Last update: 10.08.2020 09:00 CET

This document contains Frequently Asked Questions collected during the HSMonitor Open Market Consultation (OMC) events in March-May 2019, as well as questions submitted to suppliers@hsmonitor-pcp(dot)eu. The answers provided represent the joint position of the five HSMonitor procurers to their best knowledge at this point in time. This document will be continuously updated to include new questions and their answers. In some cases, questions may have been merged and generalised to avoid duplication.

Q: Specifically for Turkey: Can we receive patient data in accordance with KVKK (Turkish counterpart of GDPR)?
A: The data of the patients are shared with the suppliers who conduct the pilots on 2 main conditions: 1) the patient's open consent, 2) after the signature of necessary agreements between MOH and the supplier.

ID:1; Submitted via OMC Turkey webinar on 25.03.2020

Q: Can we receive this presentation?
A: Please check the project website. If you cannot find it, please send an email to suppliers@hsmonitor-pcp.eu

ID:2; Submitted via OMC Turkey webinar on 25.03.2020

Q: For phase 1, should we consider all procurers' health systems in our offers?
A: All procurers' health systems and health information systems should be considered in all phase offers.

ID:3; Submitted via OMC Turkey webinar on 25.03.2020

Q: Is there a platform for the interested suppliers to find and meet other interested suppliers from other countries? How can we communicate with other suppliers?
A: Not a "platform" but this questionnaire serves the same purpose. The profiles of suppliers seeking partnerships are posted here.

ID:4; Submitted via OMC Turkey webinar on 25.03.2020

Q: Are prototype studies going to be conducted in all procurer regions?
A: All phases of prototypes, demos, and trials will be conducted in all procurer regions.

ID:5; Submitted via OMC Turkey webinar on 25.03.2020

Q: Can existing solutions be used? Or do we have to develop all from scratch?
A: To the knowledge of HSMonitor Buyers Group, no solution that covers 100% of HSMonitor challenge exists. Existing solutions can be part of the sought-for HSMonitor systems. It

should be well justified that even though these solutions/modules/functionalities have existed before, they will be customized in order to meet HSMonitor requirements.

ID:6; Submitted via OMC Turkey webinar on 25.03.2020

Q: Is there any additional material currently available related to the project?

A: This questionnaire contains a slide deck for suppliers and a draft file of use cases. Please also check project website regularly, subscribe to the newsletter (stay tuned), and follow us on social media.

ID:7; Submitted via OMC Turkey webinar on 25.03.2020

Q: When will you launch the request for tenders?

A: The project calendar sets the launch of request for tenders as August 2020. It remains to be seen whether this date will be achieved or will have to be postponed due to the COVID-19 outbreak. Please check project website regularly, subscribe to the newsletter (stay tuned), and follow us on social media.

ID:8; Submitted via OMC Turkey webinar on 25.03.2020

Q: Will the pilot studies be conducted in each partner's health ministries?

A: The pilot trials will be conducted in the regions of 5 procurers of the project. Not all these 5 procurers are health ministries. Please check project website for detailed information about the procurers.

ID:9; Submitted via OMC Turkey webinar on 25.03.2020

Q: What are the selection and award criteria for each phase? How does the EC participate in the evaluations? What is the evaluation board's structure like?

A: For the exclusion, selection, compliance, and award criteria, please refer to the request for tender documents when they are published. The EC does not participate in the evaluations. The evaluations will be conducted in each procurer region, mainly by 3 aspects: clinical, technical, work plan. These aspects are tentative. The evaluations of all procurers will then be consolidated. The scorecard which will be used in the evaluation of the technical sections of the offers, as well as more information about the evaluation of the offers, will be available in the request for tender documents.

ID:10; Submitted via OMC Turkey webinar on 25.03.2020

Q: Will you share the video record of this event?

A: Please check project website.

ID:11; Submitted via OMC Turkey webinar on 25.03.2020

Q: Do the number and quality of suppliers in a consortium of suppliers play an important role in the evaluations?

A: The call for tenders is open to any type of operators whether they are small, medium-sized, or large, and to any operator from any country, as long as at least 50% of the work will take place in EU member states or Horizon 2020 associated countries. The quality of the suppliers may be a good advantage but it is not a direct advantage if the offer is poor in terms of clinical support, technical plan, work plan, etc. Geographical coverage of a tender, i.e. the tenderer's ability to cover all procurer areas in terms of product development and pilot execution, may be considered more important than the number of suppliers in a supplier consortium.

ID:12; Submitted via OMC Turkey webinar on 25.03.2020

Q: If we already have part of the solution in the market (some part to be developed), can we still apply in the tender?

A: Please check Q ID6.

ID:13; Submitted via OMC webinar on 16.04.2020

Q: Will we have to provide medical devices? If yes, can we use devices from Korea, Israel, China or other manufacturers outside Europe?

A: Medical devices may be offered by a tenderer. All medical devices, regardless of their manufacturing country or region, should have CE certification. Please also check Request for Tender documents for more information when they are published.

ID:14; Submitted via OMC webinar on 16.04.2020

Q: Will you take precautions concerning import-export rules since Turkey is outside the EU market?

A: It is solely the tenderer's responsibility to take such precautions. Besides, for Turkey, offering to use devices which are not registered at the national authorities (e.g. medical devices not registered at Turkish Medicines and Medical Devices Agency or mobile phones not registered at Information Technology and Communication Authority) may be considered a flaw.

ID:15; Submitted via OMC webinar on 16.04.2020

Q: Are any needs to certify the solution under the medical devices' regulation?

A:

- For **Turkey** the software (applications, etc.) developed for HSMonitor does not need to be certified under the medical devices regulation, as these applications will be used by a small number of users for piloting and testing purposes. Certification as medical device is necessary for large scale or commercial use, which is out of the scope of HSMonitor project.
- According to the **Croatian** national regulator, solution needs to be checked with this regulation https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en if the solution that will be tested is going to be classified as a medical device. Also, it is important to check if the piloting of the solution is classified as "clinical trial" or not and also to check if it needs ethical or not. This check can be made together with the suppliers in the early stages of the PCP (Phase I)
- In **Campania** applies the Italian Regulation on Medical devices, the same all over the Italian National Territory, though it is very likely that both medical devices and leisure devices will be used to monitor patient's clinical and non-clinical parameters. As for the Ethical committee, approval is required when a drug or a medical device is used for purposes that are not meant in the approval from the AIFA, or when collecting data for a repository or an observational study, to gather information on outcomes. On the other hand, the GDPR states that hospitals

are already authorised to use clinical data collected for the everyday practice when they are used to ameliorate the service. Using a digital platform to support the delivery of usual care does not require therefore an ethical committee approval.

- In **Lombardy**, medical devices used to monitor the patient's status should be certified according to the Class they belong to. Therefore, decision Support software should be assessed to see if it falls under Class IIa or IIb, according to the Medical Device Regulation. I suggest this assessment will be performed in Phase 2, when technical specifications will be consolidated.
- In **Sweden,** non-certified solutions may be tested within a trial. However, ethical approval is necessary where you describe the test (what and how) in the application.

ID:16; Submitted via OMC webinar on 16.04.2020

Q: What countries will pilot the solutions?

A: Please check Q ID5.

ID:17; Submitted via OMC webinar on 16.04.2020

Q: What are the consortium requirements for participation? Minimum and maximum number of partners, how many countries, etc?

A: Please check Q ID12.

ID:18; Submitted via OMC webinar on 16.04.2020

Q: How many languages / countries should the prototypes be able to address?

A: The prototypes and solutions should be delivered in the procurers' languages (Croatian, Italian, Swedish, and Turkish) and English

In addition to the required languages, the suppliers could also deliver the solutions in additional languages for dissemination or marketing purposes, but this may not necessarily be considered as a superior work is accomplished.

Please also check Request for Tender documents for more information when they are published. Please also check Q ID5.

ID:19; Submitted via OMC webinar on 16.04.2020

Q: Will the Hypertension protocols vary by county or will it be standard for the EU?

A: There is no unified pan-European hypertension guideline for hypertension (or any other diseases). The deviation between different national guidelines though are minor and the European Hypertension Society guidelines, or similar international guidelines, could most likely be used. A clinical comparison of the different national guidelines and the international guideline chosen is recommended. Procurers have to check for possible updates in the guidelines before deployment.

However, there may be some differences in the clinical workflows of each procurer the details of which will be shared with the suppliers of Phase 2 during the site visits and v1 and v2 demonstrations. Co-design plays its role in the customization of applications.

ID:20; Submitted via OMC webinar on 16.04.2020

Q: About consortia, if in Phase II for example, we realize that we need another partner in consortium, can we add another partner to our consortium? Or do we have to finish with partners who we made the consortium with in the beginning?

A: Inclusion of new partners to a supplier consortium is not allowed. However, inclusion of subcontractors is possible within limited capacity. Please check Request for Tender documents for more information when they are published

ID:21; Submitted via OMC webinar on 16.04.2020

Q: Is there any restriction regarding the size of a consortium applying to this PCP??
A: Please check Q ID12.

ID:22; Submitted via OMC webinar on 16.04.2020

Q: For integration with procurers' EHR software and other systems, will there be specifications??
A: The Request for Tender documents will provide information about the existing systems of the procurers that new solutions need to integrate into. The information will include, for example, the organisation owning/maintaining the system, any publicly available description, APIs, etc. where available.

ID:23; Submitted via OMC webinar on 11.05.2020

Q: How is expected that the cocreation process with the different health organizations will be conducted (e.g. regular meetings, workshops)??
A: In Phases II and III the contractors are expected to work closely with the procurers, and appropriate means (online meetings, face-to-face meetings and workshops) need to be planned in the offer.

ID:24; Submitted via OMC webinar on 11.05.2020

Q: What's the TRL suggested at the end of the third phase??
A: PCP projects focus on the exploration and design of technological solutions (Technology Readiness Levels-TRL 6-8). The aim is to bring innovative ideas and solutions of first products or services to initial development, on a small scale.

ID:25; Submitted via OMC webinar on 11.05.2020

Q: Is there any limitation on adding partners that might be introduced to a joint tender?
A: Please check Q ID 12 first. In case of joint tenders, the participants must be identified clearly in the tender. There may be no change in the composition of a group that tendered at the beginning of the PCP procedure. Addition of subcontractors may be possible in some circumstances, which will be detailed in the Request for Tenders.

ID:26; Submitted via OMC webinar on 11.05.2020

Q: Is participation possible using the results of previous Horizon2020 funding?
A: Tenders that receive public funding from other sources will be excluded if this leads to double public financing or an accumulation of different types of public financing that is not permitted by EU legislation, including EU state aid rules. An on/off award criterion related to this point will be part of the Request for Tenders.

ID:27; Submitted via OMC webinar on 11.05.2020