EUROPEAN COMMISSION
Directorate-General for Communications Networks, Content and Technology

Sustainable and Secure Society
Digital Social Platforms

Brussels, 8 February 2014

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

Document history	
Version 1	8 February 2014

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.

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?

(Sub-topic PHC26 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 select the experts carefully 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 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: PHC26 ii)) 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: The Work Programme specifies the following: "Proposals should focus their research on application development for disease management with the following characteristics: […]." "Pre-frailty" should be interpreted in the context of disease management.

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: What is the budget for eHealth interoperability?

(PHC34) *What is the budget for this topic and its subtopics?*

A17: The total budget is € 4 million for the topic and its subtopics, for which one proposal and one consortium is expected.