indicated an age range on purpose as we are taking an approach of lifelong health promotion and prevention.

There are many older working persons who need support and could use digital or non-digital innovative solutions (to be supported while they still work).

What are the previous projects which have already been funded in this area, which the proposers must take into consideration?

There are many events & initiatives around the Silver Deal, the most important initiatives would be Active and Assisted Living, European & Innovation Partnership on Active & Healthy Living, More years, better lives initiative, pilots supporting active & healthy aging & integrated care

There is a list with over 80 actions in H2020

In the call text you can find references on previous projects.

DESTINATION 2

HORIZON-HLTH-2023-ENVHLTH-02-02

Evidence-based interventions for promotion of mental and physical health in changing working environments Could you elaborate which kind of interaction with the NEB community is expected and with whom and how this should be addressed in the proposal?

Interaction should be established after the proposal approval, as is the case for JRC. Outcomes of the selected research projects relevant to the NEB should be communicated to our colleagues working on this topic for potential uptake (a FAQ will be published shortly related to this question).

Evidence-based interventions for promotion of mental and physical health in changing working environments (post-pandemic workplaces): diseases and disorders are allowed? Or only diseases? e.g. back pain is not always a disease.

Both diseases and disorders can be considered (a FAQ will be published shortly related to this question).

I's a very broad topic which covers mental and physical health, social & psychosocial issues and a wide range of profiles with different experiences in terms of work. From new people entering the workforce to other people coping with digital technology and adaption.

Is it possible to specialize when approaching this topic opposed to having it really broad. How broad or narrow do you want this? Because you could have very focused projects addressing to a niche group of people.

Proposals should address several and not all or most of the activities listed thus more focused approaches will also be considered (a FAQ will be published shortly related to this question).

DESTINATION 3

HORIZON-HLTH-2023-DISEASE-03-01

Novel approaches for palliative and end-of-life care for non-cancer patients: if cancer is a co-morbidity of the main disease, it is still ok for this topic?

No, this topic is for non-cancer patients. We had a similar topic focus on cancer patients in the WP 2021.

What is the link/difference with the previous topic"SC1-BHC-23-2018 - Novel patient-centred approaches for survivorship, palliation and/or end-of-life care" and Why funding a new topic on this subject, what do you expect more/different this time?

The difference is that the 2018 topic was open to all diseases including cancer, here we don't have cancer research in the scope. That's the main difference. The focus is on chronic diseases not related to cancer. There is a big need (for research) on other diseases like Parkinson disease, Alzheimer disease, COPD, etc.

Comparing to other disease areas, the network for cancer patients is very well developed and there is need for research on other diseases. We are acknowledging the importance of palliative care, life care and survivorship of cancer patients (that's why we had a specific topic) but this time we propose a specific topic that focus on palliative and en-of-life care on other diseases except cancer.

HORIZON-HLTH-2023-DISEASE-03-04

"such as those included in the list of priority diseases of the WHO, with particular attention to those meeting the criteria identified by HERA": is it possible for a proposal to address a virus not included in those list but still meeting the criteria "viruses for which there are no currently available effective therapeutics or for which the therapeutics available are sub-optimal?

Viruses within the scope of this topic are those with "**high epidemic or pandemic potential** for the EU, **such as** those included in the list of priority diseases of the World Health Organization (WHO) (https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency[1]contexts) , with particular attention to those meeting the criteria identified by the Health Emergency Preparedness and Response Authority (HERA) (https://health.ec.europa.eu/system/files/2022-07/hera_factsheet_health-threat_mcm.pdf)."

The criteria for pathogens with high pandemic potential identified by HERA are:
• rapid transmission mode;
• likelihood to reach a sensitive population, for example persons with minimal pre-existing immunity;
• their high potential to cause high morbidity and mortality
While these criteria according to the HERA fact sheet "largely include respiratory RNA viral families", the scope is not limited to those respiratory RNA viruses. But viruses within the scope of this call need to have an epidemic or pandemic potential.

While the topic 03-18 identifies the viruses to be addressed, these viruses were deliberately not listed in this topic. This means that the focus of 03-04 covers in principle all viruses with epidemic potential.

Are the lists in reference (WHO lists of pathogens and the HERA health treats list) final ones?

The WHO list was taken into account in the treat assessment of HERA. The factsheet you find online was published together with a press release and is not explicit with regard to the virus families and family members. It is the result of a vulnerability assessment done by HERA but could not be published for security reasons.

HERA will assess whether the list of threats needs to be updated on a yearly basis. If deemed necessary, the assessment will be updated. At this point the list but can be considered as stable for the next 1-2 years.

What is disease X ?

Disease X is a disease that we don't know like COVID SARS2, in the beginning we didn't know it and it was treated as disease X. So it's any new emerging pathogen that we have not identified yet.

Regarding the development of the workflows. You speak about artificial intelligence (AI). What is the level of development that you are expecting for these? Is it including the development of the tool or are you expecting something closer to the markers?

This is early development. Phase I, early development is the focus.

HORIZON-HLTH-2023-DISEASE-03-07

More and more publications show links between microbiota and NCD. Is it relevant to this call? (could microbiota be considered as ID?)

Microbiome is not to be considered as an infection. As indicated in the scope, microbiome could be considered and integrated in the proposal as a relevant factor in the interplay between NCD & infections**.**

Vulnerable people: elderly, pregnant women & children included or only people with pre-conditions?

Regarding vulnerable people: it is not restricted to people with existing pre-conditions. It is included as an example (such as).

Applicants are free to consider other type of vulnerability in their proposal. So, it is not only restricted to people with preconditions.

Should proposals mostly address infections with pandemic potential on other infections? Or infections with pandemic potential will be considered more important?

And

Special attention should be given to a particular target group such as those with known existing preconditions? Could you please specify the age range of this target group or are there no restrictions?

The topic is open to all infections, there is not priority list for the pathogens and applicants can choose to address infections other that those with pandemic potential.

In the scope, there is no restriction with respect to the age range of the target group with existing preconditions.

HORIZON-HLTH-2023-DISEASE-03-17

Would it be eligible to include vaccine candidates in a proposal? Or do you expect only vaccines already on the market ?

Is it possible to use animal model studies together with human samples to study vaccine induced immunity?

Vaccine induced-immunity: for the different vaccine types (mRNA, vector, inactivated, subunit, attenuated,…) are we talking about candidate vaccines ? vaccines on the market ? or a mix of both ?

Proposals should address the immune response induced by vaccines that are already on the market. Experience with COVID vaccinations showed a partial protection. Some vaccines had a low antibody reaction while eliciting a cellular response and there were non-responders. .

Projects should take a retrospective look how the immune system reacts to vaccination and how we can steer that process in order to improve the vaccination efficacy. While the topic text addresses primarily vaccine induced immunity in humans, it does not explicitly exclude animals.

HORIZON-HLTH-2023-DISEASE-03-18

According to the topic text "proof-of-concept studies in humans of the vaccine candidate" is possible. However, "proof-of-concept studies" usually are phase 2 studies or human challenge studies (which would require a phase 1 study before). This is difficult to achieve within the given timeframe and budget. Are rally phase 2 studies expected or rather phase 1 or first in human trials?

Indeed we were rather thinking of first in human studies so not necessarily phase 2

The starting point of this topic is to develop immunogenicity profiles of viral proteins with the perspective to be prepared for disease X. This is based on the assumption that the virus that will cause a next pandemic will be derived from viral families we know already.

During co-creation the possibility to open this topic and to allow advancing towards vaccine development was introduced. In view of the allocated budget and the time frame this may be challenging. So it is an option, I would not expect topics/proposals to advance that far, but if they can use this funding.

There seems to be no consensus in the field whether proof of concept is part of phase 1 or of phase 2 in a clinical trial. Experts we contacted associate it with phase 1. We would be surprised if projects would reach phase 2.

My question is on International cooperation, especially in terms of funding of International cooperation partners.

I've received, for example, questions from Brazilian researchers about this topic. So we know that in general we would say that Brazil is not eligible for funding, not automatically, not anymore since a few years.

What would you expect? Would you prefer to have researchers and facilities from other countries, like Brazil? And would the EC still keep the rule that they're not funded? I mention Brazil because I got a question on it but so many other countries could apply in this topic.

So specially on International Cooperation we have a dedicated session this afternoon with the colleagues answering all these questions on international cooperation.

In the final text published on Funding & Tenders I cannot see the condition that coronavirus and influenza not included. Or I have missed it?

The final version of this topic includes a positive list of viruses that should be addressed. Therefore it is not any longer necessary to exclude Corona or Influenza. Only the viruses listed in the topic description should be addressed in proposals.

DESTINATION 4

HORIZON-HLTH-2023-CARE-04-02

How do you define "Data generation"?

There is not a definition of the term data generation specific for this topic. Actions should lead to high-quality data that can be used for future analysis and comparison. Both qualitative and quantitative methods can be used. Data that is generated under this call should be consistent with the FAIR principles (findable, accessible, interoperable and re-usable).

HORIZON-HLTH-2023-CARE-04-03

Can hospital energy efficiency projects be included?

As described in the topic scope, any research and innovation activities under this topic should be specific to health and care sectors. Activities aiming at decreasing energy demand / improving energy efficiency in the context of health and care systems can be included. To ensure more systemic solutions for hospitals and other care providers, the proposals should

cover several aspects in relation to greening of the health sector and not solely one of the aspects listed in the topic scope.

Would there be room for a series of innovative technologies that reduce electricity consumption in hospitals and therefore carbon dioxide emissions? OK?

As described in the topic scope, any research and innovation activities under this topic should be specific to health and care sectors. Activities aiming at reduction of energy consumption and reduction of CO2 emissions in the context of health and care systems can be included. To ensure more systemic solutions for hospitals and other care providers, the proposals should cover several aspects in relation to greening of the health sector and not solely one of the aspects listed in the topic scope.

When I think to "research" I would not think to Policy & decision makers' knowledge. Should this be on CSA side?

The main objective on this one is to give the necessary information to those who have to make decisions in order to facilitate this transition to greener health care systems, as they are going to be in the spotlight in the next upcoming years and are therefore considered those who should mainly benefit about the results of such research.

DESTINATION 6

HORIZON-HLTH-2023-IND-06-01

Do you expect in this large CSA a broad participation of different European countries, with different HTA bodies? Or smaller group of HTA bodies working with the communities and then providing the support to the other HTA bodies?

We expect the HTA bodies to be part of it. We do not expect the whole bodies to be part of it, but at least the representatives of the network of HTA should be there, together with experts in the field, as the idea is to identify the methods, analyse these methods, and to advance the scientific knowledge.

Is there a list of national/country HTAs (Health Technology Assessments)?

No, there is no specified list of countries or bodies in the topic description, which means it is open. As there is one topic, the HTA network will have to collaborate with the proposers (applicants?).

HORIZON-HLTH-2023-IND-06-05

Are combined ATMPs included in the scope of this topic?

Indeed, as combined ATMPs are made of ATMPs, and this is within the scope. This is also true for ATMP plus 'other' (a medical device for example). At least for the ATMP part, that is included.

Is it valid for all the calls to contribute/address all of the elements in scope and expected outcome?

it is clearly mentioned in the topic when all of the elements need to be addressed. If it is not explicitly written, then there is some flexibility (the exact wording in topics is very important – whether it mentions 'all', 'most' or 'several').

DESTINATION 5

HORIZON-HLTH-2023-TOOL-05-01

We received comments (from Spanish awardees – on delays in vaccine clinical trials) about situations when beneficiaries encounter difficulties – e.g. to timely recruit patients, or to perform the clinical trial in a way the project was initially set, etc. Is there any advice or recommendation concerning this, and how to define Clinical trials so that such problems are prevented

Phase 2 clinical trials is mentioned in the topic and this is defined in REGULATION (EU) No 536/2014.
It is also clearly mentioned in the topic that the technologies ready to undergo interventional clinical trials.

Additional aspect: The duration of the project needs to be chosen in a way that such difficulties that may cause delay (like e.g. recruitment of patients, etc.) do not hamper the overall schedule and the attainment of the projects' goals.

Please send in writing your questions so we can respond later. In any case here clearly Phase II of Clinical Trial is mentioned, and this is a defining factor and a regulatory definition (not observational studies).

It is sometimes when projects have problems recruiting patients that a clinical trial is delayed and the beneficiaries run out of time and budget to conduct the clinical trial within the scope of the project.

When you write the proposal you should identify critical risks, including delays, and suggest mitigation measures. Your project may, possibly, be granted an extension, but the work and time defined at the beginning needs to be well defined. Such situations are not specific for this topic, but such issues are encountered often - the extensions granted in Horizon 2020 were because of clinical trials.

How do ATMPs relate to the JU on clinical trials EDCTP?

In case there are valid reasons to liaise with EDCTP the applicants should mention this, but a clear link is not evident in this case. EDCTP's work is related mainly to infectious diseases and not to advanced therapies.

HORIZON-HLTH-2023-TOOL-05-03

Proposals in this topic should focus on groups of communicable and/or non-communicable diseases - what should be understood by « groups » of diseases ?

When it comes to the group of diseases, the applicants can take a medical science view here: Neurodegenerative diseases is a good example, because in order to model that part of human pathophysiology, it would be most likely necessary to use a multi-disciplinary combination of modelling based on the musculoskeletal and the nervous system. Another example are musculoskeletal diseases in themselves: for example osteoarthritis and fibromyalgia, where an appropriate combination of muscular and skeletal modelling could be needed. This is the key aspect of this topic – ultimately, the selection of these diseases must center on the call requirement of the topic to produce such advanced multidisciplinary multiscale models.

HORIZON-HLTH-2023-TOOL-05-08

You refer to pathogens with pandemic potential and also other health threats, such as chemical, radiological and nuclear threats. Do proposals need to cover several, or is it sufficient to focus just on pathogens? Or is some combinations covering several threats expected?

The focus of HERA is wider than pandemics or diseases and encompasses also AMR, or CBRN threats related elements mentioned. Even after the process of finalising the WP several topics still have in their title the expression 'Pandemic preparedness and response', while in this case 'cross-border health threats' would be more appropriate. Indeed this topic is rather wide and includes also diagnostics with regards to CBRN threats (Chemical–Biological–Radiological-Nuclear threats), so it should address 'several of the following'. A proposal that does not address nuclear accidents should still be eligible. The scope of this topic goes beyond pandemic preparedness.

The source of confusion from the stakeholders is as in the expected outcomes it is specified 'and' (as in 'need to address both') and in the scope it says 'or'. Can you confirm that it should be 'or'?

An expected outcome can also be understood in a broader way. We will inform the colleagues from the executive agency, so the experts are briefed properly to not penalise the applicants.

We believe that in vitro bio (?) diagnostics would be very different to nuclear diagnostics, so in logical terms it should be 'either – or', since developing one that would cover both is next to impossible.

Quoting from the WP: "proposal should cover pathogens with pandemic potential in humans or other health threats such as CBRN..."

Is AMR (Third threat on the HERA list) included in the scope of this call?

This topic relates to in vitro diagnostic devices – and therefore apart from a case where the proposal would be about a specific need and a particular device needed for AMR, it is assumed it is not included. Or another angle could be developing diagnostic tools that can identify resistant germs. This is not excluded so as long as the proposal meets scientific criteria it is possible.

The topic states "Proposals should cover pathogens with pandemic potential in humans or other health threats, such as chemical, radiological and nuclear threats…" and does not specifically mention AMR. HERA considers AMR as a market failure issue – there are no incentives to produce new antibiotics and if someone does develop new antibiotics going through all the constraints, in the end it may be listed as a reserve antibiotic with a limited market.

Can you give us some more background info on destination 5 and 6? Why is the budget for the topics so different?

The reasons are numerous, one of them being that the scope and the expected impacts are very different. Furthermore, decisions concerning an optimal project and budget size were formed with budget availability in mind, and taking into consideration also the prioritisation and feedback provided by the Programme Committee throughout the process.

The destinations differ in their nature – destination 5 is really about the development of technologies, and needs to have competing proposals. Destination 6 is more on support to market uptake with a lot of topics oriented towards e.g. regulatory needs, regulatory agencies, CSA, or topics with one resulting project, etc. If in the future we have innovation procurement in destination 6 the budget would be probably much higher.

General question on the whole WP – Why are there no procurement actions foreseen, neither for 2023 nor for 2024?

This was for destination 5 and 6 (the fifth intervention area of the specific programme) identified as a gap in the analysis. Initially, we had procurement for the AMR but this did not work, as we had the CSA to prepare and it was abandoned.

To develop topics for pre-commercial procurement or topics for public procurement of innovations is very challenging - in Cluster 1, but also in other clusters. This is where your help and feedback on what do you consider the main reasons for some of these topics attracting only little attention or why some proposals did not quite match the ambition, etc. would be essential. There is still a lot of work ahead to make this public procurement tool an effective tool.

We have an ongoing CSA on Innovation Procurement

GENDER

*Gender balance is used to work on **priority list** of funded proposal. In that case evaluators are going to count how many female and male researchers are involved?*

The evaluators do not need to count as the calculation is automatic, generated as a standard CORDA report based on the amount of researchers named in the proposal's researchers' table that self-declare as either woman or man. The proposal closest to gender parity is prioritised.

The GEP will be checked at the Grant Agreement Preparation stage: What would you advise to an organisation that has no Gender Equality plan in place at the application stage, but is planning to follow up by the time of GA signature? What shall they indicate in the proposal?

It needs to be highlighted that GEP is an eligibility criterion that has been announced already in 2020 in the General Commission's Gender Equality Strategy and there was a year's grace period awarded to prospective applicants. The organisation is supposed to have a GEP in place before signing the GA. The proposal contains a self-declaration and the organisation is supposed to indicate the truth. There are several months in between the moment a proposal is selected. Even if the organisation at the proposal ticks 'no', it will need to have it in place by the time of GA signature, but the proposal will not be blocked by selecting 'no' initially.

Question related to researchers' table and persons included in this table: some stakeholders raised the issues that while there is stronger focus on impact now in the HE programme, where it is necessary to include impact partners, industry, SMEs, etc. these are not reflected in the above mentioned table. Therefore, only the gender of researchers is taken into account and not overall, regarding all contributors. Is the Commission looking into this?

This was a decision that was taken at the beginning of HE, in particular because there is an underrepresentation among researchers. The focus was indeed put on researchers (not only for gender, but also the level of experience and role in the project of researchers).

This argumentation is also in EIC, but there the focus is on Industry, and there you also have some requirements on gender. In EIC they do look at industry, because they say that at high level in industry you also may have gender related problems.

Indeed. The EIC also has an entire set of specific measures – for example to promote women in innovation and in decision-making positions in innovation. To be noted is that the definition of 'researchers' is quite broad – covering a broad range of occupations (but not for example communication officers or administrative staff, which are often women). (Frascati definition). There may be researchers also in industry.

If it is an eligibility criterion, why is it not mandatory at proposal stage?

This is the way it was chosen to be implemented, while this is not uncommon and there are several other eligibility criteria that are applied at the GA preparation and signature stage.

LUMP SUM FUNDING IN HE

*How will the **lump sum be implemented**? in all calls?*

There are no lump sums in 2023 calls, and Cluster 1 only has lump sums in 2024 WP. In general, if a topic uses lump sum funding, this is clear from the topic description. The principle is that the topics is either using actual cost or lump sum funding.

In Horizon 2020 there was a limit of 21 on the number of possible Work Packages (it was related to the Excel IT tool where these packages were). Is there a maximum again?

There is no maximum number of Work packages and the new Excel IT tool should not limit. The limit is in the sense that the work plan should make sense and a proposal should not include minute little work packages that are not really such. There needs to be a substantial sub-division of the work plan. Experts are briefed to check this but there is no hard limit or prescription. This will be evaluated at the implementation criterion and is an important decision for the consortia to decide on when they are writing a proposal. For reference: in the pilot the Lump sum packages had 1.5-2 times more work packages compared to the previous statistics.

Can you share some experiences concerning the pilot in 2018 the projects reported back (it was a pilot on clinical trials, partly infectious diseases)?

What we have seen by now is that 99% of all requested LS payments have been made in full. Only a handful of packages have been paid partially. There was no single case where a work package was not paid at all. There was not a single case of contentious payment – disagreement between EC and the beneficiaries. This shows a certain stability of the system.

We are also not aware of any dispute and of a reduction for example. But we would need to consult colleagues if there was something to report back on.

Regarding splitting of Work-packages: applying the example of a work package referring to management, in past there would be one Work package where one description of work would be provided. In LS the applicants would now need to describe the work several times (or its' several aspects)? In this manner the different calculation of costs has quite far reaching consequences for the content of what you are doing.

If the work package on management is split, there is no need to repeat the content: an approach could be to describe the Work package as this was done before in the first package of management, and then in the second (and third, etc.) to refer to the first description and clarify that this refers to different reporting periods.

We often receive questions from academia concerning advance payments – how much advance payment do projects receive in case of LS?

For pre-financing the basic rules applied, including to calculate this, are exactly the same standard rules as in the case of actual-cost-grants. These can be found in the General Annexes of the Work Programme. The authorising officer/service managing the grant could modify this, but that would be independent of whether it is LS or not.

PILOT ON BLIND EVALUATION

In the general annex of WP 2023-24 page 13 there is a reference to the Horizon Europe Programme Guide where further details on the blind evaluation scheme should be available. However, the programme guide available on the F&T portal does not contain any info on the blind evaluation.

*How does the **rebuttal** work in practice?*

The rebuttal process is still being piloted. Cluster 1 calls are not participating in the pilot. At the start of 2023, once the pilot is finished, the EC will take a decision on whether to continue with this process all across the Programme or not. The process consists in sending back to applicants the comments from individual evaluators before they go to the consensus

phase. Participants can react to these comments and reaction from participants is taken into account by evaluators during consensus phase.

Will the blind evaluation apply to all Cluster 1 topics?

No, the pilot on blind evaluation only concerns all first stage proposals of the Horizon Europe 2023-2024 two-stage topics. As there are no CL1 two-stage topics in 2023, the pilot only concerns the first stage proposals of the CL1 2024 two-stage topics. The relevant conditions appear under the topics and are as follows:

Applicants submitting a proposal under the blind evaluation pilot (see General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in Part B of their first stage application (see General Annex E).

This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.

Will the Commission provide guidance on how to write "blind proposals"?

The Commission will include instructions in the proposal template.

Are references allowed in blind proposals under the blind evaluation pilot?

References are allowed as part of the description of "state of the art" as long as participants do not claim them as theirs, even if this is the case. Applicants should describe the state of the art from a neutral point of view.

In the 'excellence part' of the proposal, applicants will usually refer to their previous work (models etc) and/or national and international projects when they e.g. want to convince evaluators of the credibility of their approach. How can they make those references without disclosing who they are?

Such references or references to national or international research and innovation activities that feed into the project should be provided in general terms (from a neutral point of view) to preserve the anonymity of the proposal.

Will a proposal be rejected if it e.g. describes a unique infrastructure without revealing the identity of the applicants?

In such case, it would be impossible to anonymise the proposal and the information in question will not lead to the rejection / inadmissibility of the project. The pilot will help identify cases such as this one (or e.g. the case of research fields in which very few researchers are active) where it would be straightforward for evaluators to identify the applicants and where organising blind evaluations would not be effective.

What happens if the evaluators can guess the identity of the applicants although no mention of organisation names, acronyms, logos or names of personnel is made in the proposal?

In cases where evaluators can guess who is behind the proposal although there is no mention of names and no intention on the part of applicants to reveal their identity

indirectly, we will most likely not reject the proposal. The indirect disclosure of the identity will be assessed on a case-by-case basis by the Commission central legal services

How can the Commission defend that some excellent proposals may be declared ineligible because of some minor sentences that would indirectly expose the participants?

It is a clear admissibility criteria for topics under the blind evaluation pilot that applicants do not disclose their identity. Applicants should be aware of this. If applicants intentionally or unintentionally e.g. name their organisation in their application, their proposal will unfortunately be declared inadmissible (just as it would if any other Horizon Europe admissibility criteria was not respected). The indirect disclosure of the identity, (i.e. information other than organisation names, acronyms, logos or names of personnel that can lead to the identification of applicants) will be assessed on a case-by-case basis by the Commission central legal services

INTERNATIONAL COOPERATION

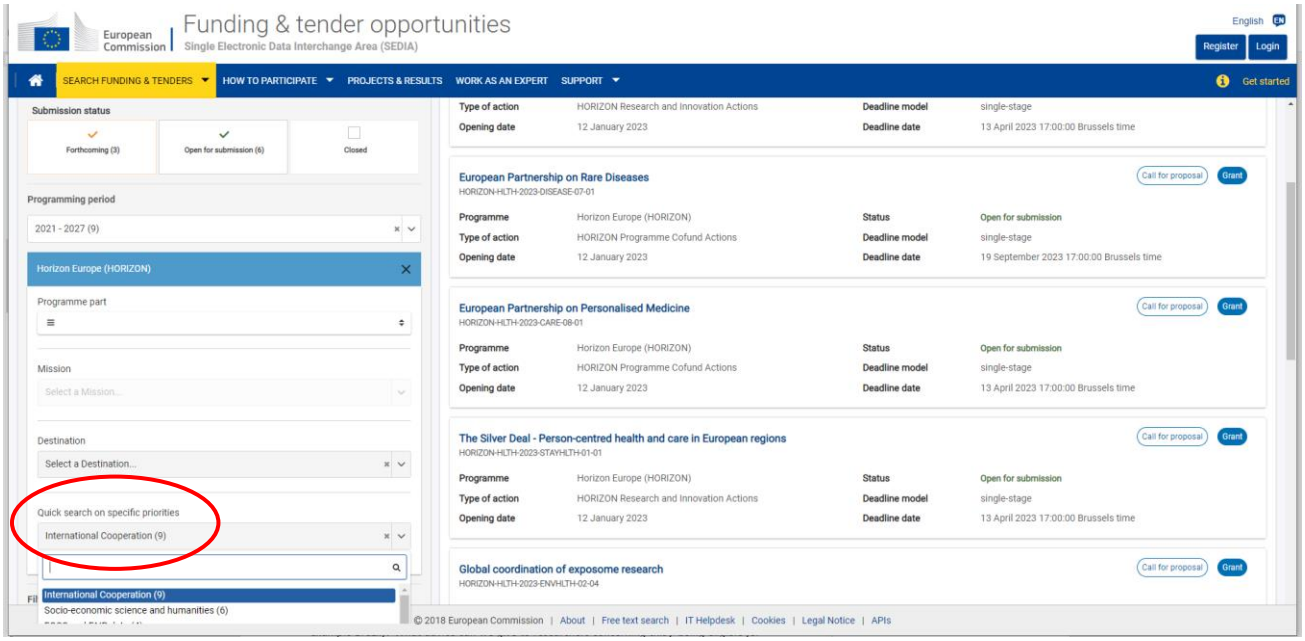
As New Zealand and Canada are negotiating association – can you advise how we should advise in connection to their status for the next calls?

Official communication on the association of NZ will be published mid February. NZ is already indicated on the HE Programme Guide.

Canada has still the status of Third Country.

Can you specify which are the INCO flagged topics (16% - 7 topics)? There are supposedly filters on the F&T portal, but we were not able to find these?

The filter for international cooperation can be found under "Quick search on specific priorities", see link here.



The 8 call topics in Cluster 1 explicitly flagged as relevant for international cooperation are:

- HORIZON-HLTH-2023-STAYHLTH-01-01 - The Silver Deal - Person-centre [...]
- HORIZON-HLTH-2023-ENVHLTH-02-04 - Global coordination of exposome [...]
- HORIZON-HLTH-2023-DISEASE-03-01 - Novel approaches for palliative [...]
- HORIZON-HLTH-2023-DISEASE-03-03 - Interventions in city environmen [...]
- HORIZON-HLTH-2023-DISEASE-07-01 - European Partnership on Rare Dis [...]
- HORIZON-HLTH-2024-DISEASE-03-11-two-stage - Pandemic preparedness [...]
- HORIZON-HLTH-2024-DISEASE-09-01 - European Partnership: One Health [...]
- HORIZON-HLTH-2023-CARE-08-01 - European Partnership on Personalise [...]

Please remind that a topic does not need to be flagged in order to be open for third country participation. Also the other calls are open for third country participation (unless otherwise described in the work programme) as Horizon Europe by default is open to almost all countries. By flagging a certain call topic, we wish to emphasize the relevance of and to encourage more explicitly international cooperation in general or with specific countries or regions.

Among the topics entitled 'pandemic preparedness' is there any particular intention of opening towards or funding of specific countries, as these topics are tackling infectious diseases that could for example be endemic in some countries of Africa or South America (for example Brazil)? What advice can we give to researchers concerning this / being eligible for funding in these topics?

Please remind that a topic does not need to be flagged for international cooperation in order to be open for third country participation. Horizon Europe is by default open to almost all countries to participate.

Hence, the topics referring to pandemic preparedness, are as well open to participation of third countries even if these call topics are not specifically flagged for international cooperation. The consortium is free to decide if and which third country partners they wish to include when deemed relevant, depending on the scope and the objective of the project proposal.

Concerning funding of third countries, we remind that legal entities established in most low- and middle income countries or in associated third countries, are eligible for Horizon Europe funding (see list of countries eligible for HE funding here). In addition, as can be seen in the additional eligibility conditions of these calls, any legal entity established in the United States of America is as well eligible to receive Union funding in recognition of the opening of the US National Institutes of Health's programmes to European researchers,.

Could the EC explain which calls the EC will and won't fund US organisations for? And explain any changes on this since last WP?

All CL1 topics foresee funding for US organisations. In WP21-22, the relevant condition appeared in the introduction, while in WP23-24 it appears under each topic, so that it is more visible to the applicants.

For RIA/IA topics the condition is: *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.*

For CSA topics the condition is: *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.*

For COFUND topics the condition is: *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.*

Please note that:

For CSA topics there is an additional condition that: *Coordinators of projects must be legal entities established in an EU Member State or Associated Country.* (In other words, in CSAs, there can be no coordinator from US).

For COFUND topics, "*the US contribution will be considered for the calculation of the EU contribution to the partnership*" and also "*the concerned consortium of research funders from eligible EU Members States and Associated Countries must expressly agree to this participation*".

*How can the **JRC participate** in the proposals?*

According to the WP General annexes JRC may participate provided it is foreseen under call conditions:

Joint Research Centre ('JRC')— Where provided for in the specific call conditions, applicants may include in their proposals the possible contribution of the JRC but the JRC will not participate in the preparation and submission of the proposal. Applicants will indicate the contribution that the JRC could bring to the project based on the scope of the topic text. After the evaluation process, the JRC and the consortium selected for funding may come to an agreement on the specific terms of the participation of the JRC. If an agreement is found, the JRC may accede to the grant agreement as beneficiary requesting zero funding or participate as an associated partner, and would accede to the consortium as a member

Swiss participation

The Swiss Federal government has a dedicated website with regular updates on the status of Switzerland in HE: www.horizon-europe.ch

UK participation

Q&A on the UK's participation in Horizon Europe | Research and innovation (europa.eu)

Other cross cutting issues

Clinical studies / trials

*How about the **clinical trial annex**? Has there been a change in procedure, will an absence of the annex lead to an ineligibility of the proposal?*

The procedure has not changed. As defined in the WP, the upload of the annex is not legally binding. However, it is strongly recommended if the proposal includes clinical trials. The absence of the annex **will not** lead to ineligibility of the proposal, but if clinical trials are not sufficiently described in the proposal, it will be reflected in the excellence score. Also, to use the annex allows for a more elaborated and better structured description of the clinical studies.

The WP says: Applicants envisaging to include clinical studies should provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

This is not an obligation.

The absence of the annex will not lead to an ineligibility of the proposal. However, applicants envisaging to include clinical studies in their proposal are advised to use the annex, as it allows for a more elaborated and better structured description of their clinical studies.

Artificial intelligence

Can you give examples on how to advise clients on Artificial intelligence in proposals? What to pay attention to? Examples?

Applicants need to address, whether they included AI technologies in their proposal, and address certain points in this regard. The RIA/IA template has been adapted recently to guide applicants in their submission, with a view to give structured information to evaluators to assess the robustness if the AI aspects of the proposals. AI is a horizontal issue and also depends on the focus of the topic, how important the AI element is.

If you plan to use, develop and/or deploy artificial intelligence (AI) based systems and/or techniques you must demonstrate their technical robustness. AI-based systems or techniques should be, or be developed to become:

- technically robust, accurate and reproducible, and able to deal with and inform about possible failures, inaccuracies and errors, proportionate to the assessed risk they pose
- socially robust, in that they duly consider the context and environment in which they operate
- reliable and function as intended, minimizing unintentional and unexpected harm, preventing unacceptable harm and safeguarding the physical and mental integrity of humans
- able to provide a suitable explanation of their decision-making processes, whenever they can have a significant impact on people's lives

We do not provide examples, but applicants should address the points raised in the template.

SSH integration

*Topics flagged for **SSH integration:** have the evaluators followed up on this in previous calls? How it should be achieved is not always evident - any good tips?*

When the integration of SSH is required, applicants have to show the roles of these disciplines or provide a justification if they consider that it is not relevant for their project. A proposal without a sufficient contribution/integration of SSH research and competences will receive a lower evaluation score in the excellence criterion.

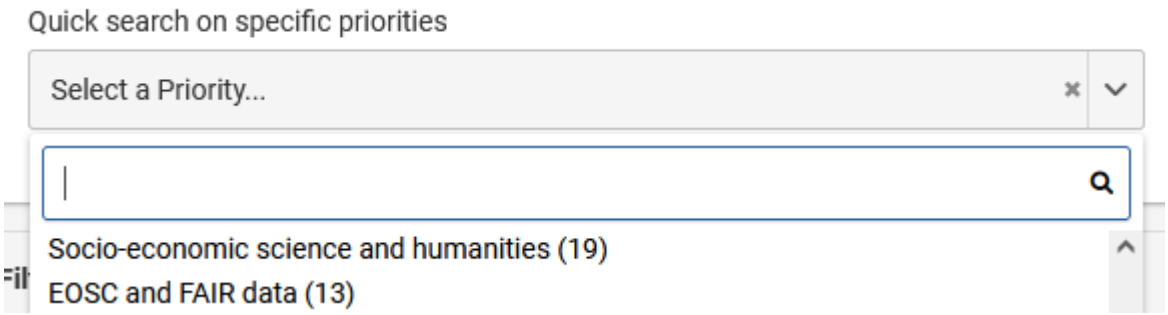
For the evaluation of interdisciplinary topics/proposals, e.g. flagged for SSH

- experts are briefed about the evaluation of horizontal issues like SSH

- experts have also access to some support material and a video on how to assess SSH dimension, see e.g. How to evaluate Social Sciences and Humanities in Horizon Europe proposals - YouTube

- Generally, the objective is to always assign the experts with the necessary expertise, including horizontal issues.

Also: Please note that the policy flags will no longer appear on the F&T portal under each topic's description. However, the relevant search functionality remains in place (see image).



Changes in the template

*Can you please highlight the **last changes** made on the **RIA/IA template**? Last update was 8th of September and now any new updates?*

Latest version of the proposal template part B for RIAs and IAs was published on 15 November 2022. The only change included was to instructions on the page limit for Lump sum topics.

The following updates were made in the RIA/IA proposal template:

2.0	21.01.2022	▪ Changes in tables on section 3 avoiding duplication of information

		▪ Reorder of points in 'Impact' section
3.0	11.07.2022	▪ Consolidation, formatting and layout changes. Tags added
3.1	08.09.2022	▪ Added instructions on Artificial intelligence
3.2	15.11.2022	▪ Added page limit for topics using lump sum funding

Statistics

***TRLs**: mostly not relevant for Cluster Health. Nevertheless some ESRs criticized when little reference to TRLs was given in a proposal - how to advise clients?*

It depends on the topic if TRLs are relevant or not. Generally, TRLs are an appropriate way to describe the level of maturity or planned progress in the development of technologies.

Do you have information available for the participation of start-ups and SMEs?

This information is not available.

When results are received, what kind of information are NCPs allowed to disclose before the Grant Agreements are signed (e.g. aggregated statistics/successful organisations)? What can the retained projects disclose themselves before the GA is signed?

The projects can say that they were selected for funding, but they cannot say that the GA was signed or the project funded. In all cases it is safer to wait until the signature.

*Can you explain more the role of **Copernicus and/or Galileo/EGNOS data**, why has this been included as eligibility in some topics?*

We understand that in some proposals the applicants may foresee to use satellite-based earth observation, positioning, navigation and/or related timing data and services. In CL1 we have identified the topics where **the use of such data and services may be relevant** and because of this the corresponding condition has been included under the topic conditions section. This condition by no means dictates that the applicants are required to use such data and services; it only specifies that **when** such data and services are used, beneficiaries must make use of Copernicus and/or Galileo/EGNOS.

The condition states: *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).*

*Can you help clarify which **separate study** is referred to in **note 177**?*

In a footnote is says: "*The European Commission is commissioning an independent scoping study to help identify under-researched high-burden medical conditions and define the type of research and/or research priorities to better address the different needs of patients with these conditions.*"

Can you elaborate on the political background of the Work Programme?

This WP is part of 4-year cycle – 2021-2022 together with 2023-2024, seen as a package for the strategic Plan for 2021-2024. Back in 2019 (and 2020) together with the Programme Committee we elaborated on political priorities and what would be a good package of 4-years of work programmes, where not every year we can do everything the same way, but looked at from a 4-years perspective. The political background you can read about in particular at the very beginning / in the introduction of the WP text and the Strategic plan – including areas like resilience of our health care systems, public health, pandemic preparedness, and new discoveries and more effective ways of preventing and curing communicable and Non Communicable Diseases. In coming years we will be looking more into the climate-health side and conversion of digital, green and resilience.

Why is the budget distributed so unevenly between the six destinations? Is this due to political priorities? Could we get more background info on this?

In every programme you try to group some questions, some research challenges together and there has never been a situation when it was all set up right – to make 4-5 destinations or intervention areas, key technologies with the same budget – the research questions are so different, together with the types of work that needs to be done. For 2023 we had a push to fund more infectious diseases type topics – in the post COVID-19 period.

The importance of synergies is transversal to EU programmes, could the Commission provide a matrix with expected synergies between the Clusters and EU initiatives?

Concerning this, we have given a short overview of how this would work together in the first 2 pages of the Strategic Plan and also in the first paragraphs of this Work Programme, where it is highlighted how this programme links with other programmes. Important question is how would one define synergies? Is that between programmes (e.g. Horizon Europe and EU4Health and Digital Europe Programme); or in terms between these topics and others in the partnerships; or between this Cluster and other Clusters (Cluster 1 is especially linked to what is happening in Cluster 6 for example); while another dimension connects to working with the Member states' own national programmes, etc. There is no complete overview for health research and innovation across all the EU programs.

Two clarifications

1) **The general threshold** of 12 and excellence 4, impact 4 and implementation 3 is applied in WP23/24 in all topics, including CSA and co-fund. (While I said that it applies only to RIA, not to CSA).

2) The **proposals selected for funding from reserve list of the two-stage call** will be known normally when we have the overview how much budget will be left. This will be after the end of the GAP of the two-stage call. The reserve list proposals from the 2022-single-stage will normally invited to the GAPs in January? (While I had confused single-stage and two-stage and said the two-stage reserve list will be known early next year).