List of SC1 Related FAQs published on the H2020 PP
version 20.12.2017

Category (Topic Specific (TS)/Clinical Studies (CS)/Other (O))	Topic	Question	Answer
TS	BHC-09-2018	Under call H2020-SC1-BHC-2018-2020, topic SC1-BHC-09-2018, is a therapeutic substance/product an advanced therapy medicinal product?	Advanced therapy medicinal products (ATMPs) are medicines for human use based on genes, cells or tissue engineered products as defined by the Regulation (EC) No 1394/2007 and Directive 2001/83/EC. The committee of advanced therapies (CAT) from the European Medicines Agency gives recommendations on the classification of advanced therapy medicines. E.g. the CAT classified native mesenchymal stem/stromal cell-derived microvesicles as not advanced therapy medicinal product. Should you be in doubt of whether your therapeutic product is an ATMP, please see the scientific classification advice of article 17 of the Regulation.
TS	BHC-09-2018	Under topic SC1-BHC-09-2018 what is meant by an 'innovation platform'?	The term 'innovation platform' is an umbrella term which encompasses all stages and elements of Advanced Therapy Medicinal Product development. As specified in the scope, platforms should comprise the components and expertise necessary to create a solid foundation on which to build possible new therapeutic approaches and/or aim to overcome particular development bottlenecks. Possible components could include studying the basic biology of the potential therapy and investigating its mode of action, proof of concept (in vitro, in animal models – where necessary - or first-in–man studies); safety, efficacy, characterisation, refinement and manufacturing of the product. For this call the use of the word 'platform' is not intended to describe a service platform or any type of infrastructure, but more a programme or plan of action/activities. The expectation is that projects should not only comprise knowledge creation around innovative concepts in advanced therapy development but also its testing and exploitation, as described in the call text.
TS	BHC-21-2018	Under call H2020-SC1-BHC-2018-2020, topic BHC-21-2018, are the costs for Russian researchers covered by the Russian Federation?	Yes, the co-funding mechanism means that the Ministry of Education and Science of the Russian Federation will provide funding to Russian applicants that have been successfully selected under both the EU (SC1 WP 2018) and the related Russian call http://www.fcpir.ru/participation_in_program/contests/list_of_contests/ Russian applicants should indicate "0" under "EC contribution" (according to Horizon 2020 rules), since they will not be funded by the European Commission, but – in case of successful selection – by the Ministry of Education and Science of the Russian Federation.
TS	BHC-21-2018	Under Societal Challenge 1 (SC1), topic SC1-BHC-21-2018, Research on HIV, tuberculosis (TB) and/or hepatitis C (HCV), what is the budget made available by the Ministry of Science and Education of the Russian Federation?	The information on the budget commitment made available by the Russian Federation, as well as the other conditions for the Russian applicants are indicated in the Russian call published on the website indicated in the topic call, with reference 2019-14-588-0001: http://www.fcpir.ru/participation_in_program/contests/list_of_contests/
TS	BHC-27-2018	Under call H2020-SC1-BHC-2018-2020, topic SC1-BHC-27-2018, would proposals including also (but not solely) the development of environmental test guidelines, be taken into account?	The call text includes this sentence: for in vitro tests, appropriate coupling of their results to human health effects should be ensured. Therefore and if the appropriate links are established, activities involving the development of environmental test guidelines, could be taken into account.
TS	HCO-01-2018-2019-2	Under call H2020-SC1-BHC-2018-2020, is topic SC1-HCO-01-2018-2019-2020 open to applicants which are not represented in ICPerMed?	In this topic no link between the identity of the applicants/beneficiaries and the participants in ICPerMed, is required. The fact that actions from this call should support ICPerMed means that beneficiaries will have to become familiar with the work of ICPerMed. The beneficiaries will have to establish close links with them when a granted project starts and applicants are not restricted to the entities or countries represented in ICPerMed.
TS	HCO-04-2018	Under call H2020-SC1-BHC-2018-2020, topic SC1-HCO-04-2018, can research organisations from Member States or Associated Countries, not represented in the ERA-NET Consortium, apply for funding under the co-funded call launched by the ERA-NET Consortium??	In calls launched by ERA-NETs the eligibility for funding is usually limited to legal entities from participating countries, within the limits of the national funding rules and their respective eligibility criteria. Normally national programmes do not allow for funding from legal entities from other countries. Therefore funding under the call launched by the ERA-NET will in practical terms be limited to legal entities from those countries that put a programme into the ERA-NET.
TS	HCO-04-2018	Under call H2020-SC1-BHC-2018-2020, is topic SC1-HCO-04-2018 restricted to the Joint Programming in Neurodegenerative Diseases (JPND) members? Should all JPND members be part of the applying consortium?	This call topic is open to national or regional funders in EU, Associated and third countries and does not require any participation in JPND. JPND should indeed make an active effort to get more countries involved in the call, independent from their current or future JPND involvement. All funders represented in JPND are encouraged, but not required to participate in this call. The ability of JPND members to participate depends for example on the availability of co-funding for the planned ERA-Net call.
TS	HCO-10-2018	Under topic SC1-HCO-10-2018, is the topic calling for specific communities of researchers to apply for this specific CSA (Coordination and Support Action) topic?	Bearing in mind that this topic is about coordination of research rather than direct support to research, the scope of the topic includes: "Identify areas of neurosciences where the need for enhanced coordination of research communities into active clusters is particularly acute" and "Support the emergence of these clusters". Therefore, a successful proposal should enable the coordination of European brain research and/or developing global initiatives in a range of different thematic areas (eg epilepsy, neurodegenerative diseases, addiction, etc.) or on cross-cutting issues (imaging, data sharing, etc.) at the request of various communities (or clusters) of researchers. It should have the capacity to reach out to the entire neuroscience community and be in a position to provide advisory, organisational, networking and financial support to help various communities (or clusters) of researchers to emerge and request support to develop coordination and cooperation actions at a very immediate and operational level and/or at a more strategic and future-oriented level, including beyond Europe
TS	HCO-10-2018	Under call H2020-SC1-BHC-2018-2020, topic SC1-HCO-10-2018 'Coordinating European brain research and developing global initiatives', is 'brain tumour research' within the scope of the topic ?	Under SC1-HCO-10-2018 , brain tumour research is usually considered as part of the cancer area. However, it can be also be considered as part of the neuroscience area and, as it is not specifically excluded from the topic description, it should be eligible to benefit from this Coordination and Support Action (CSA).
CS		In a topic under call H2020-SC1-2018-2020, can applicants annex detailed protocols or other documents to the template for clinical studies or other sections of the proposal?	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.
CS		Under Societal Challenge 1 (SC1), which costs are eligible under H2020 in the implementation of clinical trials/studies/investigations?	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.

List of SC1 Related FAQs published on the H2020 PP
version 20.12.2017

CS		Under Societal Challenge 1, SC1, which kind of clinical trials/studies/investigations can be supported under Horizon 2020?	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.
CS		Where can I find more detailed guidance on the use and calculation of unit costs for clinical studies in Horizon 2020?	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).
CS		Under Societal Challenge 1 (SC1), is the use of unit costs for clinical trials/studies/investigations mandatory?	Each beneficiary can choose independently, whether it wants to use unit costs or actual costs.
CS		Under Societal Challenge 1 (SC1), 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), 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 comply with the obligation of ensuring 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 identied 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
CS		Under Societal Challenge 1 (SC1), can certain tasks of a clinical trial/study/investigation be subcontracted to a contract research organisation (CRO)?	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.
CS		Under Societal Challenge 1 (SC1), which information from the accounting department is needed to calculate personnel costs when using unit costs model for clinical studies?	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.
CS		Under Societal Challenge 1 (SC1) 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? 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.
CS		Under Societal Challenge 1 (SC1), is the use of the template for 'Essential information to be provided for clinical trials/studies/investigations' mandatory?	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: PM-02, PM-07, PM-08, PM-10, PM-11 and HCO-07 (for the calls of 2017) 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.
CS		Under Societal Challenge 1 (SC1), can beneficiaries agree on unit costs per patient that are lower than their actual costs?	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 pay an fixed amount per patient for all centres – this amount needs of course to be lower than or equal to the agreed unit costs claimed under the H2020 action.
CS		Under Societal Challenge 1 (SC1), what about cases where some partners (but not others) are reimbursed by their national health systems for certain tests or treatments?	Example: in a given country, health insurance may reimburse only up to two Magnetic resonance imaging (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.
CS		Under Societal Challenge 1 (SC1), can applicants use a different format or a different methodology for the description of clincal studies unit costs? Can applicants define different or additional cost categories (e.g. for additional personnel categories)?	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.
CS		Under Societal Challenge 1 (SC1), how to deal with patient' drop-out or long follow-up period when using the unit cost model for clinical studies?	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.

List of SC1 Related FAQs published on the H2020 PP
version 20.12.2017

O		I have heard that the Commission will not fund research which involves non-human animals. Is this correct?	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 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF) 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 a 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.
O		Under Societal Challenge 1 (SC1), can WHO be considered as an "international organisation of European interest" and apply for EU funding under Horizon 2020?	WHO is an international organisation, but it is not considered an "international organisation of European interest". Therefore, WHO is not automatically eligible for funding in Horizon 2020 open 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 (http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-3cpart_en.pdf)