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Questions and Answers

Document history		Changes/ additions
Version 1	6 November 2015	
Version 2	24 November 2015	Additional questions: 9 and 15
Version 3	4 December 2015	Additional questions: 7 and 8
Version 4	16 December 2015	Addition of general questions and renumbering Replacement of question 41 with a different version on the same subject within the same topic Addition of question 49
Version 5	10 August 2016	Deletion of questions related to 2016 topics, deletion of one question on clinical studies unit costs and a question on the previous open data pilot, addition of question 33, minor edits.

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General questions

❖ Contact with European Commission staff, understanding scope, expected impact and specific terms used in topic descriptions

Question 1: I would like to talk to a member of the EC staff to ensure that I understand the requirements of the topic. Is there any published contact list for EC staff as it was done in previous years?

Answer:

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. 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). You can identify contact information for your National Contact Point. The topics as published are entirely self-contained. Evaluators will evaluate proposals solely based on the topics as published.

Question 2: Is my proposal in scope?

Answer:

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. You can identify contact information for your National Contact Point [here](#).

Question 3: How can I be sure that my understanding of specific terms in the call topic is the same as that of the evaluators?

Answer:

The European Commission uses independent 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. Any additional guidance on terms used is included in specific questions and answers for under 'Topic Conditions and Documents' for the topic concerned.

Question 4: 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?

Answer:

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.

❖ **2017 call deadlines**

Question 5: What are the call deadlines?

Answer:

The call topics and deadline for each topic can be found on the [Participant Portal](#) under Funding Opportunities > Calls > H2020, then by selecting open calls of Societal Challenge 1, Health, Demographic Change and Wellbeing. This information is also given in the [Work Programme 2016-2017 for Health, demographic change and wellbeing](#).

❖ **Page limits, guidance on budget and consortium size and on project duration**

Question 6: What is the page limit for proposals?

Answer:

The page limit depends on the funding instrument specified for a topic. Please refer to the standard proposal template provided on the participant portal under the 'Topic Conditions and Documents' for your topic of interest.

Question 7: What about consortium size, budget and project duration?

Answer:

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. The Commission suggests an EU contribution level for proposals for each topic but this does not preclude submission and selection of proposals requesting smaller or larger amounts.

As, however, proposals are assessed according to a set of evaluation 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.

Question 8: I have heard that there is unofficial guidance given to evaluators regarding the distribution of budget between partners. Is that true?

Answer:

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

❖ Evaluation of proposals

Question 9: Who will evaluate my proposal?

Answer:

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](#) and in [Annex H](#) ('Evaluation Rules') to the Work Programme.

❖ Clinical trials/studies/investigations

Question 10: Which kind of clinical trials/studies/investigations can be supported under Horizon 2020?

Answer:

Depending on the call topic, in principle any type of clinical trial/study/investigation can be funded under Horizon 2020. 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.

Question 11: Does every clinical centre that enrolls and treats/follows patients need to be included as a beneficiary?

Answer:

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), based on the fact that patient data are considered as the in-kind contribution. 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 with the 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.

Question 12: Can certain tasks of a clinical trial/study/investigation be subcontracted to a contract research organisation (CRO)?

Answer:

Generally, yes. Specialised services from CROs (such as GMP manufacturing, monitoring etc.) might be indispensable for the implementation of the clinical study but not available in the consortium. The Commission will consider accepting subcontracting in these cases. However, core study expertise such as general regulatory expertise, study design and high-level study management and oversight must be available in the consortium and cannot be subcontracted if the clinical study is the main element of the action. If the clinical study is just a small part of the action, i.e. if most of the research performed is preclinical activity, the clinical study might be subcontracted in its entirety. ‘Academic CROs’ exist (e.g. the ECRIN network) and might be willing to become a full beneficiary.

Question 13: Is the use of the template for ‘Essential information to be provided for clinical trials/studies/investigations’ mandatory?

Answer:

The template called ‘Essential information to be provided for clinical trials/studies/investigations’ is available under ‘Call Documents’ in the Participant 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 2017: PM-02, PM-07, PM-08, PM-10, PM-11 and HCO-07

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 clinical studies, you are welcome (but not obliged) to use the structure provided in the template (or a version adapted to the characteristics of your particular clinical studies) 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.

Question 14: Can applicants annex detailed protocols or other documents to the template for clinical studies or other sections of the proposal?

Answer:

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

Question 15: Which costs are eligible under H2020 in the implementation of clinical trials/studies/investigations?

Answer:

Costs related to clinical studies can be reimbursed either as actual costs or as unit costs. The method to calculate unit costs for clinical studies is determined by [Commission Decision C \(2014\) 1393](#). 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.

Question 16: Is the use of unit costs for clinical trials/studies/investigations mandatory?

Answer:

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.

Question 17: Does my proposal have an advantage when unit costs for clinical studies are used for the reimbursement of the clinical study? Or can an incorrect calculation of the requested unit costs for clinical studies have a negative impact on the evaluation results?

Answer:

No, both actual costs and unit costs for clinical studies can be used to calculate and describe the resources required for a clinical study and this has no influence on the scoring. Technical errors or misunderstandings in the calculation of unit costs will also

not have a negative influence on the evaluation results and can be corrected during the preparation of the grant agreement.

Question 18: Can applicants use a different format or a different methodology for the description of unit costs or can applicants define different or additional cost categories (e.g. for additional personnel categories)?

Answer:

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 study will have to be charged on the basis of actual costs.

Question 19: Which information from the accounting department is needed to calculate personnel costs when using unit costs model for clinical studies?

Answer:

Only the 'magic 3 numbers': For the calculation of personnel costs with the unit cost model only the 'average hourly cost' for 'doctors', 'other medical personnel' and 'technical personnel' documented in the accounts of the institution in year n-1 have to be provide by the accounting department of a legal entity. These 'magic 3 numbers' can be used for all unit cost calculations of this entity during year.

Detailed information about the calculation of personnel unit costs are available in the respective [Commission Decision](#) and in the clinical study presentation of the [Info Day 2016](#) of Societal challenge 1.

Question 20: How to deal with patient' drop-out' or long follow-up period when using the unit cost model for clinical studies?

Answer:

Unit costs can only be claimed for patients that have completed the entire protocol covered by the respective unit costs. In order to capture the costs of patient, who drop out of a clinical study prior to completion of the entire protocol, you might consider establishing 'sequential unit costs' for one clinical study, covering different treatment sequences or follow-up periods.

Question 21: Can beneficiaries agree on unit costs per patient that are lower than their actual costs?

Answer:

Calculations for clinical studies 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 than or equal to the agreed unit costs.

Question 22: What about cases where some partners (but not others) are reimbursed by their national health systems for certain tests or treatments?

Answer:

For example, in a given country, health insurance may reimburse only up to two MRI scans in the course of the treatment of a patient as part of a clinical study. If the clinical study requires three MRI scans, 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.

Question 23: Is more detailed guidance available for the use and calculation of unit costs and clinical studies in Horizon 2020 in general?

Answer:

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 'topic conditions and documents' section of each topic description. Detailed information about clinical studies in HORIZON 2020 is also available in the related presentation during the [Info Day 2016](#) of Societal Challenge 1 (in particular in the back-up slides after the core presentation).

❖ **The use of animal models**

Question 24: I have heard that the Commission will not fund research which involves non-human animals. Is this correct?

Answer:

If your question refers to "non-human primates", the answer is no. The Commission may fund research using non-human primates. However, such research is limited to purposes as defined in Articles 8 and 5 of the Directive 2010/63/EU on the 'Protection of animals used for scientific purposes'. Being in line with this Directive, any proposal has to satisfy all relevant evaluation and eligibility criteria, and has to convince the evaluators that research conducted on non-human primates is absolutely necessary for the performance of the work and for reaching the scientific objectives. Such a proposal would also undergo a strict ethics review to ensure that all required standards are adhered to.

❖ **SMEs**

Question 25: What opportunities are available for small and medium-sized enterprises under the SME instrument programme?

Answer:

Societal Challenge 1 contributes two challenges to the SME instrument call:

- SMEInst-05-2016-2017 – Supporting innovative SMEs in the healthcare biotechnology sector

- SMEInst-06-2016-2017 – Accelerating market introduction of ICT solutions for Health, Well-Being and Ageing Well

For SMEInst-05-2016-2017, phase 2 projects will be reimbursed at 100%. For SMEInst-06-2016-2017, phase 2 projects will be reimbursed at 70%. For both topics, phase 1 projects will receive a fixed amount of Euro 50 000. Please note specific limited cut-off dates for the two subtopics of SMEInst-05-2016-2017. Full details of the SME instrument call (H2020-SMEInst-2016-1017) are provided under the Horizon 2020 Work Programme area Innovation in SMEs (Part 7 of that Work Programme).

❖ **Technology readiness levels**

Question 26: What are Technology Readiness Levels (TRLs) and are they applicable to the health, demographic change and wellbeing challenge?

Answer:

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, defined in [Annex G of the H2020 work programme](#); TRL 1 being the lowest and TRL 9 the highest.

The use of TRLs in the SC1 Work Programme 2016-2017 is mentioned only in relation to topic SMEInst-06-2016-2017 – Accelerating market introduction of ICT solutions for Health, Well-Being and Ageing Well (SME instrument call H2020-SMEInst-2016-1017).

For other topics in SC1 Work Programme 2016-2017, 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 SMEInst-05-2016-2017 –Supporting innovative SMEs in the healthcare biotechnology sector.

❖ **Participation of third countries, WHO and ERICs**

Question 27: What is the status of Swiss participants in SC1 of Horizon 2020?

Answer:

Please refer to the general Horizon 2020 FAQ section on [Swiss participation](#).

Question 28: Can US organisations be funded in SC1 of Horizon 2020?

Answer:

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 Health, demographic change and well-being Work Programme 2016-2017, page 72: "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 the following topics: SC1-PM-02-2017, SC1-PM-03-2017, SC1-PM-07-2017, SC1-PM-08-2017, SC1-PM-10-2017, SC1-PM-11-2016-2017, SC1-PM-15-2017, SC1-PM-16-2017, SC1-PM-17-2017, SC1-PM-20-2017, SC1-HCO-03-2017, SC1-HCO-07-2017, SC1-HCO-08-2017." (2016 topics omitted)

Question 29: Can WHO be considered as an "international European interest organisation" and apply for EU funding under Horizon 2020?

Answer:

WHO is an international organisation, but it is not considered an "international European interest organisation". Therefore, WHO is not automatically eligible for funding in normal competitive calls. However, if the participation of WHO in an action is deemed by the Commission to be essential for carrying out that action the WHO may be eligible for funding. Further information concerning funding of applicants from non-EU countries & international organisations may be found [here](#).

Question 30: What is the status of an ERIC in a proposal, in terms of eligibility criteria?

Answer:

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.

Topic related questions

Question 31: When is a condition considered to be a rare disease for proposals submitted to the call topic SC1-PM-03-2017 (Diagnostic characterisation of rare diseases)?

Answer:

For the Horizon 2020 call topics a disease is considered rare when no more than 5 per 10.000 persons in the European Union are affected, as defined in the context of the EU legislation (Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medical products, O.J. L18/1-5 of 22.1.2000).

Question 32: Regarding SC1-PM-08-2017 (New therapies for rare diseases), how long will it take to obtain the EU orphan drug designation? How long will it take to get EMA's protocol assistance? When do I need to have the EU orphan drug designation and EMA protocol assistance?

Answer:

Please refer to the guidelines on mandatory regulatory proceedings with the summary of deadlines from EMA that can be found [here](#). The call topic specifies that the

intervention must have been granted the EU orphan designation at the latest on the date of the full proposal call closure. Therefore it is required before the second stage deadline.

Question 33: In the scope of SC1-PM-10-2017 (Comparing the effectiveness of existing healthcare interventions in the adult population) it is stated 'randomised controlled trials, pragmatic trials, observational studies, large scale databases and meta analyses may be considered.' Does this mean that these are the only ones that can be used?

Answer:

The categories mentioned are non-exclusive. These are the main types of trials used but if consortia come with other options experts will be better placed to decide if appropriate or not.

Question 34: Does the topic SC1-PM-10-2017 (Comparing the effectiveness of existing healthcare interventions in the adult population) exclude elderly (people over 60)?

Answer:

Screening and / or the involvement of elderly populations are not excluded.

Question 35: Topic SC1-PM-10-2017 (Comparing the effectiveness of existing healthcare interventions in the adult population) is similar to the one of last year. Will the healthcare interventions already funded in the previous call be excluded in this new call?

Answer:

The healthcare interventions already funded in the previous call will not be excluded in this new call.

Question 36: Within SC1-PM-11-2016-2017 (Clinical research on regenerative medicine), page 23, note 20, it is stated: "Project abstracts will be provided on the call page on the Participant Portal". However, I cannot find these project abstracts in the Participant Portal. Where can I find them?

Answer:

The project abstracts can be found at the very bottom of the documents provided for this topic: "topic conditions and documents", together with the "essential information for clinical studies" template.