Frequently asked questions concerning the Horizon 2020 societal challenge "Health, demographic change and wellbeing"

Note that the present document should be read in conjunction with this additional guidance on topics PHC19 and PHC20, as well as topics HCO1 and HCO2, concerning "advancing active and healthy ageing with ICT" in the "health, demographic change and wellbeing" societal challenge of Horizon 2020.

Document history	
Version 3.1	16 May 2014

The present document is subject to ongoing revision and further questions may be addressed to the research enquiry service. Our goal is to answer questions within 5 working days and a new version of this document uploaded to reflect this.

1. Contact with European Commission staff and the purpose of these FAQ

I would like to talk to a member of the EC staff to ensure that I understand the requirements of the topic. Why haven't you published contact names for EC staff as in previous years?

Our goal is that the work programme and accompanying information provided on the participant portal provide all of the information that an applicant requires in order to have a fair and equal chance of accessing Horizon 2020 funding.

While there is no question that EC staff have in previous years provided fair and independent guidance on work programme topics, it is important that clarifications issued to one set of potential applicants are made available to all, for reasons of fairness and transparency.

It is also the case that despite our best efforts, some information may not be quite as clear as we would like; we therefore consider the provision of FAQ to serve the dual goals of fairness and transparency, and the need to respond to the legitimate questions posed by potential applicants.

This is a living document and as indicated above, further questions may be submitted to the research enquiry service. Our goal will be to respond to these questions within 5 working days, publishing a new version of these FAQ.

The topics as published are entirely self-contained. Evaluators will evaluate proposals solely based on the topics as published.

2. 2015 call deadlines

When will the 2015 call deadlines be announced?

The current version of the Horizon 2020 Health, demographic change and wellbeing challenge work programme (2014-2015) includes a disclaimer that the parts which relate to 2015 (topics, dates and budget) are provided on an indicative basis only. The formal adoption of the 2015 sections of the work programme is planned for mid to late July 2014, and depends amongst other things on the favourable opinion of the EU Member States, represented by a group known as the Programme Committee.

Without prejudice to the above, our intention is that PHC topics which are subject to a two stage evaluation procedure (2, 3, 4, 11, 14, 16, 18, 22 and 24) will see their first deadline in October 2014 and the second deadline in April 2015. PHC 12 (using the SME instrument) will see deadlines in March, June, September and December of 2015 (in addition to those already announced for 2014). PHC topics which are subject to a single stage evaluation procedure will see their deadlines fall in February (9, 15, 33) and April (21, 25, 27, 28, 29 and 30) 2015. The remaining HCO topics will see their deadline fall in February 2015.

3. Page limits, guidance on budget and consortium size, and on project duration.

What is the page limit for proposals?

In a two stage evaluation, the page limit for stage 1 proposals is 7 pages, and this includes the cover page. The page limit for stage 2 proposals, and for single stage proposals, is 70 pages (not including sections 4 and 5).

Example proposal templates can be found under the 'call documents' tab on the participant portal corresponding to each topic. Note that the proposal template is specific to the 'type of action' and you must ensure that you use the correct one.

What about consortium size, budget and project duration?

In line with the Horizon 2020 approach to be less prescriptive in topic descriptions, there is no limit on consortium size, budget or project duration. As, however, proposals are assessed according to a set of criteria which judge the quality of the work proposed, the likely impact of the work proposed, and the quality of and efficiency of implementation, applicants should justify the chosen size of consortium, budget and project duration according to their suitability to meet the goals of the proposal.

I have heard that there is unofficial guidance given to evaluators regarding the distribution of budget between partners. Is that true?

Absolutely not! The distribution of budget between partners is assessed according to whether or not it is appropriate to achieve the work proposed.

4. Understanding scope, expected impact and specific terms used in topic descriptions

Is my proposal in scope?

The European Commission will not advise potential applicants on whether or not their proposal is within the scope of the topic called for. Every effort has been made to ensure that the scope is clearly described in the corresponding section of each topic.

But terms are sometimes used which may have a specific meaning, and which are undefined. How can I be sure that my understanding of these terms is the same as that of the evaluators?

The European Commission uses independent, high level experts (further information on whom is included in the question below) to review all proposals received. Unless an explicit definition of a term is given in a topic description, or elsewhere in the work programme, you may assume that meanings of terms are understood by the evaluators as those which represent the general consensus of experts working in that domain at this time.

Likewise, evaluators will evaluate (amongst other criteria) proposals on the basis of the expected impact statements. Proposers are therefore advised to read the 'expected impact' statements closely in order to determine whether or not their interpretation of a term is more or less likely to convince evaluators that the expected impact will be achieved.

Additional guidance on terms used in specific topics is however requested, and this is provided below:

- The term ‘prevention’ as used in PHC4 is intended to refer to ‘primary prevention’ only.

- Eligible ‘biomarkers’ are defined in PHC12 as *in vivo* and *in vitro*, and clarification is provided that ‘preference will be given to the validation of disease related biomarkers (i.e. diagnostic, susceptibility/risk, monitoring and prognostic biomarkers)’ as well as to ‘the validation of biomarkers with high potential for short term uptake into clinical practice’.

- The term ‘chronic, non-communicable disease’ as used in PHC13 may be understood to conform to the definition provided by the World Health Organisation, in which the four main (but not only) types are described as being cardio-vascular diseases, cancers, chronic respiratory diseases and diabetes.

- The reference to the guidelines and policies of the International Rare Diseases Research Consortium, IRDiRC, in PHC14 clarifies the definition of the term ‘rare diseases’.

- PHC11 includes a statement that ‘the novel application of existing tools and technologies is not included’ in the scope of the topic. One may reasonably then ask if this means that the combination of existing technologies to create a new tool is also excluded. This is not the case; the specific challenge text states that ‘innovation in this area relies on the development, translation and update of existing, new or evolving, and often complex technologies’. Thus the creation of a new tool from existing technologies would be considered an innovation and such an application would be scored according to the extent to which it would have the desired impact.

- Also, in PHC11, work which makes use of cells or cell lines is not explicitly excluded. It does however seem that evaluators would consider such work ‘ex vivo’ and would be likely to score such a proposal correspondingly less well. Proposers are encouraged to think carefully about the extent to which they focus on such activities, in the light of the requirements listed in the expected impact section, namely, ‘the provision of new in vivo diagnostic tools and methods…’.

If you are concerned that your understanding of a term may differ from conventional wisdom (given the emphasis that the European Commission places on innovative ideas, new participants and ground-breaking research this cannot be excluded) you are advised to be explicit in your application and to provide a sound justification.

Topics sometimes include more than one ‘expected impact’. Am I supposed to demonstrate that each of these expected impacts is likely to be achieved? Or can I focus on a selection? When listed as bullet points, are ‘expected impact’ statements mutually exclusive?

Applicants who in the opinion of the evaluators demonstrate the greatest likelihood of achieving the greatest level of impact as described in the topic description will be scored the most highly in the corresponding section of the evaluation forms. Each expected impact bullet point is not necessarily entirely independent of the others, reflecting the complex nature of the challenges described and the often interdisciplinary approaches required.

5. **Who will evaluate my proposal? Are the experts used at stage 1 identical to those used at stage 2?**

The use of independent experts by the European Commission for the evaluation of proposals submitted in response to Horizon 2020 calls for proposals is described here.

The evaluation of stage 2 proposals is usually conducted by many of the evaluators who evaluated the shorter stage 1 proposal. If additional or alternative evaluators are used at stage 2, the reason for doing so (other than the unavailability of stage 1 evaluators) would be to reinforce expertise in a particular domain, or to remove expertise which is no longer relevant.

As you will be aware, the scope of topics has been enlarged in Horizon 2020 such that, for example, one topic may for example result in the selection for evaluation at stage 2 of proposals which focus on a variety of diseases. As such, if successful proposals relate to cancer and diabetes, but not to cardio-vascular disease, adjustments to the range of stage 2 evaluator expertise would be made.

6. Preparation of a stage 2 proposal

If I am successful at stage 1, can I make changes to my proposal when submitting the full version to stage 2?

Section III.5.2 of the Horizon 2020 Grants manual: Section on: proposal submission and evaluation states that for two-stage submission schemes, 'the full proposal must be consistent with the short outline proposal and may not differ substantially'.

This means that changes are not recommended, but if absolutely necessary, they should be clearly explained and the evaluators will determine whether or not these changes are legitimate, and whether or not their insertion compromises the evaluator judgement made at stage 1.

7. Clinical trials/studies/investigations

Which kind of clinical trials/studies/investigations can be supported under H2020?

Depending on the call topic, in principle any type of clinical trial/study/investigation can be funded under H2020. There is no restriction with regard to methodology (observational, interventional, (cluster-) randomised, etc.), type of intervention (medicinal products, medical devices, advanced therapy medicinal product, surgery, education/training or psychotherapy) or phase of clinical development ('phase 0' to phase 4).

In practice, the scope section of the topic description will indicate if any approach is preferred.

Does every clinical centre that enrols and treats/follows patients need to be included as a beneficiary?

Every clinical centre *can* be a beneficiary, and the Commission will not oppose or discourage a large number of beneficiaries for this purpose. Alternative ways to include and reimburse such clinical centres are:

(i) As third parties providing in-kind contributions against payment (Art. 11 of the grant agreement). A requirement for this is a written agreement between the beneficiary and the third party prior to the start of the work. These third parties need to document their costs in the same way as beneficiaries (actual costs or unit costs). Wherever possible, third parties should be listed in section B4.2 of the full proposal.

(ii) As subcontractors (Art. 13 of the grant agreement). In this case, the beneficiary needs to ensure that it complies with the obligation to ensure the best value for money and institutional rules for subcontracting and if the beneficiary is a public body, with national and EU legislation on public procurement. Subcontractors would not usually be named in a proposal given the necessity to undertake the processes required to ensure compliance with the conditions described above. If however such processes have been undertaken in advance, subcontractors may be named in a proposal.

(iii) Another option, to participate as 'linked beneficiary', is limited to entities that fulfil the specific conditions of Art. 14 of the grant agreement on 'affiliated entities and third parties with a legal link to a beneficiary'. As these conditions are rather specific, the use of this option is likely to be limited.

Can certain tasks of a clinical trial/study/investigation (CT) be subcontracted to a contract/clinical research organisation (CRO)?

Yes.

'Core expertise' needs to be available in consortium and only a limited part of the action can be subcontracted. But specialised services (pharmacokinetics, regulatory assistance etc.) from CROs might be indispensable for the implementation of the CT. 'Academic CROs' exist (e.g. the ECRIN network) and might be willing to become beneficiary. But most CROs are for-profit and the Commission will consider accepting subcontracting in these cases. If CT is just a small part of the action, i.e. if most of the research performed is preclinical activity, the CT might even be subcontracted in its entirety.

Is the use of the template for 'Essential information to be provided for clinical trials/studies/investigations' mandatory?

When the use of the template is mandatory, this will be indicated on the participant portal. Of the topics currently undergoing evaluation, the use of the template is mandatory for PHC-1, PHC-5, PHC-10, PHC-13, PHC-17 and PHC-23 only.

In all other cases, if a proposal contains a CT, you are welcome (but not obliged) to use the structure provided in the template (or a version adapted to the characteristics of your particular CT) and integrate this information into the appropriate work package or any other appropriate section of the part B of the proposal.

Which costs are eligible under H2020 in the implementation of clinical trials/studies/investigations (CT)?

Costs related to CTs can be reimbursed either as actual costs or as unit costs. The method to calculate unit costs for CTs is determined by Commission Decision C(2014) 1393. http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit costs_clinical_studies.pdf

Only unit costs calculated according to this methodology are eligible. Beneficiaries cannot use their own methodology to calculate unit costs.

What about cases where some partners (but not others) are reimbursed by their national health systems for certain tests or treatments?

For example, in a given country, the health insurance might reimburse two MRIs in the course of the treatment of a patient as part of a clinical study. If the clinical study requires three MRIs, only the additional one should be reimbursed by the Commission for the beneficiary in the given country to avoid double financing. All other partners will claim the costs for all three MRIs.

If unit costs are used, partners who are reimbursed for some of the resources should deduct that reimbursement from the unit cost, and claim a correspondingly lower amount.

Is the use of unit costs for clinical trials/studies/investigations mandatory?

No, it is an option. Each beneficiary can choose independently, whether it wants to use unit costs or the normal way of documenting actual costs.

Is more detailed guidance available for the use and calculation of unit costs?

Yes. Detailed guidance on the use and calculation of unit costs is available as part of the template/guidance on 'Essential information to be provided for clinical trials/studies/investigations'.

8. Small and medium sized enterprises in PHC12

The templates for the SME instrument proposal state that phase 1 proposal costs will be reimbursed at 70%, yet the societal challenge 1 work programme says that PHC12 (which uses the SME instrument) is reimbursed at 100%. Can you explain?

PHC12 phase 2 is reimbursed at 100%, in contrast to the use of the SME instrument in other parts of Horizon 2020, where phase 2 is reimbursed at 70%. PHC12 phase 1 is however reimbursed at 70%. But as phase 1 is a fixed-size grant of EUR 50.000, the reimbursement rate is a technicality (all successful applicants will receive the fixed-sum of EUR 50.000). Applicants must nevertheless declare €71,428.57 as their overall budget for phase 1 of PHC12.

Further answers to FAQ on the SME instrument are available here.

9. Open data pilot

The proposal templates talk about an 'open data' pilot. Is SC1 part of the open data pilot?

No, but projects can participate on a voluntary basis should they so wish. Further information is available here and here.

10. Swiss participation

What is the status of Swiss participants in SC1 of Horizon 2020?

Please refer to the general Horizon 2020 FAQ section on Swiss participation.

11. United States participation

Can US organisations be funded in SC1 of Horizon 2020?

The general Horizon 2020 rules on non-EU country or non-associated country participation can be found here and here. In general, organisations from the United States of America can participate in Horizon 2020 projects but they are eligible for funding only in exceptional circumstances as described in the above links.

Societal challenge 1 is however an exception to this general rule. As indicated in the current health, demographic change and wellbeing challenge work programme, footnote 28 on page 57 states that "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'".

A further exception to this exception concerns PHC12 for which applicants must be legally established in an EU Member State or an Associated Country.

12. Technology readiness levels

What are Technology Readiness Levels (TRLs) and are they applicable to the health, demographic change and wellbeing challenge?

Technology Readiness Levels (TRLs) are a measurement of the maturity level of particular technologies. This measurement system provides a common understanding of technology status and addresses the entire innovation chain. There are nine technology readiness levels; TRL 1 being the lowest and TRL 9 the highest.

TRLs are not commonly used in the health sector and for that reason no references to TRLs have been made in topics of the Societal Challenge 1 Work Programme 2014-2015. References to TRLs in any other supporting documents (as for example the Guide for Applicants) should then be disregarded: in particular, the general reference to the use of TRL in the SME instrument does not apply to PHC12. The use of TRL is under review for WP2016/2017.

13. Participation of ERICs (European Research Infrastructure Consortia) in H2020

What is the status of an ERIC in a proposal, in terms of eligibility criteria?

Unless the call imposes conditions additional to those provided for in the rules for participation, an ERIC, being composed of at least three legal entities from different member states, could theoretically be eligible as a single beneficiary of a grant in societal challenge 1.