Last update: 14.12.2017 12:10 CET

This document contains Frequently Asked Questions collected at the local Market Consultation workshops held at the premise of each of the four procurers in June-July 2017, as well as a webinar open to all participants and held on 8 June 2017 and questions handed in under vendors@proempower-pcp.eu . Answers have been provided jointly by the four ProEmpower procurers to their best knowledge at this point in time. This document will be continuously updated to include new questions and their answers. Partially questions have been merged and generalised to avoid duplication.

The questions have been grouped into topics, an overview can be found below:

Language

Q: In which languages will the solution be required to be available?
A: The solution as well as any accompanying materials and documentation (manuals, guideline, etc.) is required to be provided in the languages of the four procuring countries – Portuguese, Turkish, Italian and Spanish – and in English to support the evaluation of the solution by the international ProEmpower consortium.

ID: 5; Submitted via Webinar (8 June 2017); ID: 37; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Q: In which languages will the tender documentation be provided?
A: The tender documentation will be in English only. Proposals need to be written in English

Bidder requirements

Q: Is possible for one company to apply in more than one consortium?
A: Tender entities may not participate in more than one tender, be it as single entities or as part of a consortium submitting a joint tender. The Buyers Group reserves the right to exclude any tender in breach of this provision.

ID: 38; Submitted via email to the vendors

Q: Will the tender include minimum requirements for the financial and technical capabilities of bidders, e.g. annual revenue and/or ownership of relevant certifications (e.g. UNI-EN-ISO 9000, UNI-EN-ISO 13485, etc)?
A: The tender will specify different criteria (exclusion, selection, compliance, award) and annual revenue and quality management are likely to be taken into consideration as award criteria. However, the tender is not planned to exclude applicants that do not have certifications such as the listed above or below a certain annual revenue.

ID: 1; Submitted at Naples Market Consultation Workshop (6 June 2017); ID: 25; Submitted via Webinar (8 June 2017)

Q: Is the first step to answer the market consultation questionnaireand present the company's ability?
A: Answering the questionnaire ensures that the ProEmpower procurers are aware of a company's interest. It is also a way to provide feedback to the ProEmpower consortium about what the market has to offer, so that the consortium can define realistic expectations. However, the questionnaire is not mandatory and companies can apply for the tender without having filled in the questionnaire.

ID: 11; Submitted via Webinar (8 June 2017)

Q: Do participants need to already have similar products on the market in order to be considered for the PCP?
A: Participants do not need to present any prior products on the market.

ID: 15; Submitted via Webinar (8 June 2017)

Q: Is there a limit of companies in the tender phase?
A: There is no limit on number of applicants in the tender phase, anyone can apply. Only a certain number of tender applications will be selected to continue in phase one, with a minimum of three applications. The number of selected applications in the subsequent phases depends on the financial offers, which will determine how many applications can be further funded from the foreseen phase budget.

ID: 23; Submitted via Webinar (8 June 2017)

Q: What stage does a company need to be at in order to be eligible?
A: The type of applicant – size (start-up, SME, big enterprise or a consortium of different companies) and focus (industry, academia, etc.) – is not a criterion for eligibility. However, applicants in any constellation have to be able to carry out the activities described in the tender. Different criteria such as operational capacity and a sustainable business case will be defined in the tender documents.

ID: 24; Submitted via Webinar (8 June 2017)

Q: Regarding the incompatibility with other monetary support: if start-up members are receiving economic support from the local government as entrepreneurs, are they not eligible?
A: Applicants awarded a contract in ProEmpower are non-eligible if they receive double funding for the same activity, i.e. if they receive funding for developing the same component of the solution, or the whole solution itself. Economic support applicants receive for training, assistance or coaching generally poses no conflict, in which case it will be eligible. The tenderers must be in accordance with the EU Framework for state aid for research and development and innovation http://ec.europa.eu/competition/state_aid/modernisation/rdi_framework_en.pdf

ID: 27; Submitted via Webinar (8 June 2017)

Q: Can the firms who previously developed a partial solution with a grant submit offers? (For example Vendor A received grant to develop Module X in the past. Now they want to include this product when they submit their offer.)
A: Applicants awarded a contract in ProEmpower are non-eligible if they receive double funding for the same activity, i.e. if they receive funding for developing the same component of the solution, or the whole solution itself. If a part or parts of the solution have been developed in the past using different funding, they can be used in ProEmpower as they relate to activities in the past. Previous developments must be defined as background IPR in the framework agreement to be settled between the procurers and the applicant.

ID: 14; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Time/ phases requirements

Q: What happens if only one company is selected in phase 3?
A: The project foresees a minimum number of two tenderers for the final phase to avoid monopoly. If only one company will be eligible for phase 3 the tender will need to be cancelled .

ID: 45; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Q: When will all the requirements be finalised?
A: The final requirements will be part of the tender documents, which are expected to be published in September/early October.

ID: 18; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Will the call for tender present all the requirements for the solutions or will there be new requirements on transition between phases?
A: The pre-commercial procurement process in ProEmpower is set up to facilitate continuous dialogue between the procurers and the suppliers which will result in a product that is as close to their needs as possible. The procurers however understand that constantly changing requirements

will not result in effective implementation, therefore procurers have identified core requirements and functionality. Through the dialogue with the suppliers these requirements and functionalities may need moderate adjustment, which will be agreed between the procurers and suppliers depending on the implication on the budget, time and quality involved. At the end of each phase suppliers will have the opportunity to present an offer for the next phase based on the adjustments requested.

ID: 19; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: What is the foreseen time period for submission of tender offers after the publication of the tender in September?

A: The tender will be published at the end of September and we currently foresee two to three months for the preparation of the tenders. The final deadline will be reported in the call for tenders.

ID: 13; Submitted via Webinar (8 June 2017)

Q: When will the tender be announced?

A: The tender document will be published after the review and approval of the European Commission in September 2017. The Commission has the right to extend the review time. The publication is therefore expected to be made in the period between end of September/ early October.

ID: 6; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Q: Will there be separate tender documents for each phase?

A: There will be only one tender document to be published in fall 2017, defining what the procurers are looking for in all three phases of the project.

ID: 9; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Q: The last phase (3) duration is 15 months. Not sure if this is going to be enough time to go through the ethics committee and perform a clinical trial

A: The ProEmpower procurers will form an ethics committee, and suppliers need to submit their plans already in phase 2 to ensure there is enough time. The ProEmpower coordinator will ensure that the procurers act as quickly as possible, typically within 3 to 5 months. The committee should have granted approval before starting the pilot in the third phase..

ID: 43; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Q: When do the vendors have to present the business model/plan and which is the importance given in phase 2 and 3?

A: First considerations for commercialisation, including ideas about pricing and business models, are expected to be provided in the tender applications. These need to become clearer in phases 2 and 3. The business plan is important for the procurers and for the European Commission as a co-funding body, as pre-commercial procurement aims at producing products which will be used widely in the future..

ID: 49; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Q: Will the project celebrate a minimum of 3 (three) contracts at phase 1? And will there be at least 2 contracts in phase 3? If so, will this mean that we may have 2 companies producing the same type of system and with the need for pilots to run double tests?

A: The number of contracts awarded at each phase depends on a number of things such as the budget volume applicants request and the evaluation score. The procurers seek a healthy competition and will award contracts to as many suppliers as possible. Having 2 companies in phase 3 ensures that a monopoly-type solution is avoided. Suppliers are allowed to propose their solutions based on the core functionalities and requirements of the procurers, but they are also left with

enough space to shape the solution, therefore we do not expect that any two systems will be alike.

ID: 17; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Are the vendors supposed to present a complete design and methodology for all phases?

A: The applicants need to propose a complete design and work plan for all activities when submitting their proposal. The tender documentation will include milestones and deliverables for all phases and associated interim payments..

ID: 20; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Will there be the possibility that companies which sign a contract for phase 1 and that are not selected for phase 2, may be selected for phase 3, as the project is planning to sign a framework agreement?

A: Procurers select solutions at the end of each phase, and only these solutions can continue on to the next phase and receive funding. .

ID: 23; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: What happens if one of the selected companies/consortiums in the first phase drops in a later phase? Would that mean that the ones that have not been selected initially have a second opportunity?

A: Such a case is very speculative and can only be discussed when they occur, as they depend on the time at which a company has dropped, the budget the company is allowed to receive up to that point, whether the remaining budget can be used for another solution, and whether this new solution can catch up to the timeframe of the other competitors.

ID: 51; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Q: Does Phase 2 involve co-creation?

A: The pre-commercial procurement process in ProEmpower is set up to facilitate continuous dialogue between the procurers and the suppliers which will result in a product that is as close to their needs as possible. In this sense there is a co-creation element in ProEmpower

ID: 53; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Technology requirements

Q: What is the TRL (technology readiness level) expected?

A: ProEmpower does not request suppliers to undertake "fundamental" research but "applied" R&D: industrial research and experimental development including field testing.

For more information please consult http://innovationithospitals.com/pdf/resourceCentre/FAQ%20PCP%20actions.pdf(page 17).

The TRL level to be achieved at the end of ProEmpower is expected to be 7 as in phase 3 system prototype will need to be demonstrated in an operational environment.

ID: 34; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Do you have any restriction about the technology used?

A: The ProEmpower procurers expect innovative solutions, therefore the core requirements in the tender document will be described as much as possible in a form that is independent of technology, focusing rather on the procurers' needs.

Restrictions on technologies could however result from technology already in place by the procurers, such as the EHR used in Turkey or glucometers widely used. There will be a need for an interoperable interface. No restriction is imposed on the technology as long as it fulfils the procurers' requirements regarding interoperability, usability, stability, data protection and so on.

ID: 17; Submitted via Webinar (8 June 2017)

Q: Are there any technical requirements: which EHR, glucometers, etc. must be supported in the decision support?

A: Such information will be included in the tender document.

ID: 18; Submitted via Webinar (8 June 2017)

Q: Is there a preferred standard for clinical best practice to inform the solution, for example the BMJ or Up-to-Date?

A: We will make our requirements regarding clinical best practice part of the tender documentation. We have not followed specific standards but rather a mixture of clinical best practices. Because we do not see a standard of diabetes care across the countries at the moment, and that needs to be considered together with the reality of care in the procurer countries. Expected standards of care will be found in the tender document.

ID: Xxx; Submitted via Webinar (8 June 2017)

Q: Will specifications about automatic services for patient monitoring (based on expert systems) be included in the technical and functional specification?

A: No comment at the moment. Such information, if required, will be included in the tender document.

ID: 2; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: When will we know about the features and modules of the desired solution, and about the expectations of the buyers group in detail?

A: When the tender document is published. The tender document will contain all the technical specifications of the solution.

ID: 11; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Q: For semantic interoperability which clinical terminologies should the solution cover? For example ICD10, SNOMED CT?

A: Depending on the use case (e.g. transmitting physiological parameter data, lab values, etc.) different terminologies and standards may be used. The tender will define appropriate standards, such as IEEE 11073 PHD for physiological parameters transmission, LOINC for lab values, and FHIR for personal health functionalities and web-based and RESTful technologies with regard to messaging, mapping and resource management. However, this does not preclude applicants from using other standards as long as interoperability with exiting systems can be proven. SNOMED CT is an interesting terminology but consider the licensing options for later deployment. To our knowledge only Spain and Portugal are members of SNOMED international

ID: 20; Submitted via Webinar (8 June 2017)

Q: Does the managed service need to be hosted within the geographical boundaries of each of the four countries or can it be cloud-based?

A: Such information will be included in the tender document. At this point in time the ProEmpower procurers believe that in order to meet the various regulations and IT security standards, the solution will need to be hosted within the geographical boundary of each procurer.

ID: 14; Submitted via Webinar (8 June 2017)

Q: If we already have a product that has a lot of the functionality desired but will need to be developed further to cover all the functionality required, is that ok?
A: Suppliers may have a lot in terms of functionality in their portfolio but the procurers expect them to tailor the products to the local needs. Suppliers can use their portfolio as a basis and develop it further, tailoring it to the needs of the four procurers.

ID: 2; Submitted via Webinar (8 June 2017)

Q: Will sufficient amount of data be provided to suppliers for the development of predictive algorithms?
A: This is most likely not possible, especially not in the first phases. The ProEmpower procures will state whether such data will be available in the tender document. In phase 3, however, procurers will also provide access to 100 type 2 diabetes patients per procurer, who will be testing the solution.

ID: 4 &3; Submitted via Webinar (8 June 2017)

Q: Will the suppliers be able to “add on” new features on the system?
A: Yes. As a matter of fact, there will be a competitive environment throughout the project for the suppliers to demonstrate if and how they are able to meet the unmet needs. While doing this, the suppliers will be able to offer new features that are reasonably connected to and within the scope of the project.

ID: 10; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Q: Are the IDF recommendations for care of T2DM applicable in the target countries?
A: IDF recommendations are important and are explored in ProEmpower. They are the basis for the procurers’ care recommendations and requirements elicitation. Tailoring proposals to the IDF recommendations would be a good starting point. The details for the care procurers would specifically like to see will be published in the tender documents.

ID: 34; Submitted via Webinar (8 June 2017)

Q: Will there be the need to foresee/propose medical devices? Is the call for tender going to identify them?
A:.It is not the scope of the project to develop new devices but rather work with existing on the market. The supplier should however identify those that are necessary for their proposal and also provide a limited number for testing in phase 3. In case devices are proposed the problem of vendor lock-in will need to be addressed. Some devices like glucometers will be identified by the call and interoperability wilt all of the identified will be required.

ID: 24; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Is Portugal’s Directorate-General of Health (DGS) involved in this project? How will the requirements integrate with the existing guide for diabetes (published by DGS)?
A: DGS is not an active partner in the project. Nevertheless, DGS has been involved in the project with consultant role. The requirements will contribute to the underlying objectives of the guide for diabetes and National Programme for the Prevention and Control of Diabetes, namely by introducing an integrated ICT educational and self-management tool, resting both on a perspective of clinical care and evaluation of quality surveillance and metabolic parameters.

ID: 25; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: What are we expected to provide? Do you expect we produce new content, or you just want a platform that links existing content in a single solution?
A: Validated and renowned content is preferred over new content. Validated content may, however

not exist in the form and extent necessary. In that case suppliers are requested to to produce new content.

ID: 32; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Are you heading for a communication platform (patient-healthcare services) or do you expect a learning component for the system? Will there be a focus on data analysis/technological knowledge? Comment: if the objective is that the patient becomes active part of his/her treatment, we are talking of a platform with the joint purpose of being a basis for communication and a basis for knowledge/self-management. There is the need to better explain the data communication flow.

A: The procurers envision that suppliers will be able to combine the different building blocks presented at the market consultation, so that new data is combined and used to deliver tailored communication to patients. In this sense, the solution is expected both to use data analysis/technological knowledge and communication that uses this new data to empower the patient.

ID: 33; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Are you expecting to allow/foster a system of data mining? Comment: that would be much more demanding, since it requires a lot of clinical information of patients. A predictive model requires a database with millions of data.

A: It is up to the suppliers to decide whether data mining is needed to fulfill the procurers' needs, and if yes, what devices available on the market to the four procurers the solution needs to be complementary with to collect such data.

ID: 35; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Project Focus

Q: On slide 11 ff the presentation used in the workshop you mentioned Early Detection as one of the focus of the solutions. Do you mean that you also seek solutions for the first diagnosis of patients or for the better management of already diagnosed patients? Is the project focused on type 1 or type 2 diabetes?

A: The project focuses only on type 2 diabetes patients and those that have been diagnosed but also those with impaired glucose tolerance. We are still discussing our exact needs for identifying those patients. You will find more information on the exact need in the tender documents.

ID: 7; Submitted via Webinar (8 June 2017)

Q: Is this for all types of diabetes or just the 12 million type 2 patients you mentioned?

A: The focus is on type 2 diabetes patients only. The focus is also on avoiding complications by starting as early as possible with life style changes.

A modular approach providing the possibility for adding modules dealing with complications or co-morbidities later one would be seen as an advantage as well as option to extending the solution to type 1. Our long term vision is a chronic disease management system addressing also multi-morbidity.

ID: 10; Submitted via Webinar (8 June 2017)

Q: To what extent will the solution need to address complications in diabetes? Or is it only for early detection and management?

A: ProEmpower is focused on avoiding complications. A modular approach providing the possibility for adding modules dealing with complications or co-morbidities later one would be seen as an advantage. .

ID: 29; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: If there is wide interaction with professionals, how can we limit the risk of any deviation from the original proposal?
A: Interaction with the procurers and their clinicians is crucial to tailor the solution to their needs. The core idea has been established in collaboration with professionals so deviation of the core is not expected. Later interaction with professionals should be seen as an assets not as a risk.

ID: 54; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Match-making

Q: How will the formation of new consortiums or synergies be managed? Will proEmpower put us in touch with possible partner or will we get a list of all the form submitters?
A: the list of all the vendors that are looking for partners has been published under http://proempower-pcp.eu/market-consultation/matchmaking-find-partners.html..

ID: 29; Submitted via Webinar (8 June 2017)

Q: In order to team up with other companies, is the content of the questionnaire transparent to all participants? How can we see what other companies are offering / looking for?
A: The name of the company, the contact person, the fields of expertise and what they are looking for in a partnership has been made available. The other answers are treated as confidential..

ID: 30; Submitted via Webinar (8 June 2017)

Q: Will you help with contacting device companies supplying device solutions for diabetes? Like glucometer, scales, etc.?
A: This should be part of the supplier's offer, the way to acquire or interface with devices from certain vendors is their responsibility. In case devices are already in use by the procurers they will be identified in the tender documentation

ID: 32; Submitted via Webinar (8 June 2017)

Q: Will Soresa provide any support to the local vendor in matchmaking and consortium formation?
A: This will be done by the ProEmpower consortium, please refer to question ID 29.

ID: 4; Submitted at Naples Market Consultation Workshop (6 June 2017)

Q: Can procurers recommend the vendors any other vendor for successful consortium building?
A: The vendors are responsible for building their consortium, if they would like to build a consortium. The procurers are in no position to recommend a vendor or vendors to another vendor or vendors.

ID: 40; Submitted via email to the vendors

Q: Can two firms which win and successfully complete the first phase continue the second phase as a consortium if they want to?
A: We have not assessed the legal options of this proposal, but ProEmpower would like to encourage competition and therefore we encourage vendors to build a competitive consortium upfront and provide the best solution they are capable of.

ID: 13; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Q: Can you organise another meeting to offer matchmaking for the potential vendors?
A: A questionnaire is available in the project web page for this purpose: http://proempower-

pcp.eu/market-consultation/market-consultation-questionnaire.html. In that questionnaire you can request matchmaking. The information will then be made public under: http://proempower-pcp.eu/market-consultation/matchmaking-find-partners.html.

ID: 15; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Q: Is subcontracting allowed? If so, under what Limits/conditions?

A: Participation in the tendering procedure is open on equal terms to all types of operators from any country, regardless of their geographic location, size or governance structure.

Tenders may be submitted by a single entity or in collaboration with others. The latter can involve either submitting a joint tender or subcontracting, or a combination of the two approaches.

Detailed conditions will be contained in the tender documentation

ID: 52; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Q: Are we going to share the contacts of participants in the proEmpower workshops?

A: We do not share the contacts of participants, but participants are invited to submit the market consultation questionnaire and allow for publication of their contact details. Parties that have done so can be found here: http://proempower-pcp.eu/market-consultation/matchmaking-find-partners.html

ID: 55; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Q: Can we partner with an academic institution to assist with some of the evaluation?

A: Teaming up with academic institutions is possible. However please not the evaluation as such will be done after each phase and will be done by the Procurers.

ID: 6; Submitted via Webinar (8 June 2017)

Q: Could a university research centre be part of the consortium?

A: Yes, see also above. Please note that the aim of ProEmpower is to develop a sustainable solution and plans for operation after proEmpower will be part of the project..

ID: 22; Submitted via Webinar (8 June 2017)

Legal Framework

Q: Will the EU GDPR be taken into consideration?

A: As the EU GDPR will apply automatically from 25 May 2018 onwards (which is within the duration of ProEmpower), it has to be taken into account by the suppliers.

ID: 28; Submitted via Webinar (8 June 2017)

Q: Will there be any restriction to the participation of companies related to their nationality? Do they (or a branch) need to be registered in EU Member Country?

A: The suppliers do not need to come from certain countries, they can come from anywhere in the world, it is not restricted. They need to prove in their application their ability to provide and deploy the solution in the four countries.

They also need to demonstrate that 50% of the research has been done in the European Union.

ID: 16; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: How will the framework agreement modality work? What will that first contract regulate?

A: The framework agreement will be published together with the tender documentation. To get an

idea about the framework agreement already now please consult the template provided by the the EC – Annex 1 : http://ec.europa.eu/research/participants/data/ref/h2020/other/gm/h2020-request-tenders-pcp_en.pdf

ID: 22; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Which kind of legal form is a requirement? Are there any requirements about previous projects or portfolio? We are a new team still looking for the legal form best suited to us.

A: The legal form is not important when applying, but rather the operational capacity of the applicants to ensure that the proposed plan can be achieved in reality.

ID: 12; Submitted via Webinar (8 June 2017)

Q: Is Turkey subject to the European Directive of contracts?

A: "European Directives" are binding for EU member states only. Turkey, as a candidate country, is not subject to the European Directive of Contracts. However, the terms and conditions of European Directive of Contracts may be applied in the framework agreements, as long as they do not conflict with national law (Obligations Law, and Commercial Code).

As Turkey is an EU candidate country directives are transposed in Turkish law. For example Turkish Law on Protection of Personal Data (dated 24.03.2016 and numbered 6698) is perfectly in accordance with the 95/46/EC Directive.

ID: 46; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Q: Which law applies in the contract?

Q: Which is the legal framework that applies to this contract?

A: Obligations Law, and Commercial Code of Turkey. In case of conflicts arbitration will be sought at the international chamber of commerce in Paris.

ID: 47; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

ID: 48; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Q: Which is the legal entity of the Consortium?

A: Participation in the tendering procedure is open on equal terms to all types of operators from any country, regardless of their geographic location, size or governance structure.

Tenders may be submitted by a single entity or in collaboration with others. The latter can involve either submitting a joint tender or subcontracting, or a combination of the two approaches.

For joint tenders:

the group of tenderers must assume joint and several liability for the performance of the contract;

the group of tenderers must mandate one of them with the power to sign the framework agreement and specific contracts provide in their name and on their behalf ('lead contractor')

ID: 50; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Privacy Guidelines

Q: How will the partner search questionnaire work? If my company inserts its information will this info be available for everyone in the internet? Will I see the other companies' information?

A: Some fields in the questionnaire are public, others not. Please consult http://proempower-pcp.eu/market-consultation/matchmaking-find-partners.html to see which fields are available to

everyone

ID: 27; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: How is it foreseen to ensure confidentiality of the information? Who will be the owners of the information? Who keeps the data, where will all the data be stored?

A: It is important that information related to ongoing developments and use of innovative techniques is treated confidentially, therefore the framework agreement will include such clauses, specifying that only the ProEmpower consortium partners can have access to the data and are not allowed to share it.

ID: 30; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: How will data protection be considered? Will vendors be required to abide by the current or the future data protection legislation (EU regulation expected for 2018)? How will it be in Turkey, as it is not a European Union country?

A: With regards to the data protection legislation, Turkey has transposed and is fully in line the EU directives. Future regulations like the GDPR have to be taken into account by the suppliers if they fall within the project timeframe. Also please not that the new GDPR has extra-territorial applicability.

ID: 31; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Participants engagement and contact

Q: How do companies get to know the systems their solution must be interoperable with?

A: The tender document will provide first descriptions of the available systems of the procurers. Further, more technical details will be provided during the phases.

ID: 21; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Will we have a chance to collaborate with the procurers in the first two phases as well?

A: We plan to have a good dialogue with the purchasers and what exactly the form will be needs to be discussed but it is important for a form of collaboration between the suppliers to exist, on an equal basis. As long as there is more than one supplier involved we will need to provide transparency to all suppliers, all the info given to one supplier will also be given to the others. This is a general principle of pre-commercial procurement.

ID: 16; Submitted via Webinar (8 June 2017)

Q: Will you be proactively following the participating companies, or should we regularly follow the website for updates?

A Those who have signed up for the newsletter will be informed on all important news, especially on the publication of the tender documentation and that will of course be published in the European Journal. We will inform all those whose emails we have. Subscribe to the newsletter and send us the market consultation questionnaire filled and then we will keep you up to date.

ID: 33; Submitted via Webinar (8 June 2017)

Q: How will the feedback be given after each phase? Will vendors be allowed to interact directly with the reviewers/evaluators? Like doing a live demo of the solution developed?

A: There will be things like that and we are discussing what form the presentation will take, especially for phases 2&3 demos and testing will be required; for the first phase and for the tender we have not made a decision on this matter but you will find further information in the tender documentation.

ID: 26; Submitted via Webinar (8 June 2017)

Q: How is been defined the relation model with procurers? There will always be nominated person that will be the one-stop-entry?
A: Similarly to the way the EC regulates relationship within Horizon2020, each supplier or supplier consortium will have a designated co-ordinator and more specifically a person that will be able to communicate with the ProEmpower consortium, which will have also designated a contact person.

ID: 57; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Patient involvement

Q: Will target patient groups (e.g. representatives of patient associations) be involved in the definition of the requirements and/or in the three phases of the evaluation?
A: The procurers have already consulted local patients, healthcare professionals, etc. to shape their vision as captured in the tender document. Professionals and patients will be involved in the testing phase.

ID: 3; Submitted at Naples Market Consultation Workshop (6 June 2017)

Q: Will you provide patient data from the 4 countries? Comment: in order to create those kinds of algorithms for the pilots it will be necessary to have the data for such pilots beforehand – not after phase 1 but already at tender notice
A: Exemplary anonymised patient data can be provided. Providing large-volume data is most likely not possible, especially not in the first phases. The ProEmpower procures will state whether such data will be available in the tender document.

ID: 36; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Would be considered as positive the support with the recruitment? Who is responsible of the patient recruitment?
A: Recruiting the 100 patients per procurer is a task for the procurer. Any support will surely be welcomed by the four procurers.

ID: 44; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Geography

Q: What is the number of people with diabetes in Turkey?
A: According to the national health information system of Ministry of Health of Turkey, there are around 8 million people who have been diagnosed with diabetes (2016).

ID: 5; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Q: Will different firms be responsible for different countries?
A: No. The same product(s) of same vendor(s) will be used in all four countries. If suppliers apply as a consortium, of course internally different companies can take over different tasks e.g. local installation, this is an internal arrangement among the consortium partners.

ID: 8; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Q: Will the tender have in consideration the cultural & economic differences between countries? **Comment:** if you'll propose a common solution it may lead to a minimum denominator solution, therefore prejudicial to the intent of procuring an innovative solution.
A: It is the suppliers who have to explore whether cultural or economic differences across the procurers will affect their proposed solution. An obvious area where such differences will have to be explored is the nutrition and food that diabetics are recommended to take.

ID: 26; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: Do suppliers need to come from certain countries?
A: The suppliers do not need to come from certain countries, they can come from anywhere in the world, it is not restricted. They need to prove in their application their ability to provide and deploy the solution in the four countries. They also need to demonstrate that 50% of the research has been done in the European Union.

ID: 1; Submitted via Webinar (8 June 2017)

Funding

Q: Will you divide the budget into four for four different regions?
A: No. The procurers represent a group of four buyers, led by Ministry of Health of Turkey. Ministry of Health of Turkey will be procuring the sought-for solution on behalf of the buyers group, and the one solutions will be used and tested in all 4 procurer countries.

ID: 7; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Q: **Comment:** the budget of 450.000 € for phase 1 can be short, as maybe it would only be enough for 2 projects.
A: Phase 1 is a paper based specification phase of only 2 months. If you assume a budget of €90,000 per supplier this could translate in about 20 person months which we deem appropriate to specify a product to enter phase 2 (prototyping).

ID: 39; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: How is the payments schedule? By milestones?
A: The payments schedule will be defined in the framework contract, to be available as part of the tender documentation.

ID: 56; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Evaluation process of the bidder's offers

Q: How will you be scoring the offers when you are evaluating them? Will Ministry of Health be doing this?
A: The offers will be evaluated by a panel made up of representatives of the four procurers, who will be scoring each proposal using a list of criteria to be made available as part of the tender documentation. A price-quality ratio will be defined in the tender documents.

ID: 12; Submitted at Ankara Market Consultation Workshop (31 Mai 2017)

Q: In the evaluation, is it going to be considered as positive to present an idea that will be able to deal with Comorbidity and not only with diabetes

Q: In the evaluation, is it going to be considered as positive (an improvement) to present solutions that can also manage other diseases
A: ProEmpower focuses on diabetes, but suppliers can provide more suggestions based on their budget and capabilities. Providing expendability towards severe cases, concomitant disease and co-morbidities as well as data coming from different devices will be a requirement. We encourage the suppliers to propose a modular architecture.. A final list of evaluation criteria will be provided with the tender documents, so suppliers will see whether the procurers have left space for innovative new suggestions outside of the focus set in ProEmpower.

ID: 41; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

ID: 42; Submitted at Murcia Market Consultation Workshop (24 Mai 2017)

Information material

Q: Will the slides of the Open market consultation be available?
A: All relevant slides from the local events and webinar are available here: http://proempower-pcp.eu/market-consultation/consultation-workshops.html .

ID: 8,9; Submitted via Webinar (8 June 2017)

Others

Q: What happens/how will you deal with background brought forward by companies?
A: Background can be used by the suppliers. Regarding funding, if a part or parts of the solution have been developed in the past using different funding, they can be used in ProEmpower as they relate to activities in the past. Background IPR will be documented in the framework agreement.

ID: 29; Submitted at Lisbon Market Consultation Workshop (29 Mai 2017)

Q: What is the role of patient education?
A: Patient education is of course crucial and it will be a core part of the solution we are looking for. The current education methods are not targeted and tailored to the disease and patient. We would like a more sophisticated approach to education.

ID: 19; Submitted via Webinar (8 June 2017)

Q: How important is mHealth in the project?
A: We do not set up requirements technologically but as long as the solution fulfils our needs and if a need is mobility, then mHealth is important. However, we are dealing here with elderly patients and mHealth should not be the only option. Consult the requirements of the target group and it should become clear if mHealth solution is adequate or other solutions should be looked into.

ID: 21; Submitted via Webinar (8 June 2017)