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Sustainable and Secure Society
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Questions and Answers for project proposers Horizon 2020 "ICT for Health and Wellbeing"

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The Personalising Health and Care work programme 2014 of Horizon 2020 (H2020-PHC-2014) - Societal Challenge "Health, demographic change and wellbeing" - contains the following topics related to ICT for Health and Wellbeing ("eHealth"):

- PHC-26-2014: Self-management of health and disease: citizen engagement and mHealth
- PHC-34-2014: eHealth interoperability

These two calls have 15 April 2014 as deadline to apply.

Questions related to these topics, received by the Health and Wellbeing unit of DG CONNECT, will be answered in this document. It will be updated regularly when new questions are received. New or updated questions from previous versions of the document are marked *[New Question]* or *[Updated Question]*.

These questions (Q) and answers (A) are by no means binding nor do they reflect an official position of the Commission. They are intended solely for clarification purposes. Some of the questions have been edited for linguistic reasons.

European Commission

DG CONNECT

Unit H1 – Health and Wellbeing

ec.europa.eu/digital-agenda/ehealth

Content

Q1: How crucial is the certification of software and of hardware plus software?

(Sub-topic PHC26 ii)) *Since the call addresses health applications which should benefit health data management, and since it equally addresses prevention and disease management, how crucial is the certification of software (mHealth applications) and of hardware plus software in the context of medical device regulatory frameworks?*

[Data and data management used in formal healthcare (e.g. for tele-diagnosis or control) is a serious issue. Without certifications, this remains just informal healthcare.]

A1: The question revolving around regulation in research and innovation projects is twofold.

On the one hand, regulations are requirements for the safe use of devices in healthcare delivery settings. On the other hand, it is strongly recommended, for peace of mind, to introduce innovation in care-path evidence of validated data and rigorous risk assessment of hardware and software.

The proof of concept and small scale clinical/medical validation tests are typically part of the key objectives of the project, which should address the impact-related issues. The project will have to request a formal approval from national/local ethical authorities within the first months following its kick-off and before the clinical trials can start.

It seems obvious that the medical professionals behind the concept design and software architecture will have to also contribute to writing the rules for the regulatory bodies. Yet, whoever writes the rules needs validated data.

Q2: How important it is to achieve or define the certifications during the life time of the project?

(Sub-topic PHC26 ii)) *How important it is to achieve or define the certifications during the life time of the project (i.e. the whole system from the device to the mobile application)?*

[It is seems that nearly all mHealth applications at the moment are currently not certified, just like most of the platform-like solutions (coming out of EU funded projects as well) which can be used to create the mHealth and health application ecosystem, and most of the hardware devices integrated in such platforms, be they a system or individual product. A lot of software applications, platforms and integrated hardware might have applied standards which can be useful in the certification process (e.g. according to the Continua Health Alliance).]

A2: While health and wellbeing apps currently on the market are designed primarily for consumer business without certification, the PHC26 ii) target is to address some of the big societal challenges where health self-care and disease management could help. In healthcare, the analysis of medical risks must be done carefully.

The key focus in this sub-topic PHC26 ii) is rather to develop novel, high-end and/or care-path centric apps useful in self-care as a part of the public or private healthcare delivery.

The focus in this sub-topic is neither platform development nor consumer health business. The key outcomes may include validated clinical/medical data that is IT

platform agnostic. If the existing IT platforms and middleware, including relevant healthcare non-specific attributes, can be applied, this could ensure more time for the actual development of the apps and validation.

Given that the certification of a complete integrated medical system is a big challenge, the appropriate issuance of certifications through the project would be considered an asset (see also A3). The certification itself is a sensitive legal and medical matter that would need special attention.

[New Question] Q2.2 What about the planning of a software platform?

(Sub-topic PHC26 ii)) *Does the software platform need to be already in place, or is it suitable here to plan its installation and therefore to budget the related cost?*

A2.2: The consortium should define necessary resources and budgeting to conceptualise and implement the platform. The characteristics of the platforms or needs for any further software development should be agreed between the partners.

Q3: Is a running mHealth application ecosystem expected at the end of the project?

(Sub-topic PHC26 ii)) *Does the European Commission expect at the end of the project a certified (according to the medical device regulations) running mHealth application ecosystem? Or is it sufficient to align the proposal with certain activities, such as standardization work and business development or process changes (driven by insurance providers, for example), which could allow the transfer of the project results and the project model to the formal care?*

A3: An improvement of the mHealth ecosystem for professional use (including the use of the mobile devices by patients, professionals or informal carers) would indeed be seen positively by the EC. Standardisation is typically the incarnation of the regulation and a natural part of a PHC26 project. If MDD or other regulations/certifications/guidelines can be applied, it is obviously an advantage.

However, this is not an automatic precondition in this call because a) a number of high-end apps with R&D&I potential might not qualify as medical devices, but could be considered useful for the healthcare delivery system, in the scope of PHC26 ii), and b) the foundation for the rules will have to be established first, before they can be consolidated and agreed upon.

Q4: Can an app be tested as part of a project?

(Sub-topic PHC26 ii)) *To validate or improve the technology/service in a real setting and to demonstrate its value is there any reason why an app could not be tested as part of a project under this topic?*

A4: Whatever is needed to make the expected impact on the entire solution and its components, as listed in the Work Programme, is subject to evaluation. Proof of concept and small scale validation may well serve this purpose. Clearly, in the medical domain evidence is needed. Lack of it will not ensure access to the healthcare market nor will it demonstrate a credible project proposal.

Q5: How close to the market can you come?

(PHC26 i and ii) *How close to a "market ready app" could you come under PHC 26, knowing that it is not a demonstration project as such?*

A5: The app can position itself as far as a working prototype, proof of concept and small scale validation following the rules of "General Annexes, D. Types of action: specific provisions and funding rates, Part 18 - Page 8 of 34".

PHC26 is a "Research and innovation action". It is not simply an "Innovation action".

Q6: Is some degree of technology needed?

(Sub-topic PHC26 i)) *Our proposal is expected to focus on health literacy. Reading the text, however, we get the impression that some degree of technology development is also required. Is this true and if so what kind of technology would that be?*

A6: Indeed, ICT is expected to be present in the solutions addressed by this topic - in the broader context and concept development of self-management of health and disease.

It is important to show clear innovation, be it at the component level and/or system level and/or service level, and to show how the proposal will make the expected impact. Selecting a narrow topic will have a direct effect on writing the proposal because it will be challenging to go beyond state of the art.

Q7: What is better: addressing as many issues as possible or specialize?

(Sub-topic PHC26 i) or ii)) *It seems that the scope of the sub-topic is quite broad. Would you advise to take this "broadness" into account by trying to address as many issues as possible or do you think it is better to specialize? [E.g. If one of our researchers were to focus on health in the workplace, would it be better if they broadened their scope to also include the home-situation or would they be better off keeping a narrow focus?]*

A7: It is important to build up a credible and strong case. The elements discussed in this topic and call budget allow the proposers to define the size of the project and extend the scope as they wish. It is up to the consortium to determine how broad the scope should be.

Q8: Development of new technologies or improving existing ones?

(PHC26) *Does the topic ask for the development of new technologies or does improving existing technologies also fall within its scope?*

A8: It is important to indicate in the proposal what is applied and what basic research, what technology is developed and what is taken as "ready", what is extended (see A6).

It is essential to build up the case in a way that is credible, with stepping stones, increasing complexity and realistic goals. As for the maturity of the technologies, it is up to the proposer how they see it (e.g. a project proposal focusing on a plain sensor development with limited links to the expected impact as stated in the WP is marginally

in scope). It is advisable to make the end goal/concept/case crystal clear and map it with the expected impact. The team of partners would have to agree on these aspects right from the outset.

Q9: Who should apply?

PHC26 i) and ii)) seem to be primarily intended for developers. Could you please elaborate who should apply?

A9: Whatever the situation, one should make an effort to build up the case with S&T excellence regardless who leads and how the consortium is built up. In brief, there are many types of challenges requiring different approaches in terms of academic, business ambitions or how the new services are introduced. Stretching the state of the art is an important element for making the expected impact. The call is open to any stakeholder group relevant to the domain.

Q10: Can you clarify "migration path"?

(PHC26 i)) Please clarify the last bullet point under (i) citizen engagement in health, well-being and prevention of diseases - A migration path towards comprehensive solutions that could be incorporated into healthcare processes. Is this in reference to the IT tools being developed or to the general health system?

A10: The migration path to healthcare delivery could improve the market potential, thus enabling businesses and services to become more sustainable. The proposals will not be rejected if a public player is not an official partner (depending on each case).

Q10: Can you clarify "multi-stakeholder ecosystem"?

With regard to developing a multi-stakeholder ecosystem, is it necessary to include all stakeholders listed here in proposals or only wherever relevant?

A11: The expected multi-stakeholder ecosystem relates to the consumer business models and ecosystem. The project will select those stakeholders that are relevant and necessary to build up the case. See A3, A5 and A9, they are all interrelated.

Q12: What is the background of the evaluators?

What is the background of the evaluators? Are they coming from health or IT, as it may influence the presentation of the project proposal?

A12: The EC departments carefully select the experts from various disciplines, mapping the content/concept of each proposal and the call text. In PHC26 a balanced team of experts includes (but is not limited to) competencies in medicine, healthcare, IT, business, research, policy and/or different set of skills from various types of end users.

Q13: Is the call focused on outreach or assessment?

(PHC26 i) and ii)) *Is the call focused on the advancement and outreach of technology to the citizen and patient or is it rather focused on the thorough assessment of the advancement of that technology so as to prove it is clinically effective?*

A13: Thorough assessment is not feasible in "Research and Innovation action", but small scale clinical trial is encouraged (see A5 interrelated).

Q14: Is the use of mobile devices mandatory?

(PHC26 ii)) *Is the use of mobile devices mandatory, or can it be a combination of internet and mobile based interventions (to achieve the expected results)?*

A14: The aim of this sub-topic is to build up a case based on the real needs. Therefore, any concept that can effectively combine cross sectorial competencies, including mobile-based interventions, falls within the scope of the call.

Q15: Can you clarify "pre-frailty"?

(PHC26 ii)) *How should the word "pre-frailty" be interpreted? Is it related to ageing? Or is it related to any preliminary state of decreased health (due to a disease)?*

A15: As the words "screening for pre-frailty states" appears under point "ii) mHealth applications for diseases management" in the Work Programme, "pre-frailty" should be interpreted in the context of disease management and not ageing.

Q16: What does "eco-health system" mean?

A16: "Eco-health" examines changes in the biological, physical, social and economic environments and relates these changes to human health.

Q17: Which disease should we focus on?

(PHC26) *Is it appropriate focusing on a specific disease such as Parkinson, even if we are treating all stages of the disease including early detection? And could it be wise to address two main medical targets: Parkinson disease and post stroke?*

A17: The call text does not comment on the pathology i.e., selection of diseases. Therefore, we have no comment on the selection of Parkinson disease and related areas.

Q18: Is it enough to have only one pilot site?

(PHC26) *Is it enough to have only one pilot site, which is able to attract from 50 to 100 patients in the experimentation phase? Or is it necessary to have more pilot sites in EU?*

A18: The number of pilot sites is undefined in the Work Programme.

Q19: Can you give any comments on our proposal?

We're not sure if our proposal is okay or not, can you please help us?

A19: For reasons of equal treatment of all potential applicants, the Commission is not in a position to give individual advice on proposals. This is primarily the task of the national contact points and other regional or institutional support offices.

All proposals will be evaluated by external peer reviewers and not by Commission staff. The Commission cannot interpret the call topic beyond the written text.

Q20: Is our proposal in scope of the call?

A20: The final assessment of whether something is considered in the scope is provided exclusively by the evaluators. The evaluation procedure is described in section "IV.2.2 Evaluation of proposals and operational capacity check" of the "Grants Manual - Section on: proposal submission and evaluation".

From our side, there are no additional guides related to specific topics as published in the call text. There is also no list of diseases that shall be considered or are excluded from this topic. We recommend that you analyse the description of the topics and the relevant documents carefully. We also recommend to seek advice from experts in the field.

[Updated Question] Q21: Are partners from the US accepted?

I am a US-citizen. Can we include a US site as a project partner in the proposal - if there is any possibility (and eligibility for funding), or can I just be included working for an EU-site?

A21: In footnote 28 of part 8 of the Work Program it says: "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 supported under all topics in calls under the Societal Challenge 'Health, demographic change and well-being'." So that means US sites can be included as project partner.

You can also check the relevant documents, e.g.: Standard eligibility criteria; List of countries, and applicable rules for funding; H2020 Online Manual.

[New Question] Q22: Is a dissemination plan required for sub-topic PHC 26 i)?

Section 2.2 of the Proposal Template, Measures to maximise impact (a) Dissemination and exploitation of results) states: "Provide a draft 'plan for the dissemination and exploitation of the project's results' (unless the work programme topic explicitly states that such a plan is not required). For innovation actions describe a credible path to deliver the innovations to the market. The plan, which should be proportionate to the scale of the project, should contain measures to be implemented both during and after the project."

Does this equally cover the sub-topic PHC 26 i), which is a "Research and Innovation action"? If it is not required, would it still be of value to include one? How can we include "measures to be implemented… after the project" when there will be no funding available?

A22: The dissemination and exploitation plan concerns all topics using the "Research and Innovation action" instrument in the Work Programme. It is meant to improve the quality and credibility of the proposal and to put the potential results in a realistic context. Even though "Research and Innovation action" may differ from "Innovation action" because the latter is closer to the real implementation and market, a sound dissemination and exploitation plan would pave the way for implementation.

[New Question] Q23: Gathering evidence can take a long time, how to handle that in this call?

If an expected impact requires a "strengthened evidence base on health outcomes, quality of life…" for a given intervention, then it requires research on the effect of the intervention. To show "evidence… related to… disease prevention" requires a very long clinical trial. How can the challenge be addressed in this call?

A23: The question of small v. large scale trial is a real concern in healthcare. PHC 26 has selected "Research and Innovation action" as an instrument that will not provide opportunities for large scale, long-term trials when compared to "Innovation action". However, the number of patients or the duration of the trial depends on the approach taken by the proposer.

There is a free choice in PHC26 as long as the plan is realistic and the proposal demonstrates convincingly how it goes beyond the state of the art. In practice, developing the concept from basic research to full-fledged clinical trial may be unrealistic, but first results on the efficacy and efficiency may be demonstrated also within the given timeframe. Other instruments will be introduced in future calls in order to address issues related to research on service provisioning and large scale deployment of innovative services and large scale trials, respectively.

[New Question] Q24: Support for knowledge infrastructures?

Under PHC26, "Support for knowledge infrastructures is also required...". In applying to PHC26 i), does this mean that infrastructures need to be put in place to collect knowledge or to deliver knowledge to a user/key stakeholder, or both?

A24: The consortium defines the level of details and complexity related to knowledge infrastructure depending on the case e.g., there might be support to infrastructure already in place or to knowledge management on existing sources of data.

[New Question] Q25: Research monitoring?

Under PHC26, a specific challenge is: "… research into socio-economic and environmental factors, dietary impact and cultural values, behavioural and social models... in relation to personalised health technologies. ... for monitoring and personalised services and interventions which promote a healthy lifestyle, well-being, ...

and personalised programmes for disease management". Is it sufficient to undertake a research review as part of the submission and put in place an appropriate system/capacity for analysing this research question in the future (beyond the lifetime of the project)? [In applying to PHC26 i), the challenge is that it may not be possible to collect significantly large amounts of data within a clinical trial to actually tackle this issue effectively.]

A25: Appropriate partitioning of the project in different elements including interim reviews and contingency plan should be carefully considered.

[New Question] Q26: What about predictive modelling?

Under PHC26, a specific challenge is: "... the combination of predictive personalised models with personal health systems and other sources of data". Is it sufficient to put in place a system/capacity for predictive modelling and articulate how it would be implemented/used without actually applying data to it? [In applying to PHC26 i), the challenge is that it may not be possible to collect significantly large amounts of data within a clinical trial, which would make the application of predictive modelling challenging/prohibitive.]

A26: Inclusion of predictive modelling is not compulsory for the projects. Uncertainties and limits should be taken into account when using predictive modelling. Please note that PHC26 i) focuses on consumer health and eco-systems rather than healthcare delivery, where large amounts of clinical data may be sometimes.

[New Question] Q27: Is a holistic health topic necessary?

Under PHC26, 'Scope', "Health management should be addressed in a holistic approach, from healthy lifestyle, dietary habits interlinked with disease management, and adherence to medical plans ...". In applying to PHC26 i), does this mean that it would be inappropriate to solely address one issue of a healthy lifestyle, namely exercise/physical activity, excluding the issues of dietary habits, smoking, alcohol consumption, etc.?

A27: The proposer should define which attributes mentioned in the Work Programme are applicable. See also A6 concerning a narrow topic which may be fully appropriate if the case is well designed.

[New Question] Q28: How can we implement coordination efforts in PHC 34?

Regarding PHC 34, there clearly is a need for a coordination effort across the four challenges, since there are many inter-relationships and we can anticipate there will be few essential overlapping partners. How can a proposal implement those coordination efforts?

a. Can two stages processes be envisaged, in order to have a first selection of proposals for the four challenges, then the selection of a coordinator in a second stage?

A28 a: No, all proposals will be evaluated through a single stage process, as indicated in the Work Program.

b. If not, how can we ensure the necessary collaboration between the 4 CSAs?

A28 b: The idea to have coordination activities between the different CSAs is certainly good. A consortium answering to one of the challenges could allocate part of its budget to coordination with the other CSA projects under PHC34, whatever they are and whoever will win the individual challenges. Budget for coordination activities could be also secured in different proposals from different consortia addressing the different challenges.