FAQ Cluster Santé
Programme de travail 2021 - 2022
27.07.21

Collaboration Internationale

- **Participation du *Joint Research Centre* (JRC)**

Le JRC a identifié 9 topics (4 en 2021 et 5 en 2022) pour lesquels ils souhaitent participer.
Le JRC ne peut pas être inclus dans le consortium au stade de la proposition. La CE fera le lien entre le JRC et les projets sélectionnés pour financement pour initier les discussions. Le JRC choisira de participer ou non au projet et dans l'affirmative il couvrira ses propres frais (pas de budget à réserver au JRC dans la soumission).
Pour ces 9 topics, le consortium n'est pas obligé d'inclure le JRC dans sa proposition s'il ne le considère pas pertinent
Les participants doivent décrire les potentielles collaborations avec le JRC sans les contacter.
Le projet doit rester faisable et les objectifs atteignables même sans la participation du JRC, leur potentielle participation doit rester une valeur ajoutée et non un élément essentiel du projet.
Le JRC ne compte pas parmi les 3 participants minimum pour satisfaire le critère d'éligibilité vu qu'il ne sera inclus au consortium qu'après l'évaluation et la sélection pour financement.

- **Participation des partenaires USA**

L'accord de réciprocité entre la CE et le NIH signé en 2008 est toujours d'actualité, les participants US sont donc éligibles à recevoir du financement par la CE pour leur participation dans les projets financés dans le Cluster Santé uniquement

➔ « *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 to support its participation in projects funded under the Health cluster* » (page 8 du programme de travail du cluster santé)

Les partenaires USA peuvent participer aux projets de type RIA, IA. La CE revient vers nous pour préciser ce qu'il en est des PCP, PPI, CSA et Partenariat.

Les Missions faisant partie d'un programme de travail séparé, l'accord de réciprocité n'y sera pas valable et donc les partenaires USA ne seront pas automatiquement éligibles au financement par la CE pour ces appels.

Les USA ne sont pas reconnus comme Pays Associé mais comme un Pays-Tiers ; en conséquence ils ne peuvent pas compter parmi les 3 participants minimum pour satisfaire le critère d'éligibilité du consortium.

- **Participation des Pays-Tiers**

Les partenaires Pays-Tiers peuvent coordonner des projets.

Lorsque la participation internationale est encouragée dans la description d'un topic, si le pays-tiers n'est pas un pays éligible au financement par la CE, il peut être associé au projet en apportant son propre financement.

Les pays regroupés sous l'appellation « BRIC+M » (Brésil, Russie, Inde, Chine et Mexico) ne sont pas automatiquement éligibles au financement par la Commission Européenne. L'Afrique du Sud fait partie des pays tiers automatiquement éligibles.

La liste des pays tiers automatiquement éligible au financement est disponible dans le document « Horizon Europe Programme Guide »

Destination 1 : Staying healthy in a rapidly changing society

- **Questions from NCP-EC meeting**

Many topics ask for citizen engagement, civil society...how should this work in practice?

➔ Patient organisation, Civil society, Social innovation: depends on the topic

How should we understand the budget indicated in the topic text?

➔ Budget are only indicative – this is what we have estimated as necessary in order to perform or to address the different scope of the topic but it depends on the concrete scope and range of activities that a specific proposal will do in order to achieve the expected output

HORIZON-HLTH-2021-01-02: Towards a molecular and neurobiological understanding of mental health and mental illness

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

Comments by Dirk Hadrich

Topic very broad – covering quite a lot of different aspects
Five different areas mentioned in the scope: they do not expect a single proposal to cover all five areas – at least deliver on several of the areas
The EC will ask the 6 funded projects to network – They ask the applicants to think about in advance about joint workshops and to have a budget included in the proposals

Is the involvement of patient or citizen groups mandatory?

➔ Yes, it would be good to involve citizens and we need to see citizens' engagement. The topic says that the project should ensure strong involvement of end users including citizens and patients

Is the scope only neurobiological? Could increases in the efficiency of therapeutic practice come under this topic?

➔ The scope is covering 5 different areas, one is about molecular and biological understanding and the others are about cohorts, to develop biomarkers, drug targets, clinical trial to assess the effect. It is important that the proposals cover several of the five areas.

Regarding biomarkers, is it expected to address all purposes?

➔ In principle we want that biomarkers for all the listed purposes are developed – Four different kind of purposes mentioned in the topic and all of them should be covered

The selected projects are expected to work together: will then the portfolio approach be used to select the projects to be funded?

➔ The selection will go independently according to the criteria and they are all expected to include a networking budget for joint workshop but this should be further defined afterwards during the grant agreement preparation.

Is it anticipated that the proposal should take medical pharma approach, as opposed to a psychological approach?

- ➔ It is important to note that the topic covers 5 different areas and one is more about the drug targets and it involves maintaining mental health and effective medication but the others are very different, for example developing biomarkers or analysing data from cohorts but in the end a proposers should cover several of the area but not all of them

Mental health is a very wide range of diseases, should all type of diseases be targeted or several?

- ➔ Mental health is a broad range – we want to see very multidisciplinary proposals – It is quite important to see scientist from different disciplines get involved - the evaluators will decide in the end what is the best coverage and if the proposers ca cover quite the range of discipline we want to see or if it is to narrow only dealing with fewer disciplines and covering not so much of the mental health

Would a project to validate alcohol consumption biomarkers fit this topic?

- ➔ It is covered by the topic but the applicants should carefully look at what we want to see here, we want to see the identification and validation of different types or combination of biomarkers for 4 different purposes. There is list of these 4 different purposes and all of these we would expect in the proposal.

Is there a place for early development of e-monitoring technologies and first acquisition of preliminary data on patient?

- ➔ The idea is to cover the full broad range of all the areas – it's not enough to be very specific and limited covering only one kind of discipline (imaging or monitoring) it is important to cover several of the areas listed in the scope

What are the key assets that will look for in the action?

- ➔ Cover a broad range of disciplines
- ➔ Undertake basic research but also analysing data and clinical trial

Will we see similar call in the next years of Horizon Europe?

- ➔ Already a topic open for 2022 on mental health

HORIZON-HLTH-2021-STAYHLTH-01-03: Healthy Citizens 2.0 - Supporting digital empowerment and health literacy of citizens.

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

Comments by Irina Kalderon Libal

Is the project open to involvement of public health or educational institution?

➔ It would be very important to involve public authorities, because they are very often the primary providers of education and of skills – it is also very good to know exactly what are the difficulties that they face when there is lack of health literacy and what how could digital tools help them. They could also serve as interesting use cases which is one of the item in the scope

Should the project also involve policy makers?

➔ Yes, they should be involved in this action or at least in the results. The all process of this CSA should be disseminated to policy makers. The objective to map health literacy but also to develop a strategy that could be implemented across the EU – so policy makers are an integrated part of such a strategy development. The action aim also to create a network of champions and of best practices across the EU – then very important again that policy makers are aware of such a network

Who is the target for this topic? Patients or public health organisations?

➔ The target is all EU citizens – of course patient/citizens, are the main target meaning that we want to make sure that they can use digital technologies for their better health but this goes also through targeting the administration (it cannot go separately)
➔ It is important to target patients/citizens but public administration as well because they often have the role to supply such health digital literacy courses or training for example
➔ Any actor that should be involved need to be (industries, researchers, academia educational sector, etc)

Is the development of a digital platform allowed in the project execution?

➔ It is a CSA, the development of a platform is not the main objective but it is more of a tool that could be used to support this action and this dissemination activity that is intended to be done across many Member-State and region.

Is the goal of this topic to define policies, managing real implication to digitally empowered citizens ?

➔ Yes, define policies, define real health literacy strategy on European level and of course it includes also what policy should be put in place in order to support the use of digital technologies to better support and empower citizens throughout life

What are the key assets that will be looked for in the coordination of this action?

➔ Involvement of patients and citizens, also in the co-creation of such strategy in the use of digital technologies – understand what exactly are their needs and how they could

be supported. Important to involve any actors that are relevant whether they are innovators, authorities, policy makers, academia, etc. – very broad involvement.

- ➔ Possibility to reach out to as many as possible European regions – it is very important that all Member-States and regions are included in the CSA when it comes to disseminating and exploiting its results – also to not leave behind Member-States and region that are often left behind.
- ➔ Completeness of this strategy on European level that would enhance digital health literacy for citizens independently of geographic, social or any other background – broad involvement of everybody

HORIZON-HLTH-2021-STAYHLTH-01-04: a Roadmap for personalised prevention

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

Comments by Jean-Luc Sanne

Should the project lead to a strategic research agenda?

- ➔ Topic aims at creating condition for the implementation of personalised prevention in practice. We know the advantages of personalised medicine but so far the focus has been more on treatment than on prevention. We would like to understand what are the bottleneck, why the prevention aspect is not so developed
- ➔ Purpose of the project :create a community, understand, analyse and propose a research innovation agenda so that it will be a support to a future research funding action

Should the proposal cover a single chronic disease or more?

- ➔ The topic is not oriented toward a single disease. It is not a research project. There is a possibility for the proposers to focus on one disease so they can create a community of interest in this domain, identify the bottlenecks, and come to a proposal to implement and advance personalised medicine in this domain but they can also have a more holistic approach and consider horizontal dimension
- ➔ No need to focus on one disease but it is not forbidden to approach the problem through one disease

Destination 2: Living and working in a health promoting environment

HORIZON-HLTH-2021-ENVHLTH-02-01: Exposure to electromagnetic fields (EMF) and health

- **Questions from NCP-EC meeting**

In this topic, 5G and wifi are mentioned several times: Is it possible to study other type of technologies?

➔ Could be any emerging technology

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

Comments by Tuomo Karjalainen

5G and wifi are mentioned several times: can focus be also on other technologies?

➔ 5G is given as an example but this can of course include other kind of technologies

HORIZON-HLTH-2021-ENVHLTH-02-02: Indoor air quality and health

- **Questions from NCP-EC meeting**

One project could only focus on different pollutants on a specific environment (home building, school, work place, public transport etc.) or do you expect a project to study a specific pollutant in different environments?

➔ Could be both, up to the applicant to decide, depends on the study design, could be a combination.

Is there a definition of "vulnerable population groups"?

➔ No definition but these could cover: Young age elderly people, in utero, COPD, exposed workers, pregnant women…

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

Is there a definition of vulnerable population groups? Are pregnant women also vulnerable population?

➔ There is no very strict definition – in this context, we can think that even in foetus you can be exposed to indoor air through the mother (in utero exposition), children also would be a vulnerable population, elderly, pregnant women, people with pre-existing conditions, worker groups could also be envisaged (those working in factory), people who drive metro train always inside very confined area is also another example.

How do you see the inclusion of other third countries that could bring data on air quality and act as pilot?

- ➔ Traditionally this indoor air quality has been a very big problem in the developing world, so we can imagine if it fits the scope of the work that need to be done, inclusion of some countries like India or other countries where disease burden is very high would be possible.
- ➔ Some particular LMIC are automatically eligible for funding, see list on general annexes

Outdoor AQ should be collected from Open Databases on AQ?

- ➔ It is up to the consortium to decide what are the sources of the data they will use. There is not a strict requirement to have open databases.

Networking is a collaboration between winning proposal or each proposal should be self-sustained ?

- ➔ At the proposal stage you have to reserve a certain amount of budget for this networking activities and you can identify areas where you could foresee collaboration with the other projects. Then in case your project is funded, during the grant agreement you can add maybe a whole work package or maybe a task where you then describe the common activities that will be undertaken.
- ➔ The joint activities will be negotiated between the projects after they have been selected for funding

Are partner from Hong Kong eligible?

- ➔ They are eligible to participate but they are not automatically eligible for funding – They should join consortia with their own funding.
- ➔ It is sometimes possible to fund these participants only if their participation is considered essential to the project. It is something discussed by the expert during the evaluation

Under "spread of zoonotic pathogen" are all zoonotic diseases equally considered or some special emphasis is given in certain types e.g. vector borne?

- ➔ It this area of climate change, there has been quite a lot of work done on the spread of vector-borne pathogens because these are especially sensitive to climate change so we have quite a lot of data on these.
- ➔ I think it's also good to not focus only on the vector borne but also look at some other zoonotic pathogens so we encourage a bigger view and not only focus on vector-borne (but it does not mean that is excluded)

How long may be epidemiological surveys either on general population samples or on school-children / students within the proposal?

- ➔ It really depends on the proposals – what kind of data you want to gain from the studies but there is no rule to say how long a study should be.

What "dose-response studies" are eligible?

- ➔ Any studies that are relevant to the aim of the topic, there is no restriction

What are user-friendly solutions to monitor indoor air quality?

- ➔ User friendly that means that occupants for example of an apartment or house would be very easily able to detect certain pollutants that could be harmful for them
- ➔ It is something that do not need a very high level of technological knowledge

Any particular pollutants we should focus on?

- ➔ This is up to the proposers to decide what pollutant they want to focus.

I understand that "conducting dose-response studies" on organoids or cell-lines would be sufficient. Then no needs to conduct on humans

- ➔ We do have one on the list saying "identification of body burden resulting from multi-pollutant real-life scenario indoor exposures and associated health effects with specific focus on vulnerable population groups and sensitive life stages" – To me it clearly indicates that you need to include some human studies also – it is not enough to work on in vitro systems.

What are the expected ways to improve indoor air quality?

- ➔ We will leave this to the expert that will evaluate the proposals
- ➔ You can intervene at different levels but this is up to the applicant to decide

HORIZON-HLTH-2021-ENVHLTH-02-03: Health impact of climate change, costs and benefits of action and inaction

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

"Including occupational health" is mentioned: is it a requirement or optional to include occupational health aspect?

➔ Mentioned in two places on the topic description: it is described in a fashion that it mandatory indeed.

The involvement of Copernicus and/or Galileo/EGNOS should be made at consortium level? or this is at the use level only?

➔ Context : "international cooperation is encouraged with the specific aim to support international climate policies " – "if project use satellite based earth observation, positioning, navigation and/or related timing data and services they must make use of Copernicus and/or Galileo/EGNOS – other data and services may be additional used. It is up to the consortium to decide whether to involve them at the consortium or at the use level, no strict requirement here.

Does this topic include mobility-related proiects? E.g. positive health impacts of active mobility on climate change?

➔ It is not excluded certainly. This aspect can be part of a proposal indeed.

What do you mean under "policy-relevant case studies" – could you give an example?

➔ It is a study you carry out, let's say, in 3 different cities, and you design the study closely with the policy maker – so whatever data would come out would be directly usable by the relevant policy maker – people who are involved with policy making

➔ We encourage cooperation with the policy makers to make sure that the data produced will be actually usable and feed directly into the policy making

HORIZON-HLTH-2021-DISEASE-04-01: Improved supportive, palliative, survivorship and end-of-life care of cancer patients

- **Questions from NCP-EC meeting**

Should the interventions be related to all the domains supportive, palliative, survivorship and end of life, or to one or more?

➔ Up to the applicants to decide. The topic is broadly presented on purpose, they can choose to tackle one or more – for some it is important to tackle several domains and for other it may be not possible (In the case of end-of-life study it will be difficult to address also survivorship for example)

You recently had a call on this topic. What is the reason for funding it again so soon? And to follow up, do you plan to include a similar topic without the focus on cancer in the 2023-2024 work programme?

➔ The topic was funded 3 years ago; there was a big response so it is important to repeat it. The focus on cancer is in support of the Cancer mission

➔ Yes, in the future it is planned to open it again to other topics

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

Comment by Grzegorz Owsianik

Should the intervention be related to all the domains supportive, palliative, survivorship and end-of-life, or to one or more?

➔ The topic is rather open, we leave it to the applicants to focus on the relevant domains. So it can be one, two or even all domains, it depends what the applicants would like to study and which research they plan to implement in the proposals

Are there any guidelines on pharmacological interventions? Can proposals focus solely on non-pharmacological interventions?

➔ The topic is open for both

Must the intervention target all age groups including children, adults and elderly?

➔ It is open to all group ages and it has to be relevant for the proposed research. There is no limitation on this aspect.

Can the proposal include AI if it is related to the topic?

➔ It is open to any kind of intervention so if it is relevant for the palliative, supportive, survivorship or end-of-life care then of course it can be proposed within proposals

HORIZON-HLTH-2021-DISEASE-04-02: Building a European innovation platform for the repurposing of medicinal products

- **Questions from NCP-EC meeting**

Is it expected to have several use cases on drug repurposing within a project? For example clinical trials on several drugs in different medical areas (CVD, cancer, ID, etc …)?

➔ No prescription on how many uses cases to be included but at least one

Bottleneck on drug repurposing are very different for communicable or non-communicable diseases. Could one project focus only on non-communicable diseases or on communicable diseases for example or should one proposal address both types of diseases?

➔ Done in the past: individual compound and illnesses. Here we want to develop platform technologies useful for different types of diseases – Be able to re-screen a large amount of currently available medicines – not focusing on one compound or a single disease

Are vaccines in scope for this topic?

➔ The expected outcomes of this call topic mention the "repurposing of medicines" and the expectation that "Patients have new and effective therapeutic options addressing unmet medical needs, both for communicable and non-communicable diseases." The focus lies therefore on 'repurposing' and 'therapeutics'. Therapeutic vaccines are in scope as long as proposals properly address all expected outcomes.

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

Comments by Arjon Van Hengel

The definition of a platform is not specified in the text. Is it expected to have several use cases on drug repurposing?

➔ What we have seen so far is that there are many initiatives either focusing on a single compound or a single disease. What we want to do with this specific topic is providing a kind of platform technology that is disease agnostic – so not focusing on specific disease – not focusing on individual compound for repurposing, but really developing a wide platform that can be used for the repurposing in general for both communicable and non-communicable diseases

➔ You can use the latest technology that has been developed – You might think about eHealth aspect – AI aspect – screening platform, etc.

➔ It is of course possible to have some kind of pilot studies with individual compounds to test the platform – but the focus is really on the platform technology.

HORIZON-HLTH-2021-DISEASE-04-03: Innovative approaches to enhance poverty-related diseases research in sub-Saharan Africa

- **Questions from NCP-EC meeting**

It requires at least one legal entity in sub-Saharan Africa, but do you also need additionally minimum 3 legal entities in member states/associate countries?

➔ Yes, African countries are required on top of the 3 minimum legal entities from Members States or Associate Countries

"Proposals involving pharmaceutical companies and small- or medium-sized enterprises (SMEs) are encouraged.". Does this mean large pharma companies (also from US?) are encouraged as well as SMEs or are SMEs preferred?

➔ No preference, but possibilities for SME to apply just highlighted here

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

Comments by Arjon Van Hengel

Are Non-Communicable diseases coming from infectious of the upper respiratory eligible? E.g Rheumatic heart disease – Group A Streptococci

➔ This is focusing on communicable diseases so it should come with a background of communicable diseases – and then of course we are dealing with co-infection or other sensitive patients groups that might be involved here – then there is a possibility it is not excluded from the topic but the topic is really focusing on communicable diseases.

Is the involvement of a SME pharmaceutical company viewed more favourably than involving a large pharm company?

➔ It really depends on the proposal and on the activities performed by the company
➔ In general, we very much support the inclusion of SME but of course, it has to be very relevant to the activities that are described in the proposal. In addition to that, large pharmaceutical companies are also welcome to be partner in the proposals

Are non-sub-Saharan African LMICs eligible for funding for this topic, despite the geographical focus?

➔ Mentioned in the topic text : legal entities established in all MS of the African Union are exceptionally eligible for EU funding – not restricted to sub-Saharan Africa

Is HVB considered in this topic ?

➔ The focus is really on the disease that are in the scope of EDCTP, therefore it is on communicable diseases. Of course if you are dealing with co-infections or other

complicating factors then that could be included if it makes sense for the focus on the communicable diseases.

In view of their central coordinative role, can WHO be partner?

➔ The WHO can always be a partner in proposals – here it depends on what is proposed in term of activities and whether it is a crucial partner.

It is required to "include activities that promote collaboration with ongoing and future EDCTP projects". How do you envision this?

➔ We know that project are currently funded by EDCTP2 and future projects will be funded under EDCTP3 so what we expect is that there are at least communication activities foreseen between the funded projects and the one funded through EDCTP – we expect to see that in the proposals – it is up to the applicant to describe how exactly they would see that but it should be mentioned and some budget set aside for this activities

Can interventions that are not strictly medical but are "preventive" be included, besides the medical ones?

➔ As mentioned in the topic text, it is really about medical interventions. It does not exclude preventive activities in that sense but it has to make sense within the total proposal. The focus is on medical intervention with no specific exclusion on preventive intervention.

HORIZON-HLTH-2021-DISEASE-04-07: Personalised medicine and infectious diseases: understanding the individual host response to viruses (e.g. SARS-CoV-2)

- **Questions from NCP-EC meeting**

Would a proposal tackling a RARE infectious disease with huge social and clinical impact fit to topic? If yes, should it then extra justified since it seems that COVID-19 related proposals would be preferred?

➔ Any disease is welcomed, open topic, not only focused on covid

Are interventional clinical trials eligible in the call?

➔ Don't really expect interventional clinical trials but not specifically forbidden
➔ Expect more to have non interventional clinical studies : specific mentioned in the topic to follow up patient and liaise with existing cohorts (not no but not what spontaneously expected). Idea here is more to understand, than to cure

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

Comments by Grzegorz Owsianik

Is the topic limited to SARS-CoV2?

➔ No, we give it only as an example – it is open to all other viruses as well

What are the expectations of this call if we focus on COVID (vaccination, variants …)?

➔ This is not only focused on the Covid
➔ What we want to achieve is the generation of the understanding of the individual host response to viruses. We would like to have some recognized new standard operating procedures and some new guidelines - in this case also some specific biomarkers

Are interventional clinical trials eligible in this topic?

➔ This topic focus on generating new knowledge to understand host-response to the viruses – It should follow up on the patient
➔ We rather expect observational studies than intervention, which would test new treatment. But of course this is not excluded from topic – it depends on how the applicant position this in the research but we would not expect proposals focusing on the treatment and testing certain interventions

What are the expected/reasonable duration for the projects in this topic?

➔ We leave the duration up to the applicants – Present a concise set of activities with a duration that fit with it. During the evaluation, the experts will evaluate whether the timeframe proposed is reasonable in relation to the activities.

The topic mentions that focus on Covid-19 is strongly encouraged to build links with the EU-funder project Orchestra

- ➔ Yes it is one of the suggestion to put it the context of the current research on Covid-19
- ➔ Orchestra is a large project funded under H2020 – cohort of people

Does this mean that you must be already part of Orchestra, or have one of the Orchestra members in the consortium at the time of application?

- ➔ No. We ask for connection with the Orchestra project but it does not mean it has to be the same consortium members

Orchestra communicated that they cannot engage in any proposal before it is selected. Should the link just be mentioned w/o detailing activities?

- ➔ The link can indeed be worked further out after the proposal has been selected for funding

Can the proposal focus on understanding response to Covid vaccination?

- ➔ If this is in the scope of understanding individual host response to viruses it can be also an option

Focus on SARS-CoV-2: if project starts on April 2022 hopefully most of the population will be vaccinated but vaccination is not at all mentioned

- ➔ This is not the main purpose to look at the vaccination within the topic

Are African and Asiatic partners eligible (for studies on Covid long-term impact in Europe?)

- ➔ They can participate in the project and you need to check the list of eligible countries for funding by the EU

Comment by Jean-Luc Sanne

Is it mandatory to carry out animal models or in-vitro models?

- ➔ It is not mandatory, it is described in the topic, it is up to the applicants to decide

HORIZON-HLTH-2021-disease-04-04: Clinical validation of artificial intelligence (AI) solutions for treatment and care

- **Questions from NCP-EC meeting**

The topic mentions « Assessing potential manual or automated biases for large uptake »: What is meant by "manual or automated" biases?

➔ Very important point – biais introduced in different ways, either manual (operator related) or automated: created by the algorithm itself (can it recognise itself?)

The topic mentions "current clinical guidelines for personalised treatments following current EU regulatory framework". Which "EU regulatory framework" are meant here?

➔ Medical devices, in vitro diagnostic medical device, clinical trial regulation, gdpr, guidelines for trustworthy AI, etc…

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

Comments by Grzegorz Owsianik

The AI solutions should already be developed or also AI development can take place?

➔ The topic is focused on the clinical validation of AI solutions – and also one of the requirement is that the topic should be based on pre-existing (pre)-clinical evidence

➔ In this case, development of completely new AI solutions is not really fully in the scope of the topic. What we have as interest is looking more in the application and putting this in the clinical settings, validating and trying to fit it with the current clinical guidelines

International collaboration is encouraged. How should this collaboration be with partners not eligible for fundings?

➔ There is no limitation for the participation of any countries as partners in the proposals. In term of funding, there are only some countries that are eligible to receive funding but any partner not eligible for funding can participate in the projects.

Should we propose a reproducible clinical study in different fields (oncology, cardiology …) or is only one acceptable?

➔ This is open to the applicants to choose the field of intervention

Is the topic limited to treatment and care only or are solutions which provide risk prediction suitable ?

➔ The main interest of the topic are of course treatment and care, but as written in the scope, the topic also should provide accurate prognosis for and response to a specific personalised treatment which provide the solid risk assessment which includes

potential adverse effect, side effect and so on. It depends how applicants position this type of research in the proposal.

Could this topic encompass AI driven efficiency approaches addressing mental health?

- ➔ Specific topic on mental health in destination one, so please look at the video of the destination 1 where you can see information concerning the topic – AI could be one of the approach proposed
- ➔ It is possible within this topic to focus on mental health

Are mental health diseases included in the program?

- ➔ Topic is not restricted to any disease area

« Patient, carers have access to disease-specific communication packages »: Is this the usual dissemination done in projects?

- ➔ Yes it could be part of the dissemination plan but this is a specific requirement for this topic

Clinical coordinator is suggested? or AI Engineering partners should coordinate the project ?

- ➔ This is up to the consortium to designate the coordinator

Is risk prediction in remote monitoring considered part of « treatment and care »?

- ➔ It depends how the person put the risk prediction, how it links with treatment and care and it will be up to the evaluator to decide whether it is relevant or not.

Does the clinical decision informed by the AI need to be tested in a clinical trial within the project?

- ➔ The topic is based on the clinical validation of the solution so the answer is yes

Can we start the clinical study before the contract is signed?

- ➔ Starting some work before signing grant agreement is on the own risk of the consortium because in case the grant is not signed then the costs are not eligible

What are the expectations on how much weight AI development should have over the actual clinical validation: is 50/50 budget wise OK?

- ➔ There is no specific proportion – topic focus is on clinical validation so it must be based on existing pre or clinical evidence – it is not the point to focus very much on the development, especially on the early development of AI

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

HORIZON-HLTH-2021-CARE-05-01: Enhancing quality of care and patient safety

- **Questions from EC Infoday on Destination 4**

Are existing EU-funded initiatives in this area already identified? The topic does not name any of them.

➔ REPONSE (Jean-Luc Sanne): in this topic, the EC recommends that the proposals haves lies with other EU initiatives. Actually, the EC has not named any initiative, it's open. It's not something that the EC wants the proposals to allies with the dedicated initiatives. But the EC wants them to have an idea about possibilities of synergy and cooperation with other groups.

What is meant by "patient centred"?

➔ REPONSE (Bernd Rainer): Patient centred, then "patient centric" is a general objective in the move from -- we would call it - the macro approach, the disease approach to a real person-centered approach: this is a general guideline, which is running across the entire health cluster. So, this is not only a special feature of this topic "05-01", this is something which we have across the entire health cluster as a whole.
Additional comments of Jean-Luc Sanne: It is a general approach of the personalized medicine, but it is requested in this topic, so we have to have an approach that is "patient centered" and there are specifications in the topic regarding patient reports, i.e. patient report outcome measures and patient report experience measures, so the EC definitively expects proposals to involve patients and taking into account their voice. The second element is that – when you consider safety – you could consider one thing, for example like nosocomial infections, you will concentrate on hygienic measures, but you can also see, from patient point of view, identify patient at risks, it's a different approach that the EC would like to implement.

Can the proposal be focused on a specific medical area or disease?

➔ REPONSE (Bernd Rainer): This is a good question. It is possible to focus on one specific therapeutic area, but it is not a necessity.
Additional comments of Jean-Luc Sanne: He confirms that in fact, it can be focused on a specific disease area and if there is a specific problem linked to this disease, but when the topic was written, it was more an holistic approach that the EC had in mind. So again, everything you choose has to be justified, but there is no reason why not to concentrate on a specific disease, although it was not the initial intention.

This proposal addresses only solution / intervention in hospitals/primary care? Or also secondary care can be the main implementation site?

- ➔ REPONSE (Bernd Rainer): This is not restrictive only to primary care; it could well of course also include secondary care.
  Additional comments of Jean-Luc Sanne: yes, it is correct. When we look closely the topic, it is said that there is a focus on "development and piloting of harmonised evidence-based interventions […] this should be addressed in case studies at hospitals, primary and outpatient care levels", so it answers the question of secondary care.

For CARE-05-01 and CARE-05-02 a clinical annex is not required: does it mean that clinical studies are not recommended for these topics?

- ➔ REPONSE (Bernd Rainer): when we have a look to the topics, we would say that the clinical trials are maybe not the primary target or the core of these topics, since we are here more in the domain where we address more the health system, the process and the procedures.
  Additional comments of Jean-Luc Sanne: for the topic, the EC did not think of clinical trials, it is not obedient, but it has to make sense. The applicants may need to have clinical trials in the sense that the EC say that we could expect to have pilots available for health care given. That could mean in a certain of sense that they could try clinical trials. It is not forbidden, but it is not the major thing the EC has in mind.

  The same thing goes for CARE-05-02.

Would- enhancing and systemising patient records in a clinical setting satisfy 05-01 and/or 05-02?

- ➔ REPONSE (Bernd Rainer): A priori this is not sufficient, it can certainly be an element, but if it would be the only the task or the main action to be performed for this topic, this would probably be not enough.
  Additional comments of Jean-Luc Sanne: yes, this would be very restrictive and it can be probably a tool to achieve the objective of the topic, but it is too restrictive.

  The same for the CARE-05-02, it would certainly not be sufficient for fulfilling the requirements or the scope described under this topic.

HORIZON-HLTH-2021-CARE-05-02: Data-driven decision-support tools for better health care delivery and policy-making with a focus on cancer

- **Questions from EC Infoday on Destination 4**

Is the focus of 05-02 solely cancer or mental health be considered?

➔ REPONSE (Bernd Rainer): No, here the focus of this topic (for 2021) is really on cancer. It may be seen that maybe for future work programmes there would be an opening for another therapeutic area or disease area, this remains to be seen.

The solutions to be developed should reach a specific TRL how close to the market should they be?

➔ REPONSE (Bernd Rainer): In general (I have to say) in the Health cluster, due to the specificity of health technologies, we have TRL levels to be achieved only mentioned in exceptional cases. If there is a clear technology targeted (normally this is not the case), so that's why in this topic there is no such things as a specific TRL level targeted and in principle the goal is to come up with these digital and data-driven tools which should help to enhance and to improve the decisions for both the patient, the health care provider and also the policy maker.

The dynamic relations with initiatives and areas is required at proposal level or will it be defined later on? E.g. EHDS (European Health Data Space) are still on preparation.

➔ REPONSE (Bernd Rainer): the actions supported under this topic will have to propose or to describe in their annex, in their work how they are going to interact with other initiatives and actions who will be also strongly based on health data. And, the EHDS is certainly a very important initiative in this respect.
Additional comments of Carmen Laplaza Santos: Actually, the EC cannot really provide a very concrete answer to the question, because everything would depend on the specific content of the proposals, of the work to be done by the proposals. Of course, there are different initiatives fostering the building of the EHDS and these initiatives are different and have diverse nature and at different steps of maturity. So, it is absolutely understandable that there is no a fixed and concrete legal basis. So, the EC thinks that what YOU provide as an answer is appropriating in the sense of that it is requested that the proposal will be actively interacting with the relevant initiatives in the field of EHDS, but also in any other relevant initiatives, for example also in the context of cancer. So political priority, political development, relevant initiative would be to – somehow – be interactive with. But on the concreteness that would depend on the health specific focus of each of the proposals.

- **Questions from EC Infoday on Destination 4**

(CSA) How does this call relate to existing networks and communities of practises such as Euriphi?

➔ REPONSE (Orestis Kalliantzidis): EURIPHI is one of the two CSAs that were among the last call the EC was running during Horizon 2020, related for innovation procurement. The other one being PIPPI.
While/Why would you not see this CSA, this innovation procurement network, as a direct continuation of this call (*and I would explain why*), the Project officer would like to advise potential applicants to take into account these two initiatives. So this is a valid question and how:

1) Partners or groups related into these two CSAs can of course participate as applicants in the new CSA, if of course the conditions of Horizon Europe related to CSA are met.
And I am quite sure that there is experience and knowledge could bring something into a potential proposal.
2) The second way could be that – of course during the proposal preparation stage – there is an horizon scanning by potential applicants, so they do see what activities, past or current, were there before they did the proposal, while they shape their plan, their approach and their methodology in order to avoid a duplication of work and build on those activities.
It is suggested that this scanning and these initiatives are taken into account by any potential applicants. And finally one would see, if you read the text of the call, that some basic elements of this CSA are reaching a common understanding on what the challenges are, and what the available approach and instruments and tools- are to do innovation procurement in Europe, at European and national level: it forces capacity building activities to reach this prior knowledge can be an advantage, it also forces knowledge transfer, for example training, now one can see how previous activities in the area could contribute to successful proposals like that.
Finally**,** this CSA is not focused only on European activities such as EURIPHY or PIPPI, it is about any knowledge experience and best practise that we have at national level currently in Europe or at the European level or at local level. So please be holistic in your approach when you prepare proposals.

Should the CSA include procurers and providers (i.e. SMEs)?

➔ REPONSE: To the understanding of Bernd Rainer, yes.

Additional comments of Orestis Kalliantzidis: he also answers - at the same time - to another question (ask to explain what the EC means by saying that a proposal should engage procurers in an appropriate way): so his answer will concern these two questions.
This topic is quite clear listed that it is beginning focuses on public and private procurers. So the EC would like it to be driven by the demand side and the EC does provide examples of potential other stakeholders who could participate in such innovation competence centres or health authorities, in the sense that the EC wants to point applicants having a complete

consortium which can actually help procurers carry out the activities and reach the expected outcomes that the EC wants for the demand side.
The EC does recognize now that the expected outcomes for this topic cannot be achieved without consultation and engagement with several other types of stakeholders, like patients for example, like the industry indeed, providers, such as SMEs, like policy makers not involved in the project, or like investors.
The EC does require applicants to engage in an appropriate way: what does this mean: it means decide at which level they need to be involved, in order for the project to achieve its targets: should they be partners, should they be third-parties, should they be consulted through the open market consultations, which you will find somewhere in the call topic as a requirement. Or should they participate in the training and capacity building activities? Now, this is up to the applicants to decide, who can take part. Of course, the participation of suppliers and SMEs is ok for the eligibility of the proposal like in any other CSAs, everyone who is eligible to participate in a CSA, can participate in this one. But, the EC calls for applicants to read well all the topic and see all these actors at which level they should participate in the future projects.

Additional comments concerning the CSA for the innovation procurement network by Orestis Kalliantzidis:

- ⇨ *(Introduction comment by Bernd Rainer) The CSA is somehow a building on what has been done already in the previous frameworks. But here with Horizon Europe, it is a starting point for eventual deeper actions to follow in future work programmes.*

Indeed, the EC does see this topic as being a few steps more ambitious than previous topics in Horizon 2020, but not necessarily a direct continuation of those, that's why the scopes of this topic were extended. The EC is aiming at a balanced group of procurers who are willing to cooperate, who are willing to identify common needs and challenges, who are willing to work together to systematise the way we do innovation procurements in Europe, with respective instruments, with a focus on usual instruments such as the PCP or the PPI (they are very welcome to do that), if they find that these are the best instruments of their choice for example. But there is also other instruments such as innovation partnerships, direct procurements, several sources procuring innovation actually. The EC wants them to analyse these tools, to systematise the way they do procurement and to collaborate together at the largest scale, hoping that they can plan future activities in the area. And that is how the topic is in a way more ambitious as before. But at the same time the EC did not try to prescribe a lot what a proposal should look like. The EC has foreseen a minimum number of requirements and tools that need to be there in order to achieve the objectives of such a well-funded topic. But the EC does expect procurers actually to share with the EC their experience and their approach of how it should look like, especially after COVID, where we have to re-imagine a bit the way we do things and we have to assess what the chance is where, especially for those – not only procure, because almost everybody in the health sector procure this way or with the other. Those who need to procure innovation and they need it fast and sometimes it is not so easy as the pandemic showed us.

Comments by Bernd Rainer concerning the expected outcomes:

Reminder concerning the importance of the expected outcomes, which are mentioned under the topic descriptions:

- ➔ They should be considered as the driving principles of all the work which is proposed by the applicants consortia
- ➔ Under this destination, all the users groups which are involved in the health care continuum are to be the users of the outputs of the research work. So, for the topics which are on improving the decision support system and providing decision support tools, it is very much for health policy makers, that they are enabled to use specific evidence for developing fordable and safe interventions.
- ➔ It is for the health care professionals that should – in partnership – raise empowered patients, ably harmonise procedures and guidelines securing patients safety (very relevant for the first topic), then for health care providers to integrate standardized practises with personalized treatment schemes and use quality ensure processes along patient clinical pathways and also to ensure that more and more health care professionals and patients or citizens as large are here to recommendations, which are relevant for safety.
- ➔ Concerning the second topic: the main users are supposed to be health care organisations and policy makers to equip them with modelling and other IT solutions in order to facilitate their decision-making on health interventions, as well as health care providers and citizens also in their decision-making process for interventions and to provide health system with evidence-based and participative tools that are taking into account all relevant aspects for the delivery for adequate services.to patients. And to give access for policy makers to evidence-based and interoperable decision support tools when they take their decision, which are then decisive for the health system.
- ➔ For the topic 3, the CSA is also to be looked, in the context of EU4Health programme, it will be necessary to have a close interaction with the DG Santé because it will be crucial to involved all the national actors or even local actors which are to procure in the end health innovation.

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

HORIZON-HLTH-2021-TOOL-06-01: Smart medical devices and their surgical implantation for use in resource-constrained settings

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

Comments by Bernd Rainer

What does it mean resource-constrained environments?

➔ General term used by WHO - Clinical settings which are limited in resources and eventually also in staff and utilities – do not dispose of the last healthcare technical equipment and are not only limited to LMIC – (Low and Middle Income Countries) – The aim of the topic is to really bring forward smart implants which include a diagnostic and therapeutic function and to which surgical procedure is absolutely adapted

How to quantify TRL 4? Would the integration of sensor/actuator prototypes (TRL<4) within a commercial device (TRL>10) be accepted?

➔ The topic request as starting point a TRL 4, to put the emphasis on the inclusion of the surgical procedure which is crucial four such devices. If the sensor is a proper medical devices on its own where the TRL s below 4 it would be difficult to be accepted

Would acute conditions such as bone fractures, inflammation, etc, be eligible?

➔ Yes, this is a valid intended use of such medical devices

Are the costs associated with the EC certification of medical devices eligible?

➔ Tricky question – since the topic is an IA, need to consult with colleagues – a priori all clinical validation necessary to go from TRL 4 to TRL 7 would be eligible

HORIZON-HLTH-2021-TOOL-06-02: Next generation advanced therapies to treat highly prevalent and high burden diseases with unmet medical needs

- **Questions from NCP-EC meeting**

Is it possible to use a group of rare diseases as proof of concept for a treatment to a highly prevalent and high burden disease?

➔ EC will double check – should be possible maybe

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

Comments by Christian Desaintes

Can proposals cover clinical work?

➔ The focus of the topic is really on pre-clinical work, so in principle applicant can go up to the authorization for clinical trials but the clinical trial per see are considered out of scope

Can proposals cover on the 4th area defined (immune responses)?

➔ Theoretically a proposals could address only the analysis of immune responses but as long as they are related to any of the 3 mentioned advanced therapies (RNA based therapies, Stem cell therapies and editing)

Can proposals cover cancer research?

➔ Yes absolutely, research proposals can cover cancer, but the applicants need to justify the burden and the prevalence of the cancer type they want to study, and mention the unmet need. When referring to the prevalence levels and burden, it would be wise to indicate some quantification

Can a proposal focus on a single advanced therapy or do they need to develop multiple products?

➔ The projects can just focus on one advanced therapy and do not necessarily need to cover all the areas

Is it limited to projects working with pluripotent stem cells, gene editing or RNA?

➔ Yes. These three advanced therapies are the focus of this call, and together with any studies of immune responses which are related to these three advanced therapies

How do you define highly prevalent and burdensome disease?

➔ Up to the applicants to convince the external evaluators that the disease they are tackling are highly prevalent – Providing quantitative evidence would strengthen your proposal

Must the project focus on one of the disorders/diseases named in the WHO report?

- ➔ Not necessarily but certainly it would help – The report is from 2013 so applicants could have good reason to choose another disease but it would be very important to justify the prevalence and the burden

Are the development of new small bioactive compounds within the scope?

- ➔ Yes, only if they are linked to gene editing tools, or RNA molecule

Is the development of assays for early diagnosis of infectious diseases also eligible?

- ➔ Hard to link the diagnosis of ID to a topic on advanced therapies – ID cannot be excluded from the topic but the focus is on therapies and not on diagnosis. What would be on the focus are assays of efficacy and potency but certainly not diagnosis

Does diabetes technology and treatment, particular real-time monitoring, control for artificial pancreas on mobile devices, fit in here?

- ➔ It could fit but only if it is combined with the three advanced therapies mentioned on the topic text

Would the development of a screening/diagnostic tool [hand held device] using metabolites/machine learning be eligible?

- ➔ No, it has to be related to therapies – so any tools only related to diagnostic is not in the focus

Does the topic only concern pharma or medical interventions? Would other areas be considered with unmet needs e.g. depression?

- ➔ Pharma and medical intervention are certainly covered in the focus. Mental health is also part of the focus if it is a high prevalent and of high burden disease. In any cases, the proposed intervention need to be one of three mentioned in the topic

HORIZON-HLTH-2021-TOOL-06-03: Innovative tools for use and re-use of health data (in particular of electronic health records and/or patient registries)

- **Questions from NCP-EC meeting**

Could one proposal focus on a particular medical area? Or the proposal has to focus on the tools to be developed, regardless the domain of application?

➔ The topic is really focused on the tools and not on the disease

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

Comments by Saila Rinne

What could be considered as a representative sample of the European healthcare landscape?

➔ The aim of the topic is to increase the interoperability, use and re-use of health data across different repositories and also across borders in Europe, then a meaningful set of countries and health data sources or healthcare entities would be expected to be represented in the proposals. This depends on the scope of the proposed work and the data analytics tools that are planned to be developed and piloted within the project

How are the proposals expected to contribute to the creation of the European Health Data Space?

➔ Proposals should demonstrate good understanding of the different initiatives around the European Health Data Space and how this proposal would contribute to its creation

Are privacy issues tackled by this kind of project?

➔ Yes, the proposed solutions are expected to take into account and comply with all relevant legal requirements, rules on personal data protection, security, ethic, etc., and these aspects should be integrated in the solution by design.

Could a proposal envisage the creation of data for disease areas where there is poor systematic data e.g. mental health?

➔ This would be an example – It can be any disease area or other healthcare related areas where data is not sufficiently available or unstructured, where we need tools to have better access to the data and then to do the analytics on the data to get more insight from the data set.

Should the AI-powered virtual assistants be tested in real life environment? i.e. in pilots in hospitals for example ?

➔ The idea is to demonstrate that there is a good usability of the tools that are developed during the project and that the end-users can easily use the tools – The topic does not

specify how this is done – depends on the approach and the solution the proposals is about – depends on the level of maturity you start from.

Should proposals focus on one disease?

➔ Not necessarily, it really depends on how the project is positioning itself. However, considering the size of the project (Rather big proposals, up to 8M€) and the expected outcomes we would possibly expect the projects to be more disease agnostics and to have tools that can be used in different disease areas

Is the (re)use of public and population health information for research and policy purposes also considered in this topic?

➔ The main focus is on electronic health records, patient registries – it can be also other health data sources but there should various sources. All types of relevant health for the objective of the proposals are considered but it has to involve in any case HER and patient registries

How many clinical trial sites should proposals include to ensure representative sample of the European healthcare landscape?

➔ Considering the proposals, a meaningful set of countries, entities and data sources should be in in order to demonstrate the cross-border and the cross-disciplinary aspect and different data type combination is a sufficient number

Are multiple data type integration required, such as text, imaging and structured data? Or a project based on text-only would be sufficient?

➔ All relevant data that is needed for the tools that are developed are required in the proposals. The tools should be able to extract health information from unstructured data in different medical and clinical sources and to bring the data in to the registries and EHR. This depends also on the basic challenge that the proposers are addressing in the proposals. It is not excluded but there should be enough different types of data considered for the tools to work and to bring added value.

Could the registries focus on a specific topic? (e.g. Children ?)

➔ Depending on how the proposals are framing their work, it could be, if all the other topic requirements are met.

Are ongoing registries also eligible to send proposals?

➔ It depends on the challenges to be address in the proposals and the tools to be develop and for which purpose

Is it eligible to build registries that do not exist yet?

- ➔ This is not the main purpose of the topic – Aim is to improve data quality and wider access to health data from multiple sources and across different countries to develop novel data-driven tools that will help researchers and clinicians – it should not be the main purposes of the proposed work

Are the cross-border aspects specifically relevant to this topic?

- ➔ Yes – "representative sample of European healthcare landscape". The topic is about sharing and analyzing data in a safe and legally compliant matters – so major challenge on cross-border aspects.

Could you please provide examples of priorities in term of use and re-use of health data ?

- ➔ Topic is very open – not limited on few example – Improving workflow in clinical setting and improving research – providing better access to patient data – up to proposers to come up with the concrete examples

Are patient images (radiologic data) of videos from procedures (endoscopy for instance) considered relevant for this topic?

- ➔ The topic indicates that the focus should be on data in Electronic Health Records and/or patient registries but at the same time it mentions that the tools should be able to extract relevant health information from unstructured data sources which can be the one mentioned in the question – in order to enhance the HER and patient registries and make the data structured searchable and so on. In practice the topic is not exclusively on HER but on health data at large

Could you precise the aim of the topic?

- ➔ The idea is to make sense of unstructured data, to make unstructured data structured so that it can be used for various purposes – To enrich patients registries or EHR and also to build and develop data-driven tools on top of this structured data set

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

Destination very oriented towards industry and towards creating better condition for market access and the uptake of innovation by healthcare providers

We expect an input from industry (SMEs) through these topics

HORIZON-HLTH-2021-IND-07-01: Green pharmaceuticals

- **Questions from NCP-EC meeting**

Do biologics fit in the scope of this call or is it restricted to small molecules (e.g. API)?

➔ EC will come back to us. In principle the topic is not restricted but the idea is to work on pharmaceuticals and not really on the biologics

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

Comments by Maia

Our intention behind this call is to be as inclusive as possible and to contribute to protection of environment and ultimately to public health – the topic is open to different kind of contributions

Can applicants propose activities linked to all the elements mentioned in the scope?

➔ You are not obliged to address all the elements from the topic, you can focus only on some of them (several meaning more than one)
➔ If you want to address all elements, you may need a bigger budget than the one mentioned, and the overall envelop is limited

The topic states « activities linked to several of the following elements »: how many are « several » ?

➔ There is no specific number – it would be more than one
➔ Digital aspect : if for example any solutions could also address this digital objective – we would considered this interesting

The approach is to be open and inclusive

What is meant by digital transformation with respect to this call? What is the idea behind this request?

➔ We would welcome applications that combine two objectives: greener production/pharmaceuticals and digital objective as well. This aspect can improve the sustainability of the production – it is an element to take into account
➔ There could be in the manufacturing process for example an input from digitalisation that could help producing in a way it is more efficient and less polluting

Could digitalisation be automation of equipment for example?

- ➔ The topic is not about creating new automation – if it is not related to environment then it is out of scope. If it is made necessary for the purpose of the topic, then it is in the scope.

What is the expected TRL level? Especially related to « offer deployable technical solutions ». Should pilots be included and how many?

- ➔ As long as TRL is not mentioned in the topic, you have flexibility. Considering the objective being to deploy something rather rapidly, it could be a high TRL (4 to 6) with pilots – but no prescription

Comments by Marilena-Silvia Lungo

Do the green manufacturing have to focus only on active pharmaceuticals ingredients (APIs) ?

- ➔ The aim of the topic is to address all pharmaceuticals, not only APIs but also medicines. We would welcome proposals not only on API but on all medecines that would have the aim to address manufacturing methods of having a transition towards a green manufacturing, promoting innovation towards green pharmaceuticals

Are pharmaceuticals which are « not yet subject to environmental risk assessment » based on what is NOT included in the REACH regulation?

- ➔ This call is actually on the basis of pharmaceutical regulations and is reflecting also the sustainable dimension in pharmaceutical strategy. This call is requested for our environmental risk assesment on the basis of pharmaceutical regulation that is different of what is carried out in the REACH regulation

For the eco-toxicity aspect, what is targeted? eco-toxicity of the end-products (API) or the manufacturing process ?

- ➔ The overall objective is to target both of these elements: the eco-toxicity of medicines and the manufacturing processes but it can be in different proposals (a single proposal do not have to cover all elements).
- ➔ Regarding the manufacturing processes, it can be innovative aspects related to make them more environmentally friendly, to alleviate environmental pollution
- ➔ Regarding the end-product, it can be to develop greener pharmaceuticals in the sense that they are less harmful to the environment when they are used

Is it open to the development of new ways to produce pharmaceuticals and to the improvement of existing methods to develop pharmaceuticals?

- ➔ It could be different ways in the development or the production of pharmaceuticals but that must be linked with the sustainable dimension. The objective for us is clearly in the sense of having a greener way of production in order to promote transfer from current technologies to more sustainable technologies – So, in a way, to promote these methods of production that would improve the existing methods to develop pharmaceuticals but with the aim of having greener and sustainable production.

HORIZON-HLTH-2021-IND-07-02: Development, procurement and responsible management of new antimicrobials

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

Comments by Arjon Van Hengel

Should the consortium be the same as the one for the future innovation partnership?

➔ This is a CSA in preparation of the partnership. It does not mean that the participants in the CSA have to be the same as the one in IP that will be resulting from this. These are really two separate things. Of course it is likely that the participants involved in the CSA will also apply to the Innovation partnership

Would the development of small molecules as new antibiotics fit in the scope of the programme?

➔ The answer is no, this a CSA to prepare for a pull incentive and that pull incentive should then take of the development and the procurement of antimicrobials

HORIZON-HLTH-2021-IND-07-03: Promoting a trusted mHealth label in Europe: uptake of technical specification for quality and reliability of health and wellness apps

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

Comments by Birgit Morlion

What is the current status of the CEN/ISO technical specification standard referred to in the topic text

➔ The aim of the topic is to contributing to the adoption of the standards (and not their creation). The standards has been voted by CEN (the central European standardisation body and ISO) and it was adopted and there are currently some minor editorial changes that are applied now and the standards will be very soon published and available to everybody.
➔ Member of the CEN Committee 251 have access to the document already – you can link and ask to have access if you know somebody

Does the concept of health and wellness apps exclude apps covered by the IVD device regulation?

➔ No, the concept of mHealth label covers all apps whether are medical devices or not – the developers should always respect all existing regulations – if the intended use should apply to the MD directives then they should comply with it
➔ The idea of the call is to make the quality and the reliability of the apps more transparent to the users (patients or citizens or health care professional). It applies to any kind of apps (MD or not)

What is the target audience / main beneficiaries of the results of this action?

- ➔ Multiple actors will benefit from the results: industry players – app developers – health tech industry: they are looking for a more harmonised certification and validation. It will also contribute to enhancing the single market idea within the European tech market.
- ➔ Such a label is also a benefit to citizens and patients that want to use apps to monitor their health or conditions that they are suffering from
- ➔ Healthcare professional : i twill help them to advice patients to use apps or even to prescribe apps
- ➔ Healthcare systems : it will help of integrating qualitative apps into the healthcare pathway

Is this topic focused on both health and wellness apps? Should proposals embrace both?

- ➔ « Health and wellness apps » is used to make it clear that it is not only focusing on medical devices apps but also on mental apps, the step counting, the other apps that can help you in keeping the healthy more preventive approach.
- ➔ It is not the idea of focusing only on one or the other

The goal of the topic is to create a technical specification for all mHealth apps quality and reliability or could it be about a specific topic?

- ➔ The European Standardisation Organisation (CEN) has already developed a technical specification together with a mHealth quality label that is associated to the specification and this is under the bigger umbrella of the health software standard that is already out there and now there is one specific for dealing with the health app. So the idea of this topic is really to promote the uptake and the use of the standard that is new now and to bring all necessary stakeholders together so that the standard is use and adopted.

Transversal aspects

- **Ethics**

The ethics issue table contains the question: “Is it a low-intervention clinical trial?” What is the implication (for the application/project) of having a low-intervention clinical trial or not?

➔ It is just one legal type of clinical trials that has less requirement (for example a simplified consent form)

Artificial intelligence (AI) is now included in the Ethics sections – any tips on what applicants should cover on this?

➔ About the way AI are deployed and used: technical robustness of the AI system, resilience to attacks and safety issues, biais that might be introduced, ethic by design, etc.

➔ More details can be found in the 'HOW to complete your ethics self-assessment' guide - All AI-based systems/techniques must be ethical and comply with the principles and values as enshrined in the EU Charter of Fundamental rights and the EU Treaties. This requires specific ethically-focused approach during the design, development, deployment and/or use of AI based solutions.
Such approach must be built upon the following key prerequisites for ethically sound AI systems: Human agency and oversight, Privacy and data governance, Fairness, diversity and non-discrimination, Accountability, Transparency, societal and environmental well-being

- **Clinical Trials template**

How do applicants know if the clinical trial template has to be used?

➔ When you enter the portal, look for the specific topic you want to apply to and check if the template is listed, if yes then it is mandatory

The new clinical study template does not contain the section “unit costs for clinical trials” – is this option “unit costs” still available, though? If yes, where should the applicants insert the calculation?

➔ **Unit cost not recognised in cluster health for clinical trials**

- **Proposal template**

Proposal template, chapter 2 Impact: "**impact canvas**": *layout*: how large should it be? *content*: how many aspects should be listed, how exhaustive should it be? (the template indicates "key elements")

➔ This is very flexible, how it suits you, gives just overall image of the narrative, you can change and move the boxes
➔ Canvas is optional, but D&E plan need to be drafted anyway

Will the new aspects of blind evaluation and right to react be used in the cluster Health?

➔ Not in the 2021 topics

The pathway to impact thinking is likely new to many applicants and probably also many of the evaluators. Will this affect the composition of the group of evaluators? And how do you plan to prepare the evaluators for the intervention logic criterion?

➔ No real change, it is just about better explaining ow to achieve impact, precise the target group and involve more the end users

- **Others**

What about the pilot on lump sum funding – are lump sum funded topics still foreseen? When are the results of this pilot expected?

➔ Not clear yet, periodic reports of the first pilots are currently coming in

A practical question regarding the 'do no significant harm' principle (per Article 17 of Regulation (EU) No 2020/852): when is it relevant? Does it apply to all projects or only those where the project activities may directly lead to harm of the six environmental objectives? If it's not relevant should it specifically be mentioned in the proposal as such or do we just leave it out?

➔ Applies mainly to economic activities (EIC Accelerator) – need to consult the Horizon Europe programme guide and the Horizon Europe briefing slide for experts
➔ Ask information about the principles in the template but the experts will not evaluate this aspect in the criteria - unless stated otherwise in the WP