FAQ Cluster Santé
Programme de travail 2021 - 2022
Topic 2022
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- **Questions from EC Infoday on Destination 1**

HORIZON-HLTH-2022-STAYHLTH-01-01: Boosting mental health in Europe in times of change

Comments by Sara Brazys

Is it necessary to cover climate change, digitalisation, and covid? Or is it better to focus on one of these challenges for mental health?

➔ It can be one or several of these matters then the experts will make the judgement.

Does the call encourage/expect to use digital technologies (machine learning, AI, etc) ? Are clinical partners expected?

➔ The call does not specify the use of digital technologies, but it certainly is opened for it.
➔ Clinical partners should also be included.

How broad should the target groups be? For example the elderly, would that be too narrow?

➔ The topic call only specifies vulnerable populations, and as long as the proposals contribute to all the expected outcomes and address all the requirements of the scope, there is no indication that focussing on a particular vulnerable population would be better or worse.

Are evidence synthesis (e.g., on interventions) also desired?

➔ First point is « providing a comprehensive knowledge base of how tranforming Europe influence mental health of society ». So, in a sense you could include evidence on synthesis yes.

How should policy makers be informed about the prevalence and burden of illnesses?

➔ You can have them onboard. There is ways to involve non-scientific players in a project, for example patient associations, representative of policy makers, or any other relevant players.
➔ The EC does not indicate how to reach out to policy makers, you should come up with ideas on how to better include them in your research and how to better disseminate your research results – it is up to the applicants to describe how they will do this.

Would a submission that includes continuing an ongoing cohorts study (in another EU/Horizon project) be eligible?

➔ All cohorts can be used for more than one purpose obviously – that is very clear.
➔ The legal side to consider is that EC cannot double fund for the same thing, but to make use of already existing resources, whatever they are, if that can be done, then why not ? As long as you fulfil all the expectations from the call.

HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage: Trustworthy AI tools to predict the risk of chronic non-communicable diseases and/or their progression

- **Questions from EC Infoday on Destination 1**

Presentation: Christina Kyriakopoulou

It is widely recognised that health system must put more emphasis on prevention and adopt a person-centred approach. Using this AI tools, with the increase availability of health data, really has the potential to pave the way for personalised prevention and enable progress toward risk prediction and early detection of chronic non-communicable diseases

Can we use laboratory tests to develop the AI tools even if they are not listed in the call characteristics?

- ➔ When we read the call text, there are some requirements : " in order to be able to develop robust and accurate AI tools for disease risk prediction or progression, the applicant are asked to take stock of existing knowledge, integrate the relevant available data or newly developed data". So the applicants could include all the necessary to address at the highest possible level the requirement of the topic.
- ➔ The answer is yes because it depends very much on the developmental level and the maturity of the algorithm.

Can you give recommendations on how to involve end-users in the AI development process?

- ➔ Specific requirement in the topic is that the developers should involve the end-users and for that they have to involve them from the beginning of the project. But since there is a huge diversity of needs depending on the subject of the project, it is left to the applicants to decide what is the best strategic methodology to have a fruitful inclusion of end-user.

Is cancer included?

- ➔ Open to all relevant diseases yes, no specific exclusion. Leave it to the applicants to assess if their project can achieve the scope and expected outcomes.

Can we develop AI tools as diagnosis tools (like imaging) supporting risk prediction by clinicians?

- ➔ It would fit within the scope of the topic as long as its main goal would be to develop risk prediction tools for a disease or disease progression tool. It is left to the applicant to decide what is best.

Is pneumonia considered a non-communicable disease in this call?

- ➔ The topic is about chronic non-communicable disease. Is pneumonia chronic?

All chronic non-communicable diseases have the same relevance for the topic or not?

- ➔ Yes, it is quite open to allow the applicants to come with very innovative ideas, and credible methodological plan.

HORIZON-HLTH-2022-STAYHLTH-01-05-two-stage: Prevention of obesity throughout the life course

- **Questions from EC Infoday on Destination 1**

Comments by Anna Lonnroth

Can the target population involve overweight persons, that is to say to prevent development of obesity in those with overweight (BMI 25-30)?

➔ Yes, your target population can either be people who are not at all overweight, or those with overweight already, since the objective is to prevent obesity.

The expected outcomes and scope of the call are very broad. Does the EC have any expectations to the number of facets covered by a single project?

➔ In term of the expected outcomes, the proposers need to address « some of » them. When it comes to the scope, there are actually 12 points but you need to address « several » of them.

Can AI tools be used in the project?

➔ We never tell what tools you need to mobilise in order to achieve the outcomes. It is up to you depending on your project – be convincing for the expert evaluators.
➔ Some topics specify the use of AI tools, but if not, it is not excluded.

HORIZON-HLTH-2022-STAYHLTH-02-01: Personalised blueprint of chronic inflammation in health-to-disease transition

- **Questions from EC Infoday on Destination 1**

Comments by Christina Kyriakopoulou

Are there criteria on which/how many inflammatory diseases to address?

➔ Open for all relevant diseases and disorders. It is left to the applicants to decide what is the best methodological approach and best objectives to address the relevant requirements of the topic.

Can a proposal look at patients in remission from a chronic inflammatory disease, preventing transition to disease?

➔ The topic is about to identify the factors and use them for optimising benefit for the patients, for the transition of the inflammatory pre-disease stage to the disease stage. Now, I think this is a possibility and the topic is flexible for this kind of proposal.

« The topic does not exclude any diseases/disorders », what does it mean ? Isn't about systemic inflammation and prevention of diseases ?

➔ There is no particular categories of diseases that is targeted here.
➔ Yes, it is about systemic inflammation, but it is about to understand the trigger point in a transition from a healthy state to a disease.

Is the immune system to be covered in addition to inflammation?

➔ These chronic inflammatory processes, chronic or local, at the point where this inflammation become dysregulated and create a potential basis for pathologies development, it involves also the immune system. So, it is very much linked to inflammation so it is not excluded if relevant to the objective of the proposal as long as the requirement of the call and the expected outcomes are met.

Are start-up allowed to participate?

➔ Yes, they are welcomed in all topics.

Will the chronic inflammation state be understood as the disease state?

➔ The chronic inflammation may lead to potential pathologies and this is exactly what we would like to study, this transition from the pre-disease state to the potential early stage of the disease. Depend again on the relevant diseases or disorders. As such, I would not say chronic inflammation is considered as a disease stage.

Is Cancer considered a chronic non-communicable disease in the Horizon EU programme ?

➔ Yes, it is. You have to look each topic if there is any specific exclusion

HORIZON-HLTH-2022-ENVHLTH-04-01: Methods for assessing health-related costs of environmental stressors

- **Questions from EC Infoday on Destination 2**

Should the proposals address all the metrics referred in the call (e.g. DALYs, QALYs)?

➔ We can look at all the metrics, you can look at DALY and QALY for example yes. Interestingly, in the environmental area, quite often we look at health endpoints themselves so we might talk about a case asthma or a case of cancer and it's making the link as well between those individual health points and these metrics which are used more on the medical side as well. Both are relevant.

The text refers to Impact Pathways Analysis and Health Impact Assessment methodologies. Can alternative methodologies for impact evaluation be used?

➔ We are interested in alternatives methodologies as well. We are seeing this Health Impact Assessment in general being applied in different contexts so chemicals, air quality, transport, at the EU level, at the national level so being able to look a these different methodologies and making sure they fit to the separate context whether that be national or EU or different health points all are relevant. We are interested in all of them and I think they have a lot of commonality in any case.

How can international institution participate? Should a dedicated budget for international cooperation, be considered in the proposal?

➔ If a dedicated budget for international cooperation should be considered, we have to think about that participants in consortia can be either eligible for EU contribution or not eligible. This is the main question.

➔ With the term "international institution", I assume the person wants to know if we refer to organisation that are based in different countries which correspond to the terms of what we call international organizations. In this case, the answer is the following :
They can be either made of many members based in Member States in this case they are considered European international organisation. As such, they are eligible for contribution from EU.
International organisation that are made of many members outside the European Union are not automatically eligible for funding, therefore they should not ask for EU contribution. If their contribution is deemed essential to carry out the project then they could ask for an EU contribution and they should justify in the proposal.

The national context is referred in different parts of the call. Should the developed methodologies be applicable to the national setting?

➔ Yes, they should be applicable to the national context. I think it's quite important if they are going to be applied that they are of use in a widespread number of situations. Whether that's local, regional or national, I think all of those should be of interest and should be a starting point for any work.

The topic invites for literature studies. Are experimental activities considered at all ? If yes, which kind of experiments?

- ➔ We would be interest in experimental activities. It is hard to specify which type but for example if one is looking to put a monetary value on a health endpoint then choice experiment could be a technique to explore. Its already being used but refinement of that methodology would be welcome. Also identifying ways for it to be more widespread.

Should all the points listed in the scope be addressed in the proposal?

- ➔ All the points that are listed under the expected outcomes and also under the scope are to be considered in the proposal
- ➔ The 9 topics written in the scope need to be addressed in the proposal.

How should networking activities between projects be promoted at the proposal stage?

- ➔ We think that is very important to promote the networking activities between the projects because this will increase the impact of the projects, will allow for harmonization of methodologies, increase of synergies between the projects in environmental health
- ➔ We have several ongoing clusters of projects, we have one cluster addressing the methods for assessing endocrine disruptors, the European network on exposome, and two recent clusters: the European urban cluster and the cluster dedicated to the health impact of micro and nano-plastics.
- ➔ The networking activities are not to be established at the proposals stage; they are going to be done and agreed during the grand agreement preparation stage. It is very important that proposals consider already a budget dedicated to support these networking activities that can include joint workshops, dissemination activities or the organisation of working groups on topics of common interest.

Can the US participate as a granted partner? i.e. does the EU/NIH reciprocal funding agreement apply ?

- ➔ Yes

This topic is not listed within the topics where the clinical studies templates is essential. Is access to cohorts and the (re)use of cohort data an asset?

- ➔ Use of cohort is not mandatory but it should be considered if relevant under the scope of the project.

HORIZON-HLTH-2022-DISEASE-06-02-two-stage: Pre-clinical development of the next generation of immunotherapies for diseases or disorders with unmet medical needs

- **Questions from NCP-EC meeting**

The topic states that Off-the-shelf therapies, including the cell-based therapies, will be considered as assets during the evaluation. To my knowledge, off-the-shelf therapies are used in the context of cancer immunotherapies – but cancer is excluded from this topic. Where/how are they used for other diseases?

- ➔ The EC will prepare an answer to be publish on the FAQ
- ➔ This is the innovation potential of this topic, we want to allow space for innovative idea in other areas than cancer.

If we need to use data that already existing for the cancer or just for the new disease, is it possible?

- ➔ We leave it to the applicants if they want to use cancer data to apply to another diseases.

Is it possible to develop immunotherapies which stop the immune system instead of stimulate it (e.g like what happens in Covid for example but it is not the only disease where it happens)?

- ➔ Yes, it is possible as long as the final objective is to restore the immune system in a normal way

« Passive and active immunotherapies (such as antibody-based, RNA-based and cell-based therapies, respectively) are covered by this topic": Is the topic restricted to these 3 types of therapies or is it possible to develop other methods ? (like the use of microbiota as immunomodulator for example) ?

- ➔ Gives some examples, ideas, but the applicants have the liberty to propose any innovative other solutions, as long as the focus is the development of innovative immunotherapies to restore the immune system

Related to the above question, could the use of molecules (small molecules that modulate immunity) may be eligible?

- ➔ Yes, any innovative solutions

It is mentioned in the second expected outcome "The scientific and cliinical communities have access to [...] of the next generation immunotherapies and/or combinatorial treatments" : there is no further mention of the possibility to develop and test new immunotherapeutic agent in combination with an approuved drug in the scope of the topic : would it be in the scope of the topic ?

- ➔ Combinatorial innovative approaches are allowed

- **Questions from EC Infoday on Destination 3**

Barbara Kerstiens : moderator

Comment by Grzegorz Owsianik

Is this limited to antibodies/RNA/cell-based therapies, or would non-traditional immunotherapies (e.g. small molecules) also be in scope?

➔ The topic is open to all immunotherapies, so we don't restrict the scope on any type.

What is expected in terms of Health Technology Assessment strategy?

➔ There is a requirement that there has to be a certain advice of the regulatory health technology assessment authorities before submitting the project. Somehow shows that the consortium is on the good track and can lead to final approval of the research, that there is a certain assurance of acceptability of the proposed research.

Is it out of scope of this topic all kind of cancers or only rare cancer?

➔ Cancer research is excluded, so any cancer including rare cancer is excluded

What is the expected TRL at the start and the end of the project?

➔ We do not specify TRL on this topic, but what we focus on is the early development of immunotherapy, so we don't expect very high TRL at the end of the project. It is up to the applicant to choose.

Can you define « off-the-shelf therapies »? Therapies with a marketing authorisation? Can therapies not approved yet be considered?

➔ Will be provided in the FAQ on the portal later

Are projects addressing therapies based on the interaction between immune system and the microbiota favored to those of key technologies?

➔ Nothing is favored, but any technologies can be addressed.

In the evaluation, will you adopt a portfolio approach, to ensure that different types of immunotherapies are funded?

➔ If the portfolio approached is used, it should be made explicit in the call topic text which is not the case here. The expert will carry out the external evaluation and will rank the proposals according to excellence and other criteria. There is not an up-front explicit portfolio approach.

HORIZON-HLTH-2022-DISEASE-06-03-two-stage: Vaccines 2.0 – developing the next generation of vaccines

- **Questions from EC Infoday on Destination 3**

Should/can a clinical phase I trial be included? Nice to have or need to have? Or is focus on research and GMP prod./Toxicology for lead candidate?

➔ Yes, the phase one clinical trial can also be included, but of course, the main scope is to develop the next generation vaccines, so is to make the link between the different stages of the development of these vaccines. So it cannot be only focused on the implementation of the trial.

For one pathogen, is one or two different vaccine technologies sufficient? Or do you envision different technologies pursued by different partners?

➔ We leave it to the applicants the choice of the pathogens, whether they answer one or several or which technologies they will use, the EC is not prescriptive. The focus is to provide the new generation vaccines, to envision the use of new technologies.

Are only novel technological approaches of interest? What about classical ones, like whole viruses or bacterial proteins?

➔ The topic is about to look at the development of new generation vaccines. Of course it will be in hands of the evaluators to judge whether it is innovative and makes a breakthrough comparing to the current state-of-the art.

What is the percentage distribution in the project between: understanding protective immunity versus lab-based engineering of vaccine versus GMP production / toxicology?

➔ It depends on the context of the research. There is no golden rules or standards. It has to be feasible and convincing.

For hepatitis C, there is no licensed vaccine. Thus, there is no « next generation » - only if you compare to vaccines from clinical phase I/II. OK?

➔ Come back in the FAQ on this specific question

HORIZON-HLTH-2022-DISEASE-06-04-two-stage: Development of new effective therapies for rare diseases

- **Questions from NCP-EC meeting**

Could you define what is a "group of rare diseases"

➔ The applicants should develop their context and their justification, scientific evidence of why they choose to select this group (concise scientific evidence based to persuade the evaluator that they address the requirement of the topic)
➔ This will depend on the area they choose to work on or to propose.

"in particular, proposals planning the clinical development of orphan medicinal products should demonstrate that they have been granted approval for an orphan designation at the latest on the date of the call deadline." => which call deadline, 1st or 2nd stage?

➔ The second stage

- **Questions from EC Infoday on Destination 3**

Can you define more precisely what is meant by « group of rare disease »? Is a certain level of incidence required?

➔ The innovative idea of this topic is that the project should focus on a group of rare diseases. We leave it open to the applicants the group they choose, as long as they choose groups where there are some commonalities, not necessary biological references in pathologies but other commonalities across different medical areas. It allows flexibility to define the group of rare diseases.

Projects will contribute towards the goals of IRDIRC / 1000 new therapies for RD by 2027. Projects closer to the clinics are favoured?

➔ The evaluator will assess the quality of the proposal and there is no pre-defined conditions that will lead to success.

HORIZON-HLTH-2022-DISEASE-07-03: Non-communicable diseases risk reduction in adolescence and youth (GACD)

- **Questions from EC Infoday on Destination 3**

Should each project cover both LMIC and vulnerable groups in HIC? Or could a project also focus eg on LMIC only?

➔ It is left to the applicants whether to focus on one or the other.

Does the EC have a precise definition or a complete list of LMIC ?

➔ The definition is based on the World Bank Country Classification and it is related to the Gross Domestic Income per capita. This information is on the world bank website.

What risk behaviour comports? Is it a close-ended construct? What if research ends up showing that so far « normal » behaviour turns out to be a risk factor?

- ➔ We specify certain behaviour in the topic, so we leave it to the applicant to specify and look into detail for this aspect.

Can we implement in LMICs an intervention that has already proven to be effective in HICs?

- ➔ Yes, one of the purpose is that is has to be evidence-based implementation research. So if there is an evidence that it works in HIC, it can be also tested in LMICs.

Shall I understand that any behaviour may be factored in? Is there any close list of « relevant » behaviours and chronic disease causation?

- ➔ There is no close list. We leave it to the applicants, we only mention some which are of high relevance but you can add others that are relevant to your projects.
- ➔ The topic is about implementation research, so you need to have the evidence based that would allow you to see how this evidence is translated into practice.

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

HORIZON-HLTH-2022-CARE-08-02: Pre-commercial research and innovation procurement (PCP) for building the resilience of health care systems in the context of recovery

Could you please explain the difference between the two procurement topics?

- ➔ PCP still need somehow research activities to be performed, in order to see what is the best solutions the potential needs whereas in the PPI we are much more closer to the market and the product is almost there and just the final phases are still necessary.
- ➔ Otherwise the two topics are indeed very similar in the objectives but they will support solutions at different stages of development.

Are the procurement topics expected to have link with the CSA on innovation procurement from the 2021 work programme?

- ➔ It would be difficult at the proposal stage to have a link between both because of the timing (the 2021 proposals are currently under evaluation)
- ➔ We certainly encourage the applicants to start considering this network in a structured way so that they could try to see how they could be able to leverage this network to promote some of their activities.

Are private procurers eligible to be part of the buyers group which is normally exclusively reserved to public procurers?

- ➔ Yes they are eligible as well, but you need to have at least one public procurer in the consortium.
- ➔ Refers to the Annexes H of the work programme.

HORIZON-HLTH-2022-CARE-08-03: Public procurement of innovative solutions (PPI) for building the resilience of health care systems in the context of recovery

Do the PPI will be launch after PCP is closed?

- ➔ No, both topics are open at the same time.

HORIZON-HLTH-2022-CARE-08-04: Better financing models for health systems

Technologies are not part of this topic?

- ➔ Technologies is highly relevant for destination 4 and it is also relevant for destination 6
- ➔ Projects funded under destination 6 focus on innovation and projects funded under destination 4 will be asked to work in joint activities.

Should all the points listed in the scope be addressed in the proposals?

- ➔ That is not necessary but it is of course possible if it is of relevance for your objective.

Are purely economic project eligible? Like health economic evaluation?

- ➔ What is important is to look at the scope and make sure that your research project matches what"' in there and also to look at the expected outcomes so your proposals contribute to that.
- ➔ Purely economic projects can be completely adequate if they meet the term in the advert. Basically, when you look at issues of incentives of financing, health economics can be a very useful tool for actually researching these issues and finding out what are the best financing systems. So indeed a health economic evaluation would be very appropriate.

Which kind of participant do you expect to answer?

- ➔ We don't have a particular type of actor in mind

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

HORIZON-HLTH-2022-TOOL-11-01: Optimising effectiveness in patients of existing prescription drugs for major diseases (except cancer) with the use of biomarkers

- **Questions from NCP-EC meeting**

What is the definition of qualified biomarkers?

- ➔ Concept from the EMA. We don't say that people need to have an agreement of the agency on the qualification. We would like to have project addressing the validation of biomarkers already identified for which they have substantial data on their potential
- ➔ Not early discovery of biomarkers.

A condition is that preliminary studies or publications have demonstrated that the pharmaceuticals considered are efficient in less than 50% of the population treated. " => Apparently this is not as easy as it sounds, clinicians have told me that this is very difficult => how strictly will this be followed?

- ➔ For less than 50% they should have some data, at least they should have some elements to explain in the proposals. The applicant have to make their case, come with all information and convince the evaluator they are addressing the right think. In the end, the evaluator may favoured the proposal which have demonstrate that the drugs are efficient in a very low part of population.

Would mental health be considered a high burden disease in the context of this call?

- ➔ Did not make specific reference in the topic so opportunity to the applicants to make their case.
- ➔ Anxiety or depression would be considered major and efficiency of drug is questioned.

- **Questions from EC Infoday on Destination 5**

Moderator: Bernd Rainer

The term « major disease » refers to the top10 WHO list? Or other conditions that carry a high burden of disease since childhood are considered?

- ➔ The topic does not prescribed what should be considered as a major disease, or does not point to a particular definition or reference.
- ➔ The idea being the topic is to really look at those drugs that are really choose significantly because they are targeting diseases that affect a significant amount of population. Even thoug it is not prescribed in the topic the idea behind is that a lot of people will be consuming those drugs.
- ➔ It is up to proposers to convince the evaluators that the conditions they are targeting would be major.

Is the identification of new biomarkers in the scope of the topic ?

- ➔ The focus of the topic is to validate the biomarkers to be able to come with a sort of companion diagnostic that would allow to better identify who will be the responder to those drugs.
- ➔ Although it is not prescribed from the topic, the identification, we believe it might be difficult to aim for going both for identification and validation in the same project.
- ➔ The critical part is to ensure the validation. So, if the consortium is convinced that during the life of the project it can credibly do both (identification and validation then it could be ok but it should provide strong argument to be convincing and in any case the validation should be achieve within the duration of the project which is the main focus.

Could a proposal to this call carry out an observational study, followd by a RCT?

- ➔ Yes as long as it would be followed by a randomised clinical trial that would allow to validate the identified biomarkers. But an observational study alone per see could not be sufficient, it would not allow validation.

HORIZON-HLTH-2022-TOOL-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment

- **Questions from EC Infoday on Destination 5**

Comments by Jana Makedon

National competent authorities should be involved. Can they be beneficiary? How large should be their role?

- ➔ Yes, they are invited and should be involved in the proposals. Yes, they expect to have them as beneficiary. A FAQ will be published to make it clear which stakeholders might be interested
- ➔ Their role depends on the project set up. It is up to the consortium to organize the role of the partner and see whether they should be involved as consultative bodies or should actually do hands-on works if it makes sense.

Is industry that later needs to follow the regulations an appreciated partner or considered as a risk to influence the rules towards their interest?

- ➔ Industries are not excluded from the topic and they are invited to participate if they have a valid role in the consortium. For example, as machine-learning is mentioned in the scope, perhaps there could be a role for an industry here. There can be other roles as well.

Data privacy is not explicitly mentioned in the call – why?

- ➔ If something is not explicitly mentioned in a call it does not mean it cannot be included
- ➔ When it comes to data privacy-preserving solutions, since here we are dealing with data-driven methodologies, it goes without saying that even it is not mentioned explicitly in the topic text we are implicit that this should be addressed. All of the infrastructures or the analytics developed should be privacy preserving.

What size of project are expected?

- ➔ Average size is in the range of 7M€ per project.
- ➔ In terms of the size of consortium, this is completely open and depends on the set up of the project.

What range of TRL are expected?

- ➔ As you know this topic is about methodology research so I would not be able to specify as TRL.
- ➔ Probably for the last 2 bullet points of the scope where you have machine-learning approaches being developed then we can talk potentially about TRL but otherwise it is mostly methodology work

HORIZON-HLTH-2022-TOOL-12-01-two-stage: Computational models for new patients stratification strategies

- **Questions from EC Infoday on Destination 5**

Comments by Christina Kyriakopoulou

Is it possible to focus on cancer or is it excluded?

- ➔ Yes, this tropic is broad and it does not prescribed any particular diseases or conditions thath should be addressed.
- ➔ It is open to the applicant to select the area where the computational tools development will allow more innovative stratification patient processes in comparison to existing practices, to provide an improvement.

« The topic will support the development of computational models driven by end users' needs ». Are « end users » needs those of health care professionals in this case?

- ➔ Yes the end-users can absolutely be the healthcare professional.
- ➔ In this particular topic, there are 4 outcomes, and they guide you to see the potential end-users of the projects: "clinical researchers, researchers, health care professional, regulatory bodies" depending on the maturity of the model you will build and adapt your proposal to address relevant end users.

Is the participation of SME a plus or is the participation of big enterprise as partners a good solution too?

- ➔ Private/industry partner are invited to be partners in those projects.
- ➔ There is flexibility for any type of entities to participate as long as they will justify their role and necessary to achieve the objective of the proposals.
- ➔ In this particular topic, there is a reference about encouraging the participation of SME but it is open to all kind of partner to contribute.

Destination 6: Maintaining an innovation, sustainable and globally competitive health industry

HORIZON-HLTH-2022-IND-13-02: Scaling up multi-party computation, data anonymization techniques, and synthetic data generation

- **Questions from EC Infoday on Destination 6**

Are the proposals expected to describe the data sets they plan to work on and how to ensure access to data?

➔ Yes, the proposals should include a clear description of the data sets that are available for the project and they should also described how the access to the distributed testing data sources and how the appropriate scale can be reached.

HORIZON-HLTH-2022-IND-13-03: New pricing and payment models for cos-effective and affordable health innovations

- **Questions from EC Infoday on Destination 6**

Can national authorities for pricing and reimbursement decisions be members of applicant consortia?

➔ As indicated in the topic text, applicant consortia should include regulators and public entities that are in charge of attributing value tag to health technologies meaning that applicant consortia not only can but should include entities such as pricing and reimbursement authorities and there input is crucial to tackle the issue described in the topic.

HORIZON-HLTH-2022-IND-13-04: Setting up a European Smart Health Innovation Hub

- **Questions from EC Infoday on Destination 6**

Are there specific criteria to be respected for the creation of the reference EU repository of ready to market solutions?

➔ The intention is to create repository which build upon existing repositories of ready to market solutions. Minimum criteria would be that they are ready for deployment, with a TRL of at least 6 or 7; that they have been successfully deployed in a specific facility, community, region or why not in a Menber State; be interoperable and scalable in other health and care environment; be privacy preserving. If possible, to come from various MS or regions and have as much as good examples coming from different locations.

Which type of consortium is expected for this call? Are only national innovation hubs eligible or are other type and size of actors also eligible?

➔ The aim is to have a consortium which is as comprehensive as possible. It does not aim at national hub only at all. All kind of technology transfer organisation, research transfer organisation, accelerator, knowledge hubs, regional organisation which have

a very wide outreach to various region, authorities, representativeness of all stakeholders when you try to reach scalability.

➔ In the call there is a specific reference to build upon some repositories, already created in the lasted decade through the partnership AAL. Very important to make sure to create a mechanism which include repositories, and the network, exchange of practices that have proven that are working already and to aim to create a sustainable hub, after the duration of the action.

Could for profit company (large or SME) apply?

➔ Yes, SMEs or any other companies can apply as part of a consortium with the purpose of course to promote the achievement of the goals of this topic which is of interest for all EU citizens.

HORIZON-HLTH-2022-IND-13-05: Setting up European Electronic Health Record Exchange Format (EEHRxF) Ecosystem

- **Questions from EC Infoday on Destination 6**

Proposals should aim at a public infrastructure based on the EEHRxF principles. To what these principles refer to, more precisely?

➔ On the 6th of February 2019, the EC published a recommendation on the European electronic health record exchange format. So these principles that are referring to in the text of this topic refer to the 1st pillar of the framework that has been set out in that recommendation (comprehensiveness machine readability, data protection and confidentially for example).