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 PHC 19 and PHC 20, 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 3.4	11 August 2014
Modifications (compared to Version 3.3):	- Question 4: modification for the topic PHC 14.
Version 3.3	25 July 2014
Modifications (compared to Version 3.2):	- Question 1, 2, 3, 5: Editorial changes for clarity. - Question 4: modification for the topic PHC 14. - Question 7: Addition of questions on (i) no annexing of additional documents, (ii) prescribed format for unit costs, (iii) agreement on unit costs lower than actual costs. Update of topics for which template is applicable and how to integrate CT information into other applications. - Question 12 added (WHO participation).
Version 3.2	24 June 2014
Modifications:	- Question 2: Instruction to refer to the participant portal for distribution of topics according to calls and deadlines rather than a listing of topics. - Question 3: Clarification of links to proposal templates as 2015 templates are not yet available. - Question 4: Clarification of terminology used in PHC 4 and PHC 22. - Questions 5, 7, 8, 9: Editorial changes for clarity. - Question 14 added (use of animal models).

The present document is subject to ongoing revision and further questions may be addressed to the National Contact Points (NCPs).

Contents

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 has 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 National Contact Points (NCPs).

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?

Please refer to the corresponding sections of the participant portal for the attribution of topics to deadlines.

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

What is the page limit for proposals?

Note that in the case of Societal Challenge 1 (SC1) in a two-stage call for proposals, the page limit for stage 1 proposals is 7 pages and not 15, 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).

The 2015 proposal templates will be published once the call is open. Make sure that you use the correct version when preparing submission as while substantial changes are unlikely, the correct forms must still be used and minor changes cannot be excluded.

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. Please refer to your NCP for any further related question.

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 expert evaluators is included in question 5) 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 **PHC 4** is intended to refer to 'primary prevention' only. In the same topic, "Existing international activities" would include, for example, the Canadian Institutes of Health Research Initiative on the Environments and Health (http://www.cihr-irsc.gc.ca/e/43567.html).

- Eligible 'biomarkers' are defined in **PHC 12** 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 **PHC 13** 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.

- In **PHC 14** the term 'rare diseases' should be understood as defined in the Regulation (EC) No 141/2000 (http://ec.europa.eu/health/files/eudralex/vol-1/reg_2000_141/reg_2000_141_en.pdf). Proposals should advance the development of new therapeutic options for patients living with rare diseases and contribute towards IRDiRC objectives (see www.irdirc.org).

For information about how to apply for an Orphan Designation, please see the EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000519.jsp&mid=WC0b01ac05804ece5e.

The EMA website also provides an explanation for how to submit for Scientific Advice and Protocol Assistance:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000049.jsp&mid=WC0b01ac05800229b9.

- **PHC 11** 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 **PHC 11**, 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…'.

- What does the word 'physical' mean when used in **PHC 22**? Physical here is used in a very broad sense and should be read as an example of the breadth of the work that is invited. To put in in another way, the text says "Proposals may address the role of external or internal determinants of mental health, including…". Thus physical stressors may include too much light, noise, insufficient physical exercise, various mechanical stressors, as well as the built environment, and so on.

Applicants may be as broad or as narrow as they like, but all things being equal, two proposals of equal quality in all other respects would be differentiated on the basis of the expected impact – such that one which looks at more factors will score more highly. Of course, applicants will be best placed to determine whether or not taking too broad an approach will have a negative effect on the quality of the rest of the proposal.

- Also in **PHC 22**, what are 'internal determinants of mental health'? Objectively, 'internal and external determinants' means: everything that may have an impact on mental health, intrinsic and extrinsic. Applicants should note that the topic talks about 'wellbeing' which necessitates an holistic approach: brain structure and function, for example, are clearly included in the 'intrinsic' or 'internal' factors. But looking only at mental wellbeing through the lens of brain structure, function and pathology (again, for example) might not encompass all of the factors that have an effect on wellbeing. The topic therefore calls for a broad examination of a variety of factors which impact mental wellbeing. If you remain 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. You are also welcome to direct any further questions to the Research Enquiry Service as indicated above.

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. Evaluation of proposals

Who will evaluate my proposal? For two-stage calls 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.

The scope of topics has been enlarged in Horizon 2020 such that, for example, one topic may 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?

A template 'Essential information to be provided for clinical trials/studies/investigations' is available under 'Call Documents' in the Partcipant Portal. Of the topics currently undergoing evaluation, the use of this template is mandatory for all clinical studies included in a single-stage or second stage of the two-stage proposal submitted to topics:

- For the calls of 2014: PHC 1, PHC 5, PHC 10, PHC 13, PHC 17 and PHC 23
- For the calls of 2015: PHC 2, PHC 3, PHC 11, PHC 14, PHC 15, PHC 16, PHC 18, PHC 22, PHC 24, PHC 33 and HCO 6.

For these topics, you will have the possibility to upload the completed template as a separate part of your application in the submission system.

For all other topics, 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 in section 1.3 ('Concept and approach') or in the relevant work package in section 3.1 ('Work plan – Work packages, deliverables and milestones') of part B of the proposal. If required, the table provided in section 1.9 of this template on unit costs can in this case be provided in section 3.4 ('Resources to be committed') of part B of the proposal.

Can applicants annex detailed protocols or other documents to the template for clinical trials?

No, only the information specifically requested in the template should be provided. Additional sections or annexes (such as full trial protocols) will be disregarded and not evaluated.

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. When a beneficiary intends to use unit costs, the detailed and complete calculation must be provided in Table(s) X.9 of the above mentioned template.

Can applicants use a different format or a different methodology for the description of unit costs?

No. Description of unit cost that do not adhere to the table provided and follow the instructions and conditions in the Commission Decision cannot be accepted as a basis of unit costs – if such a proposal is successful, costs for the clinical trial will have to be charged on the basis of actual.

Can beneficiaries agree on unit costs per patient that are lower than their actual costs?

Calculations for CT unit costs must always comprise the full resources and costs per patient in the respective centre(s). We also recommend to always *claim* the full eligible costs. This is notwithstanding agreements in the proposal, the grant agreement and/or the consortium agreement to *reimburse* less than this full amount. Investigators could for example agree to reimburse the same fixed lump sum per patient for all centres – this lump sum needs of course to be lower or equal than the agreed 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, health insurance may reimburse only up to 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.

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 of its preferred method 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' available for download from the relevant 'call documents' tabs.

8. Small and medium sized enterprises in PHC 12

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 PHC 12 (which uses the SME instrument) is reimbursed at 100%. Can you explain?

PHC 12 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%. PHC 12 phase 1 is however reimbursed at 70% throughout Horizon 2020 (including SC1). 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 PHC 12.

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

9. Open data pilot

The proposal templates mention 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 PHC 12 for which applicants must be legally established in an EU Member State or an Associated Country.

12. World Health Organization participation

Can WHO be considered as an "international European interest organisation" and apply for EU funding?

According to the article 2 "Definitions", indent 12 of the Rules for participation - International organisations, "**international European interest organisation**" means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

Furthermore, international European interest organisations are automatically eligible for funding, in line with the article 10, letter b) of the Rules for participation.

As WHO cannot be considered as an international European interest organisation, the organisation is not automatically eligible for funding.

How can WHO participate in the H2020 projects?

Regarding the participation of the WHO as a beneficiary of H2020 funded projects two different concepts are to be distinguished:

The participation – Article 7 of the Rules for participation:

Article 7
Legal entities that may participate in actions

1. Any legal entity, regardless of its place of establishment, or international organisation may participate in an action provided that the conditions laid down in this Regulation have been met, together with any conditions laid down in the relevant work programme or work plan.

The funding – Article 10 of the Rules for participation:

Article 10

Eligibility for funding

2. In the case of a participating international organisation or in the case of a participating legal entity established in a third country, neither of which are eligible for funding according to paragraph 1, funding from the Union may be granted provided that at least one of the following conditions is fulfilled:
(a) the participation is deemed essential for carrying out the action by the Commission or the relevant funding body;
(b) such funding is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and the international organisation or, for entities established in third countries, the country in which the legal entity is established.

In summary, the WHO can participate in the H2020 actions if they fulfil the required conditions set by art. 7 paragraph 1 of the rules for participation.

Regarding the funding by the EU, at least one of the conditions set by the article 10 paragraph 2 of the rules for participation have to be fulfilled, i.e. either the participation is deemed essential for the action (this should be already indicated in the proposal) or there is a bilateral agreement.

You will find additional information from the Guideline on Third country participation in H2020, including also the participation of international organisations:

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-3cpart_en.pdf.

13. 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 PHC 12. The use of TRL is under review for WP2016/2017.

14. 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.

15. The use of animal models

I have heard that the Commission will not fund research which involves non-human animals. Is this correct?

No. All other relevant evaluation and eligibility criteria being satisfied, a proposal which convinces the evaluators that research conducted on non-human animals is necessary for the performance of the work may be funded and will then in some cases be subject to an ethics review as part of the usual evaluation procedure to ensure that the relevant standards are adhered to.