HNN 3.0
HEALTH-NCP-NET

Health NCP Net

Workshop “From Theory to Practice: Navigating Pre-Commercial Procurement in Horizon Europe”

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HNN3.0 (The Cluster 1 Health consortium of NCPs for Horizon Europe) has received funding from the European Union's Horizon EUROPE research and innovation programme under Grant Agreement number 101057279

INTRODUCTION AND BACKGROUND

This workshop aimed to provide a comprehensive understanding of PCP within the Horizon Europe framework. Insights were shared into both theoretical concepts and practical applications. The webinar will also feature an interactive Q&A session, allowing direct engagement with experts and clarify any doubts. During this session not all questions could be answered. The questions where collected and here answers provided.

This workshop was open to Horizon Europe National Contact Points (NCPs) of Cluster 1 "Health", as well as Health researchers and innovators (e.g. Hospitals, Regions, Health Ministries) interested in the PCP mechanisms and demand-driven innovation. HNN3.0 | Workshop "From Theory to Practice: Navigating Pre-Commercial Procurement in Horizon Europe" | Health-NCP-Net (healthncp.net)

WORKSHOP QUESTIONS & ANWERS

Q1: Are there any legal barriers that a PCP needs to be aware of and can possibly assist in solving?

A1:

(1) *In the health care sector, there are cases where public procurers need to get approval from an ethical board in the countries where testing needs to be done (e.g. to perform tests that involve patients). It is important to start applying for this approval as soon as possible during the PCP project, so that testing does not run into delays. If the PCP project obtains timely ethical approval and performs all testing during the PCP in line with the ethical requirements, then the PCP project helps the PCP suppliers to already pass this hurdle and it provides them with a seal of approval that their innovative solutions have been tested in compliance with ethical legal requirements.*

(2) *Innovative solutions may need certification before they are allowed to be sold on the market. If you wait with addressing certification after the PCP project is finished, there is a risk that the procurers forget to taken into account requirements in the PCP tender specs that are important for certification bodies, the PCP vendors will need to adapt again their solutions to meet certification requirements after the PCP and this will delay the route to market for the innovative solutions after the PCP project. PCP projects help assist the PCP suppliers prevent such delays by already engaging with certification bodies during the PCP project. Procurers can include requirements from certification bodies in their PCP tender specs, certification bodies can even participate in the PCP project itself and monitor the ongoing development and testing to see if there are perhaps changes needed to their certification process to accommodate the certification of innovative solutions, and companies can be required by the PCP tender docs to engage with certification bodies during the testing phase of the PCP (so that possibly the solutions can already be certified during the PCP project itself).*

(3) *It is important to ensure that during the PCP the innovative solutions are developed in line with regulatory requirements. There may also be cases where the existing regulatory framework is not ready for innovative solutions to be sold on the market and some derogation, clarification, or flexibility in the interpretation of existing regulations in the healthcare sector are needed to enable the development and testing of solutions during the PCP. Again to avoid delays in getting the solutions to the market, PCP projects are advised to check the regulatory situation in the beginning of the PCP project, include important regulatory requirements from the beginning in the PCP tender specs and engage with the competent regulatory authority to obtain from them any clarifications on applicable regulations and to get their authorization for any derogations or flexibility in interpretation of regulatory requirements that are required for the development and testing of the solutions during the PCP. In this case, it is possible that the PCP development and testing work is implementing in fact a regulatory sandbox. The regulatory authority itself can even participate in the PCP in defining the requirements, following up the development and testing. The PCP tender specs can require the suppliers to provide a deliverable that describes any regulatory learnings from the development/ testing that can be shared with the regulator so that he can ensure that regulations are fit for purpose by the end of the PCP when the innovations will be coming onto the market.*

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Q2: As there are many stakeholders involved, who will own the solution?

A2: *It is up to the public procurers to define what they want to own after the PCP. the general annexes provisions on IPR state: "The PCP procurers must not reserve the R&D results exclusively for their own use. The providers generating results must own the attached IPR, and the procurers must enjoy at least royalty-free access rights to use the R&D results for their own use. The procurers must also enjoy the right to grant (or to require the granting of) non-exclusive licences to third parties, to exploit the results under fair and reasonable market conditions, without any right to sublicense. A call-back provision must ensure that, in case the providers fail to commercially exploit the results within a given period after the PCP, or use the results to the detriment of the public interest, including security interests, the procurers can require transfer of the ownership of the results."*

It is up to the procurers to decide if they want to buy already during the PCP procurement a certain amount of products that were tested during the PCP. If yes, the procurers will specify in the PCP tender specs how many of the tested products they want to keep/own after the PCP. In case the testing during the PCP is a destructive testing (e.g. as is the case in car crash testings) then it may not make sense for the procurers to buy/own destroyed solutions after the PCP, but it may be very useful to leave the solutions with the PCP suppliers as they can learn from the destroyed material to improve their products further in the future. In case the PCP focuses on creating open source software solutions, then may not be a need for procurers to buy any solution because they will be published and free of charge for anyone to use. There are also cases where the target buyers of the solutions is not the procurer but for example other end-users (e.g. citizens). Also in that case it may not make sense for procurers to buy solutions as a result of the PCP, but it makes sense for procurers to include already in the PCP those end-users that would need to buy the solutions and/or those healthcare insurance companies that would need to approve the reimbursement of solutions bought by citizens. In general, it is recommended to discuss with potential bidders what is the best approach for this during the open market consultation.

Q3: Is purchase of the solution at the end of the project a joint purchase from all the partners or up to the buyers in the various organizations?

A3: *The deliverable that describes the eventual purchase of the solution at the end of the project should reflect the realistic situation at the time, and it could include buyers beyond the original consortium. The intention here is to ensure that the buyers within the applying consortium reflect on the deployment pathway of the sought solutions.*

If some or all of the procurers in the consortium want to buy already some of the tested solutions during the PCP procurement, then this purchase of solutions is part of the joint PCP procurement (so then it is indeed a joint purchase). Make sure then that the procurers that want to buy solutions are also already testing them during the PCP, so that the solutions can simply remain where they are after the testing (with the procurers that tested them). In case procurers in the consortium prefer to buy solutions after the PCP procurement, then they can choose to buy the solutions they need individually or in group.

Q4: Are there any obligations or recommendations to purchase the resulting solutions?

A4: *There are no obligations to purchase resulting solutions however the applying consortium needs to describe in the proposal the deployment pathway it has in mind once solutions will be successfully developed and tested, and this will contribute to the overall assessment of the impact of a given project.*

In case procurers want to buy solutions, it can save time to already include this purchase in the PCP procurement (because then there is no need to do another separate procurement procedure for this afterwards and the PCP can be implemented as a fast-track PCP that can be implemented in 2 phases instead of 3 phases).

Q5: Why does the contracting authority need to commit to a deliverable to purchase the solutions if there is no funding and the outcome and timeline of the PCP are uncertain?

A5: *There is no commitment to purchase needed rather this deliverable is a proclamation of intent from the consortium that they will facilitate the further development or deployment of successful solutions. It allows for consortia to either do the purchase or prepare the tender documents for a follow up procurement to deploy solutions still within the cost and time of*

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the project. So if the consortium decides to purchases solutions there is no issue of lack of funding or uncertain timeline for getting deployment budget because the 100% EU funding for the PCP project will pay for the purchase of the solutions and the timeline for deployment is not uncertain because it will already happen during the PCP project. In addition, the procurers can then implement the PCP procurement as a fast track PCP which also gains time.

Q6: Why do the obligations of the procurer change in the case of a two-phase or three-phase procurement, and what are the differences?

A6: *There is no change in obligations for the procurers in case of a 2 phase or 3 phase PCP. In both cases the procurers need to implement a PCP procurement. The only difference is that in a fast-track PCP, the procurers can combine phase 2 and phase 3 into one and the same phase, which saves some time as all development and testing can be done in one go.*

Q7: If an SME participates in the consortium and has multiple owners, can all personnel costs (owners without salary) be reported as unit costs, each according to the maximum limits? And what kind of evidence needs to be documented, without a salary paid?

Please note that potential suppliers of solutions that the PCP is looking for, cannot participate in the consortium that applies for the EU grant. Potential suppliers of solutions need to wait until the consortium will have started the project and only then suppliers can engage with the project as soon as the procurers launch the open market consultation and the PCP call for tenders.
However, there may be other types of SMEs that can participate in the consortium that applies for the EU grant (e.g. consultancy firms that help the procurers with dissemination activities etc.). For those SMEs the following applies:

A7: ***Information can be found in the Annotated Grant Agreement***

Article 6.2.A.4 > E Personnel unit costs
*The work of **SME owners** for the action (i.e. owners of beneficiaries that are small and medium-sized enterprises20 not receiving a salary) may be declared as personnel costs, if they fulfil the general eligibility conditions and are calculated as unit costs in accordance with the method set out in Annex 2a.*
This budget category covers the costs of two types of persons, including:
*– **Persons who are directly owners or co-owners** (regardless of their percentage of ownership) of the beneficiary, **if the beneficiary is an SME and the person is not an employee of the beneficiary**. It applies also to SME owners whose work in the action for the beneficiary is remunerated via any type of non-employment contract (e.g. a service contract), via profit distribution or by any remuneration method other than a salary resulting from an employment contract.*

***What not?** SME owners who receive a salary (registered as such in the accounts of the SME) cannot declare personnel costs under this budget category, unless they can show that this salary corresponds exclusively to the management of the SME (and is therefore not linked to the action).*

***1.2** The costs must be **declared** as unit cost, **using the unit cost (daily rate) fixed by the authorising decision C(2020)7115 and set out in Annex 2a**.*
***The amount per unit (daily rate) is prefixed in the authorising decision, adjusted depending on the country where the beneficiary/affiliated entity is established**:*
*Amount per unit [daily rate] = **{**EUR 5 080 /18 days [i.e. 282,22]**}***
*multiplied by **{**country-specific correction coefficient of the country where the beneficiary is established**}***
***1.4** The costs must be **calculated**, for the SME owner/natural person, in accordance with the methodology set out in the authorising decision and Annex 2a.*
*The formula for calculating the SME owner/natural person personnel costs is: **{**amount per unit [daily rate]**}** multiplied by **{**number of day-equivalents worked on the action**}***
***The daily rate is fixed in the authorising decision** (see above).*

Art. 20.1 GA Record keeping
In addition, the beneficiaries must — for the same period — keep the following to justify the amounts declared: (…)
(i) for unit costs and contributions (if any): adequate records and supporting documents to prove the number of units declared

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Q8: Long-term purchase plans cannot be made, so how can a procurer commit to buying?

A8: *There are procurers that already have plans and budgetary commitment to purchase solutions. They can then implement the PCP as a fast-track PCP and already procure solutions during the PCP project. This allows for consortia to choose to earmark some of the funding provided by the grant to purchase the solution.*

In case the procurers have no commitment to purchase yet, then the deliverable that is required by the call is a proclamation of intent from the consortium that they will facilitate the further development or deployment of successful solutions after the PCP. It allows for consortia to prepare follow up procurement documents still within the cost and time of the project.

Q9: Is it always clear who pays and who implements the testing of the suggested solutions?

A9: *It is up to the applicants for the EU funding call (in particular the procurers) to clearly defined in the proposal who will pay the suppliers and who will implement the testing of the solutions during the PCP. For paying the suppliers during the PCP, the buyers group can chose either to have all suppliers paid by the lead procurer or to have each procurer pay each supplier pro rata. The first option is easier for both the procurers and the suppliers. For implementation of testing, the procurers can chose that either all procurers in the buyers group will test the solutions in all their countries, or that only some procurers in the buyers group will test the solutions. The first option is of course the preferred one, as it delivers products that are better tested and more suited to meet the needs of all procurers, and that facilitates also in particular the purchase of the solutions afterwards.*

Q10: What is meant with that the Commission is open to PCP activities within RIA-topics? Does it mean integrating a "PCP-style" procurement into a RIA proposals? If so, what would be the conditions for for example allocation budget? Would such an innovation procurement have to be a minor part of the entire project, or would the research and innovation essentially be carried out "RIA-style" in a procurement scheme?

A10:

Please note that for this call on greening healthcare, only proposals for PCP actions are eligible. This means that the PCP procurement needs to be the main objective of the action and the PCP procurement budget needs to minimum 50% of the total requested grant budget. The PCP procurement costs need to be included then in the budget table of the proposal under the PCP/PPI procurement cost category. It is not possible to submit to this call on greening healthcare a proposal for an RIA action that involves the implementation of a PCP.

If you see another call for RIA actions and it does not mention PCP, but you think it would be good idea to implement a PCP procurement as part of this RIA action, then you can propose to do that in your proposal. As a general remark, please note that if PCP is not mentioned in the call conditions / topic description, then a maximum of 49% of the grant budget can be spent on the PCP procurement cost, as these costs will be listed under the subcontracting costs of the Research and Innovation Actions (RIA) and need to be 'limited' according to the Model Grant Agreement. Please note that an RIA action requires that the beneficiaries themselves also implement R&I activities (with the remaining 51% of the grant budget), so it only makes sense to implement a PCP under an RIA action if the procurers want to do a substantial amount of RIA activities themselves and need to implement a PCP to feed into those RIA activities.

There are also calls for RIA actions where the EU itself will already explicitly call in the call conditions / topic description for projects to implement a PCP procurement as part of the RIA action. In this case, the PCP procurement cost still needs to be listed under the subcontracting costs in the budget table of the proposal for the RIA action, but more than 50% of the grant budget can be spent on the PCP procurement cost according to the Model Grant Agreement.

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Q10b. Also, what would that mean for the consortium itself and the acquisition of the solution (i.e. the buying of the product for implementation)?

A10b: As mentioned before, for this call on greening healthcare, it is not possible to submit a proposal for an RIA action that involves the implementation of a PCP. You can only submit PCP action type proposals to this call.

The same requirements for implementing PCPs (as described in the general annexes H of the work programme) apply to all PCP procurements, regardless of whether they are implemented under PCP actions or under an RIA action. So, in both cases the procurers can buy resulting solutions as part of the project or after the project and in both cases the procurers can implement the PCP as a fast-track PCP if they have already commitment to procure the solutions.

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