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This document contains questions the ProEmpower consortium has received by tenderers regarding the ProEmpower tender documents. Answers have been provided jointly by the four ProEmpower procurers. This document will be continuously updated to include new questions and their answers.

Q: Are tenderers required to make a registration at https://ec.europa.eu/tools/espd/filter?lang=pt to be eligible for the project?
A: No, the tender documents do not refer to using the European Single Procurement Document (ESPD).

ID: 1; Submitted on 18 January 2018

Q: Who has ownership of the platform and the results generated in the framework of the tender? Does ownership belong to the ProEmpower consortium members, based on what is agreed in the partnership agreement?
A: Please refer to the draft ProEmpower Framework Agreement provided with the tender documents (TD8) e.g. Article 5.

ID: 2; Submitted on 18 January 2018

Q: In phase 3 of the PCP (development of pilot systems and testing), the platform has to be accessible not only from the hospitals but also from the patients' homes?
A: The procurers expect that the developed solutions will address their needs and requirements as captured in the challenge brief document (TD2). The patient plays a central role in the diabetes management process, and this is reflected in many of the requirements. The proposed solutions need to be able to deliver on these requirements. For more details, refer to the requirements documented in the challenge brief (TD2).

ID: 3; Submitted on 18 January 2018

Q: Regarding the requirements related to the parameters, we have understood that some can be measured manually and introduced to the system (such as height), some can be recorded automatically using wearable devices (such as heart rate...) and some semi-automatic. According to p29-30 of the Challenge Brief, there is a long list of parameters that should be recorded, which ones would you consider a must for automatic measurements? (Specially, regarding the chemical parameters such as creatinine, microalbumin, cholesterol, triglyceride, LDL, HLD...).
A: Please refer to section 2.3 of the challenge brief (TD2). Section 2.3 prioritises all the requirements for parameters/measuring units. The requirements documented there, as well as in other sections of the challenge brief where automatic recording is mentioned, represent the best attempt of the ProEmpower procurers to define features of future systems which, individually and in total, represent significant innovation beyond the state of the art in the management of diabetes in a population.

ID: 4; Submitted on 24 January 2018

Q: In phase 3, the pilot is expected to be performed in 400 patients (100 patients at each of the four sites). We were wondering if the 400 patients will be tested simultaneously (requiring 400 wearable devices) or could be tested separately in each of the sites (requiring 100 wearable devices that would be reused in each of the different sites). That would be a key aspect to be determined when taking into account the budget needed in each phase.

A: Please refer to the expected outcomes for phase 3 in section 3.4. of the Request for Tenders (TD1).

ID: 5; Submitted on 24 January 2018

Q: Is there a document detailing the trial design including reports required, data to be logged, the age range of patients etc.

A: In respect of trial design, please refer to the expected outcome of each phase of the PCP phase.

ID: 6; Submitted on 26 January 2018

Q: On page 21 of the Request for tender you mention a "A study in Germany on a commercial telemedicine program in combination with clinical decision support with 538 diabetes Type 2 patients and run by a German health insurance company". Would it be possible to have a copy of it or a reference to it if the study has been published?

A: The paper mentioned in the tender refers to

Salzsieder E, Augstein P. The Karlsburg Diabetes Management System: Translation from Research to eHealth Application. Journal of Diabetes Science and Technology. 2011;5(1):13-22.

ID: 7; Submitted on 29 January 2018

Q: There seem to be a striking unbalance between the budget available for Phase 1 (90.000 Euros) and the duration of it (35 days between the start of the Phase and the Submission of offer for Phase 2). Can you please confirm that this is not a mistake?

A: The budget for phase 1 is correctly specified in section 1.4.1 of the Request for Tenders. The time between start of phase 1 and submission of offer for the next phase is specified in the time schedule in section 1.4.3.

ID: 8; Submitted on 29 January 2018

Q: Is it acceptable for a start up company with a small number of employees to apply, include a hiring plan for resources to be added if the company is granted a phase 1 funding.

A: The eligible tenderers are described in section 4.1 of the Request for Tender. Issues of financial and personnel capacity to carry out the work are discussed in section 4.3 of the Request for Tender.

ID: 9; Submitted on 1 February 2018

Q: It is stated that the whole procurement budget of the project is VAT-exempt and that bids from any country but Turkey shall not include VAT while bids from Turkey shall include VAT. We are planning a consortia with a Turkish company being us, from Spain, the leading partner. Thus, does it means that, for example for phase 1, when we (Spanish company) issue the invoice it should be of 90.000€ tax free? And, in case the Turkish partner being the leader, it that should be of 90k + 18%VAT or 90K include the 18%Tax?

A: A consortium delivering PCP R&D services to the MOH in Turkey led by a i) Spanish ii) Turkish organisation with a i) Turkish ii) Spanish organisation as subcontractor is treated for VAT purposes by the MOH as if all services were to be provided by the i) Spanish ii) Turkish organisation. Whether or not VAT is to be invoiced will have no impact on the evaluation, which will take account of net prices only.

ID: 10; Submitted on 1 February 2018

Q: In phase 2, we can choose whether to provide technology at procuring premises or offer access in lab conditions, but in phase 3 the system has to be introduced in the procuring entities's premises. In

which phase it is expected the technology being integrated to hospitals with the close collaboration of the procurers representatives?

A: Please refer to section 3.4 of the Request for Tenders, namely the expected outcome of the PCP phase 3.

ID: 11; Submitted on 1 February 2018

Q: Could you please give us more information of what a non- or partially functional prototype is in terms of data analytics, app, learning platform, etc, to evaluate the feasibility of having this prototypes 5 months before the end of the phase?

A: It is possible that different tenders will have different approaches. To comply with the request for tender, the prototype must meet the requirements defined section 3.4 of the Request for Tenders, namely the time of delivery

ID: 12; Submitted on 1 February 2018

Q: Should we include in our proposal for this phase 0 the name of the sensors in the market to which we propose to integrate our solution?

A: Any information can be included in the proposals that helps evaluators gain a proper picture of what is being offered. The administrative, technical and financial templates provided with the tender documents specify the minimum information to be provided.

ID: 13; Submitted on 1 February 2018

Q: The point 4.4.4 D) Compliance with ethics and research integrity states that we must deliver an Ethics committee opinion under national law.

What organization should we contact regarding this ethics committee? Is it an ethics committee created within our own company, one created by [ProEmpower], or should we seek a third party committee ourselves?

If this point refers to a third party audit company, should we seek one within Portuguese law, European law or International law?

A: In our view it is up to the tenderer to examine national law provisions in this respect.

ID: 14; Submitted on 5 February 2018

Q: Is there a document detailing the trial design including double-blind trial, family prevalence, reports required, data to be logged, the age range of patients etc, pregnant Yes/No as examples. The success criteria i.e. the quantitative and qualitative outputs that are expected from the trial?

A: In respect of trial design, please refer to the expected outcome of each phase. The information available is that contained in the Request for Tenders, in particular sub-point 3 of the outcomes of phase 3 in section 3.4.

ID: 15; Submitted on 5 February 2018

Q: In chapter 4.3 the selection criteria are explained very clearly. However, we do not see a separate template for a document where this is information has to be presented. Can you please confirm that the information relevant for this criteria has to be provided in section 3.2.1 of the Technical offer?

We have seen no request to provide balance sheets or P&L in the Request for Tenders. Do they have to be provided in the Administrative envelope?

A: For compliance to the selection criteria, please refer to section 5 of the administrative template.

The administrative, technical and financial templates provided with the tender documents specify the minimum information to be provided.

ID: 16; Submitted on 7 February 2018

Q: In the case of subcontracting we have to provide the names of the subcontractors and sign the TD9 document in phase 1?
A: Please refer to the subcontracting conditions in section 4.1.2 of the Request for Tenders. The Specific Contract for Phase 1 (TD9) is signed with the tenderer, not with subcontractors. Information on subcontractors is also required in the Financial Section of the Tender Application, inter alia to verify compliance with EU rules on the location and nature of R&D.

ID: 17; Submitted on 9 February 2018

Q: Regarding the submission content, (1) are we required to submit a draft business plan, a risk assessment and risk mitigation strategy in phase 1 (2) How detailed should be our description in tender's technical section template?
A: Please refer to the Tender Documentation, in particular, Section 4.6.3 of TD1. Attention is also drawn to the award criterion "Sustainability of supplier business case". Any detail of information can be included in the proposals that helps evaluators gain a proper picture of what is being offered. The administrative, technical and financial templates provided with the tender documents specify the minimum information to be provided. Page limits apply as specified.

ID: 18; Submitted on 9 February 2018

Q: Are we required to obtain a security certification according to ISO/IEC 15408 for the end - product or we have just to comply with CC standards? Refer to document TD1, "Requirements related to security (R4.2)", specifically on requirement number R4.2.11 Security profile "The service will develop a security profile which can be certified according to Common Criteria for Information Technology Security Evaluation (ISO/IEC 15408)
A: R4.2, which is explained in Section 2.4 of Challenge Brief, specifies clearly that a security profile is to be developed which can be certified according to Common Criteria for Information Technology Security Evaluation (ISO/IEC 15408).

ID: 19; Submitted on 9 February 2018

Q: Regarding the requirement related to the provided devices "R1.3.5 Parameters - device numbers and use", page 15/186, "the ProEmpower solution may use sensors to measure and collect certain parameters. In such cases, the ProEmpower solution shall aim to combine functionalities in one sensor to avoid overload of patients with different sensors. In any case, the ProEmpower solution shall offer no more than two different devices per patient. The device(s) shall be as unobtrusive and compact as possible." and regarding the requirements related to the parameters/measuring units recorded by the ProEmpower solution (R3.1) page 29. What parameters should be measured automatically from a device? The answer would be useful in order to propose two appropriate devices complied with the requirements.
A: Please refer to the answer of the ID4 question.

ID: 20; Submitted on 9 February 2018

Q: All the proposed devices should be compatible with requested standard IEEE 11073 PHD? Can we propose Bluetooth Low Energy (LE) devices based on GATT profile? Refer to document TD2, paragraph R1.3 requirements related to recording of parameters, page 15, point "R1.3.6 Parameters - sensor standards".
A: R1.3.6 clearly states that any used sensors should comply with international standards **like** IEEE 11073 PHD. To the extent that other international standards apply to devices proposed in the tenderer's solution, those standards should be complied with. Applicable standards and the intention

to comply should be clearly stated in the Tender Application.

ID: 21; Submitted on 9 February 2018

Q: Regarding the EQ5D questionnaire are you entitled to use it in the ProEmpower solution by the EuroQol Research Foundation or this is an obligation of tenderers? Refer to document TD2, paragraph R3.1, "requirements related to the parameters/measuring units recorded by the ProEmpower solution", point "R3.1.23 EQ5D questionnaire "The ProEmpower solution shall offer the EQ5D questionnaire to track patients' health outcomes. The questionnaire shall be administered at minimum when enrolling the patient, as well as when the ProEmpower project operational phase ends."

A: The requirements provided with TD2 are expected to be addressed in tenderers' offers. Tenderers must ensure their offer is complete and that achieving the expected outcomes relies at most on responsibilities of Buyers which are explicitly mentioned in Request for Tender documentation.

ID: 22; Submitted on 9 February 2018

Q: Clarify whether patient appointments need to be managed via ProEmpower solution for training sessions in the different training facilities or doctor offices in the member countries. Will there be existing solutions to integrate with? How to integrate?

"The ProEmpower solution shall support training of diabetic patients in the facilities foreseen at the procurers' pilots - either designated facilities or in doctors' offices." (R1.2.6 Training facilities)

A: Please refer to the description of UC7 in TD2 and the descriptions there of existing procurer systems in Section 2.2. Attention is also drawn to the award criteria in TD1 Section 5, in particular "Soundness of the approach to integration with procurer systems". To meet this criterion the approach to integration must be described in Tender Application Technical Section TD6, Sections 1.2 and/or 1.3.

ID: 23; Submitted on 9 February 2018

Q: Please clarify what other systems contribute information to the TR PHR (Turkey's Personal Health Record characteristics)

A: Information on procurer systems for tenderers to plan and cost their offer is contained in Section 2.2 of the Challenge Brief, TD2.

ID: 24; Submitted on 9 February 2018

Q: DOC TD3a, section 7: Any document or declaration have to be provided just upon request?

A: Yes, as indicated in TD3a, Section 7: *the person must provide information on the persons that are members of the administrative, management or supervisory body (…)* ***upon request*** *and within the time limit set by the contracting authority.*

ID: 25; Submitted on 9 February 2018

Q: DOC TD3a, section 8: Any declaration has to be provided just upon request?

A: Section 8 requires a declaration by the signatory, to be submitted with the tender, of ability to provide certain documents upon request and without delay.

ID: 26; Submitted on 9 February 2018

Q: TD3b, section 1.1.4: Which kind of evidence has to be produced? (An ETHIC SELF ASSESSMENT per each partner?)

A: Dully filled in TD3b is expected to be provided by the lead contractor. Section 4.4.4 of the Request for Tenders clearly specifies when an ethics self-assessment is required.

ID: 27; Submitted on 9 February 2018

Q: TD3b, section 1.1.5: Which kind of evidence has to be produced?
A: Different vendors may have different methodologies and approaches. It is up to the vendors to self-assess if their offer may raise security issues. Section 4.4.5 of the Request for Tenders clearly specifies in what cases documentation must and may be required.

ID: 28; Submitted on 9 February 2018

Q: TD5: has the document to be produced just by the lead partner (collecting all partners documents) or one per partner?
A: One TD5 is to be submitted by each tenderer. If a tenderer is submitting the offer in the name and on behalf of other members of a group of tenderers, information from each other member of the group of tenderers is to be included where appropriate.

ID: 29; Submitted on 9 February 2018

Q: TD5, section 2: if every partner has to produce TD5, which document has to be produced in section 2? (the Legal Entity Form?)
A: See question ID 29.

ID: 30; Submitted on 9 February 2018

Q: TD5, section 5: has section 5 to be completed by any partner or by the leader as a consortium?
A: See question ID 29.

ID: 31; Submitted on 9 February 2018

Q: TD1 par 4.1.2 and 4.6.4, TD7 template : we plan to have a sub_contract in Phase 3 (for first level support and reselling of the solution in Portugal). Questions: - Is it mandatory to indicate already in the Phase 1 offer the name of that sub_contractor? - Is it mandatory to provide hourly rate and No. of hours cost even in case of a turn-key sub_contract? - Which of the sub_contractor items (name, total cost, hourly rate, No. of hour) would be binding for Phase 3 contract?
A: Please review again the conditions for subcontracting specified in section 4.1.2 of the Request for Tenders. Also note that, following section 4.6.4, a related entry of hours and location of subcontracted R&D work in the Financial Section of the Tender Application will be necessary if subcontracting is substantial, and particularly if other R&D work takes place outside the EU. Compliance with EU funding rules on the location of R&D services must be shown. For rules on the nature of R&D services, it must additionally be clear what, if any, proportion of any subcontract comprises products rather than R&D services.

ID: 32; Submitted on 9 February 2018

Q: Should we assume that we'll have to procure smartphone/tablet/PC for all expected participants (both patients and clinicians, for a total of 248 devices to be procured by each supplier)?
A: Please refer to the expected outcome of each phase of the PCP as documented in TD1 Section

3.4.

ID: 33; Submitted on 9 February 2018

Q: Can a WP be distributed across more than one phase?

A: It is up to each tenderer to define appropriate work packages and their duration. Independently of the duration of a WP, the expected outcomes for each phase must be delivered as set down in TD1 Section 3.4 at the times specified there. A specific contract will be concluded with a tenderer for a phase of specified duration without regard for any WP which may extend before or after that phase.

ID: 34; Submitted on 9 February 2018

Q: Which of the information (person months/organization, GANTT) related to Phase2/3 provided in Phase 1 Technical offer is binding for the next phases contracts?

A: Binding information is listed in at least the following sections of the Request for Tenders TD1: 4.4.1, 4.4.3. 4.6.4, 4.7.1. In Section 4.6.4 of TD1 it is stated that the financial offer must contain "a fixed total price for phase 1 and an estimated total price for phases 2 and 3." A restriction on later phases set out there is as follows: "The price for phase 2 and 3 offers must be based on the binding unit prices in the tender and the price conditions set out in the framework agreement". The note to TD1 Section 3.4 on offers reads: "The offer in phase 1 for phase 2 and in phase 2 for phase 3 shall be an update of the original tender. All revisions and additions possible through work in the completed phase shall be made."

ID: 35; Submitted on 9 February 2018

Q: As there is an already fixed deliverable/milestone scheduling in the Request for Tender Document (TD1) for each phase, which additional information (besides the specification of responsible organization and of the number of WP for each deliverable) it is expected to be filled in the Table “List of Deliverables”?

A: Essential deliverables are listed among the expected outcomes for each phase in TD1 Section 3.4. It is possible that the offer may include additional deliverables and milestones.

ID: 36; Submitted on 9 February 2018

Q: One of the Evaluation Criteria for the Implementation section is “Relevance of the proposed way to involve clinicians and patients in design and development”. In the description of the expected results/outcomes of Phase 2 it is specified that “a suitable number of individuals (n>10) will be involved in each country”. Is the recruitment of this number of users a buyer’s responsibility as it is in Phase 3? Can we assume that we’ll be able to involve these users also in Phase 1?

A: The following statement in Section 3.4 of the Request for Tenders TD1 "User recruitment is the responsibility of the Buyers Group representing the procuring regions" can be taken to apply to all necessary access to clinicians and patients in all three phases. Please note also that Section 3.3 of the Tender Template, Technical Section (TD6) does not conflict in requesting tenderers to "Explain how clinicians and/or patients will be involved in the design and implementation phases"

ID: 37; Submitted on 9 February 2018

Q: Would it be possible to document the background by attaching to the offer manuals describing it and referring to these in section 3.4.3 of the Technical Offer?

A: Please refer to the submission content and format described in section 4.6.1 of the Request for Tender, as well as the page limit and policy for exceeding it documented in the executive summary of TD6.

ID: 38; Submitted on 11 February 2018

Q: We need some clarification on a question on VATs.

If a company from Turkey makes a subcontractor agreement with a European consortium company, does the Turkish company has to add a VAT to the invoice? Will the Turkish company be responsible for the VAT?

The 2 paragraphs from the tender doc (GA 727409 ProEmpower RfT - TD1 Request for tenders; Page: 38-39) created some confusion.

And lastly, where can we have an access to the VAT-exempt certificate by Ministry of Finance of Turkey.

A: The VAT exemption certificate granted by Ministry of Finance of Turkey to Ministry of Health of Turkey is assigned for the exclusive use by Ministry of Health of Turkey. It doesn't exempt vendor subcontractors from VAT when they submit their invoices to the vendors.

The certificate may be reached at https://ebelgedogrulama.gib.gov.tr/ with the following information. Tarih 15 OCAK 2018, Sayı 19940, and PIN TSPEG3N2S1MWPY8.

ID: 39; Submitted on 11 February 2018

: In the Administrative Section of the proposal, section 1, we should provide documents to identify the tenderer. Which documents are required? I understand that one of them is the legal document of the company describing the duly authorized person for signing, correct? Which companies should provide this information, just the lead contractor or also the other partners in the consortium?

A: The name of the tenderer with a copy of the official register document would provide the documentary evidence necessary to identify the tenderer. This should be provided along with a complete list of authorised signatories for the tenderer.

ID: 40; Submitted on 13 February 2018

Q: What local support is available for language translations for product development? Are we expected to find and fund our own translators?

A: Tenderers must ensure their offer is complete and that achieving the expected outcomes relies only on those responsibilities of Buyers which are explicitly mentioned in Request for Tender documentation.

ID: 41; Submitted on 14 February 2018

Q: Will the consortium pair us with clinicians/ patients/ users to assist with the work or are we expected to find our own cohorts of patients and clinicians to work with? If so, do they need to be in the countries who are procuring the services?

A: Please refer to Section 3.4 of the Request for Tenders (TD1). See also the answer of the ID37 question.

ID: 42; Submitted on 14 February 2018

Q: Can you clarify the word limit for the section 5 of the administrative sections of the tender bid - compliance with the selection criteria?

A: There is no limit foreseen, however we expect concise descriptions that provide evidence which clearly substantiates the criterion in question. See also the answer of the ID38 question.

ID: 43; Submitted on 14 February 2018

Q: Do each of the partner sites have existing clinical data repositories containing patient data that can be used to extract data to present individual records to the patient in a personal health record? These may include primary or secondary care systems or shared clinical data repositories. If so, can you provide further information on these systems and any associated application programming

interfaces (APIs) that may be used to extract data?

A: Turkey does have a personal health record system, which is explained in detail in TD2 Challenge Brief. Currently two main kinds of APIs exist to extract data: one for PHR, which is used by the patients, the other one for decision support system and statistics analysis, which are used by Ministry staff. The infrastructure allows additional APIs if there is any need. For the illustration and explanation of the existing systems of Ministry of Health of Turkey, please refer to Section 2.2 of TD2 Challenge Brief.

Campania: Campania pilot site (Federico II University Hospital) uses MyStar Connectis, as EHR connected with Hospital's clinical data repository, and AirDiabete is for periodic reports assessing the participation of the GPs to the integrated management of the diabetic patients. They are explained in detail section 2.2 of TD2 Challenge Brief.

Murcia: Murcia has a central repository for EHR of each patient that has been attended in a hospital or in a primary care centre.

This repository includes hospital data and primary care data as visits, reports, lab results, pharmacy, radiology,…

The repository is updated in real time or twice a day, depending on the item.

Regarding the interfaces, there is a set of web services offering data to external systems in a secure way. The format of these web services is mainly based on HL7, although there are another possibilities.

Portugal: Portugal has an Electronic Health Record. However, the underlying database is not nationally centralised. Whenever a health professional consults a PHR this entails that a series of local databases with clinic information are consulted. As such, the system is that in Portugal there are the local services which, all together, form the central EHR; there are however some central services for EHR, concerning namely: chronic medication, vaccination, allergies and citizen identification.

ID: 44; Submitted on 14 February 2018

Q: Are vendors expected to host, and pay for, servers and technical infrastructure, or will appropriately secured managed services be offered by partner sites? If not, what are the requirements for secure hosting, and can data be stored outwith the partner country (e.g. in the UK)?

A: In respect of servers and infrastructure, tenderers must ensure their offer relies only on those responsibilities of Buyers which are explicitly mentioned in Request for Tender documentation. Any solution proposed must comply with the appropriate legislation in each of the procurer countries. Attention is also drawn to the award criteria in TD1 Section 4.5, in particular "Soundness of the approach to integration with procurer systems". To meet this criterion the approach must be described in Tender Application Technical Section TD6, Sections 1.2 and/or 1.3. Please also see the response to question ID59.

ID: 45; Submitted on 14 February 2018

Q: Will the exemption indicated above will also be applicable to procurements made by vendors for the purpose of executing the contract? Will there be a certification for exemption from VAT (similar to IPA, like CFCU contracts) for vendors corresponding to products and services within the scope of this particular PCP?

A: Please see our response to question with ID39.

ID: 46; Submitted on 14 February 2018

Q: Is the supply of the mobile devices (PC, Tablet, Phone, Glucosemeter, Pedometer, etc.) for the purpose of pilot application (200 patients) falling within the scope of this procurement? Should the devices that are going to be integrated with the system be supplied by the vendor?

A: No equipment need be supplied unless essential to delivering the required R&D services.

ID: 47; Submitted on 14 February 2018

Q: Should the servers and infrastructure required for the pilot application be supplied by the vendor? Will the vendor be able to utilize current infrastructure and servers of procurers?

A: See the response to question with ID45.

ID: 48; Submitted on 14 February 2018

Q: In Use Case-7 and several other parts of the document, it is denoted that the training materials are expected to be delivered by the suppliers. What will be the review and approval mechanism at procurer's side for such training materials, or work flows, rule based decision support tools? Most of such knowledge is highly localized and should not be generalized. Does this content also includes hard copy materials?

A: It will be clear from UC7 and other places in the Request for Tender documentation the extent to which solutions should include an appropriate and effective approach to training. Review and approval mechanisms may well be appropriate, with process and organisational integration with procurer systems. Note that the feasibility of a proposed solution may be called into question if it relies on any contribution by procurers not explicitly written in the Request for Tender documentation. Attention is also drawn to the award criteria in TD1 Section 5, in particular "Soundness of the approach to integration with procurer systems". To meet this criterion the approach must be described in Tender Application Technical Section TD6, Sections 1.2 and/or 1.3. Reference may be made to TD2 Section 2.2.

ID: 49; Submitted on 14 February 2018

Q: Implement Strategy (p.104 - Challange Brief)

In this item it is stated that the procurers will be implementing change management activities at sites for a smooth transition. The change management measures and strategies are supposed to be mostly delivered by the vendors. Will the vendors be also responsible for the expenses related with implementation of such activities?

A: In respect of necessary expenses, tenderers must ensure their offer is complete and that achieving the expected outcomes relies only on those responsibilities of Buyers which are explicitly mentioned in Request for Tender documentation. The scope of the procurement is to be described by the tenderer who must ensure that all necessary elements are fully included in the price offered.

ID: 50; Submitted on 14 February 2018

Q: What are the existing methods/techniques for authentication? There is little information on currently applied methods like SSO, username-password-token triple. 6.1. ITEM: R2.5.2. User authentication: "The ProEmpower solution shall enable authentication using existing authentication techniques of the four procurers"

A: Information is provided in the Request for Tender documentation on current systems, techniques and methods at procurer sites, see in particular TD2 Section 2.2. Should information be missing, it is for tenderers to develop an approach which can ensure they meet R2.5.2.

ID: 51; Submitted on 14 February 2018

Q: What is the exact scope of offline operation? There are several phrases where "offline operation"

is emphasized, but no complete explanation on which parts of the system is required to be operated in offline mode.

A: Section 2.3 of the challenge brief (TD2) prioritises requirements for proposed solutions. The requirements documented there, as well as in other sections of the Request for Tender documentation, in some cases refer to operations of a proposed system which may be required to operate without a functioning internet connection. The technical implications drawn from requirements in the Request for Tender represent the best attempt of the ProEmpower procurers to define features of future systems which, individually and in total, represent significant innovation beyond the state of the art in the management of diabetes in a population. Vendors are invited to improve on this and to implement yet better systems.

ID: 52; Submitted on 14 February 2018

Q: Is the purpose of Research Consent is flagging patient data for potential usage, or is this item corresponds to a requirement which encompasses a module for flagging, anonymization, and querying for Research Consents and consent given data.

A: R4.1.9 states "Consent to re-use care data for research purposes will be collected separately from consent to use data for care purposes. Data used for research purposes will be anonymised or pseudonomised format if possible."

ID: 53; Submitted on 14 February 2018

Q: In Use Case-8 it is denoted as SCP will utilize a medication database, and in some parts of the document it's stated as it will be integrated with existing databases currently in use at procurer sites. At national level, there are databases for Turkey and Spain, for Portugal and Italy we couldn't reach such information. Will the system be integrated with national medicinal/prescription databases/services, who will be responsible for the implementation of integrating web services developed within the scope of the project. Are there any web services already usable for this purpose?

A: The usability of existing web-sites for the purpose of the project depends on the tenderer's approach to improved diabetes management. In respect of database and web-service integration, we point tenderers to TD1 Section 5, in particular "Soundness of the approach to integration with procurer systems". To meet this criterion the approach must be described in Tender Application Technical Section TD6, Sections 1.2 and/or 1.3. In respect of existing systems, reference may be made to TD2 Section 2.2.

ID: 54; Submitted on 14 February 2018

Q: R2.1.7-8: App-Android-iOS: "The ProEmpower solution shall support visualisation using the listed mobile app platform."

Is this item corresponds to a native application for these platforms or is it also applicable for operability in these platforms using mobile versions of web browsers? In case of mobile applications; the process of validation and verification for AppStore release is highly complex. The delays in such processes may affect the interim deliverables, will there be a flexibility for such unexpected/uncontrolled latencies?

A: On the flexibility to respond to delay in AppStore release, on current understanding there will be no flexibility in interim deliverable timing. Fixed timing is essential to limit procurer resource commitment and for fair treatment in parallel operation of multiple suppliers / supplier groups. Please note in particular that the offered solution must be fully operational in due time in line with the expected outcomes documented in TD1 Section 3.4. The question on how or whether a web browser customised to mobile devices is included in the proposed solution depends on the approach taken by the tenderer.

ID: 55; Submitted on 14 February 2018

Q: For the purpose of reviewing previous prescriptions, updating them, and suggesting medicinal products the system is expected to have a module for these particular purposes. Does the system also have to integrate with the payback systems like SGK in Turkey, or e-prescription systems? Are there any web services provided for 4 procurer sites?

A: See the response to question with ID54.

ID: 56; Submitted on 14 February 2018

Q: Should the system be integrated with available appointment systems currently used in procurer sites? Should the system be integrated with Emergency Call Services? Are there any web services used for these purposes?

A: See the response to question with ID54.

ID: 57; Submitted on 14 February 2018

Q: There are phrases in the Challange Brief document indicating that the necessary equipment to operate the system for Encryption, Firewall, VPN, HTPPS, and Intranet should be provided. Is the vendor also responsible for the delivery of the items for security operation related hardware?

A: The feasibility of a proposed solution may be called into question if it relies on any contribution by procurers not explicitly written in the Request for Tender documentation. See also the award criterion "Soundness of the approach to integration" (TD1 Section 5). The approach to integration must be described in Tender Application Technical Section TD6, Sections 1.2 and/or 1.3.

ID: 58; Submitted on 14 February 2018

Q: Is it ok to install the prototype to a cloud system that is physically located in Europe for all procurers to use and test?

A: The tenderer is referred to requirement R2.1.1 in Section 2.2 of TD2 which specifies the servers.

ID: 59; Submitted on 14 February 2018

Q: What is your guidance about this case: During pilot phase what if some of national EHR integration points are not completed? 15.2. To our understanding, Campania's EHR integration infrastructure is not completed. During pilot, if that system will not be ready how shall we proceed? 15.3. In case the services are ready, do we still need to also integrate with MyStar and AirDiabetes directly? 15.4. If there are duplications of patient record details among facilities during their EHR integration transition phase, what will be the suggested approach? Do all the subsystems will have same data dictionary and dataset format?

A: The approach to integration with procurer systems is to be described by the tenderer, given available knowledge of procurer systems and anticipating knowledge which can be expected to be obtained before integration work takes place. To meet award criterion "Soundness of the approach to integration" (TD1 Section 5), the proposed approach to integration must be described in Tender Application Technical Section TD6, Sections 1.2 and/or 1.3.

ID: 60; Submitted on 14 February 2018

Q: Kindly clarify if the rules established in Directive 2014/24/EU shall be applicable to this procedure in situations of loopholes or analogies. If not, kindly inform which legislation shall be considered for this purpose.

With reference to the above mentioned clauses, kindly clarify if it is possible to ask for confidentiality to some documents that will be submitted with the proposal.

In particular: taking into consideration that the solutions to be presented by the competitors have an innovative character and, if the proposals are not accepted, such solutions will be provided to several

interested parties (who, ultimately, may take advantage of the know-how of such solutions or even reproduce them in other contracts), kindly clarify if it is possible to ask for confidentiality to some documents that will be submitted with the proposal as per article 20 of Directive 2014/24/EU.

A: As stated in Section 5 of TD1, 'Tenders will be evaluated in a non-discriminatory manner in accordance with the legal requirements provided for in relevant provisions under Turkish regulations'. Public Procurement Law of Turkey states that '… the contracting authorities must ensure transparency, competition, equal treatment, reliability, confidentiality and public supervision (Article 5)'.

ID: 61; Submitted on 14 February 2018

Q: Kindly clarify if the price estimation to be proposed right now to phases 2 and 3 is binding. In addition, kindly clarify if the price to be proposed afterwards must be the same price or must be inferior? Could the price be superior?

A: In Section 4.6.4 of TD1 it is stated that the financial offer must contain "a fixed total price for phase 1 and an estimated total price for phases 2 and 3." The restriction on pricing for later phases is as follows: "The price for phase 2 and 3 offers must be based on the binding unit prices in the tender and the price conditions set out in the framework agreement. Where new units/unit prices (e.g. for new tasks or equipment) are subsequently added to the phase 2 or 3 offers, they will become binding for the remaining phases." The note to TD1 Section 3.4 on offers reads: "The offer in phase 1 for phase 2 and in phase 2 for phase 3 shall be an update of the original tender. All revisions and additions possible through work in the completed phase shall be made."

ID: 62; Submitted on 14 February 2018

Q: Kindly clarify is there is any administrative entity to which it is possible to submit an appeal regarding the decisions of the Evaluation Committee.

A: Section 5.4 of TD1 specifies the procedures foreseen for appeal and where appeals may be lodged.

ID: 63; Submitted on 14 February 2018

Q: Kindly clarify if prior to the final decisions of the Evaluation Committee there will be a draft decision regarding which may be argued by the competitors.

A: Section 1.4.2 of TD1 specifies that the PCP will start with the publishing of the call for tender. The call will remain open from publication until the specified deadline. After the deadline the tenders will be evaluated and results will be announced. There is a standstill period after the announcement. This is followed by signature by the Lead Procurer of contracts with the selected tenderers, expected on 30.04.2018.

ID: 64; Submitted on 14 February 2018

Q: Taking into consideration the subjectivity of the concerned evaluation, kindly clarify if what is established in this provision is that payments will not be executed after the conclusion of the work if, for instance, such work is considered unsatisfactory.

A: The criteria given in Section 6.2 of TD1 will allow objective identification of successful completion. Payments will be subject to the satisfactory completion of the deliverables and milestones for each phase.

ID: 65; Submitted on 14 February 2018

Q: Regarding this matter, kindly confirm if it is the contractor that shall demonstrate that the work has been satisfactorily executed.

A: The criteria given in Section 6.2 of TD1 rely on specific documents and results of work by the tenderer and therefore will have to be delivered by the tenderer.

ID: 66; Submitted on 14 February 2018

Q: At last, kindly confirm how and before which entity this decision may be challenged.

A: On the resolution of disputes during execution of a specific contract please see the provisions of the Framework Agreement (TD8) on this matter, in particular, Article 20.

ID: 67; Submitted on 14 February 2018

Q: Considering that ProEmpower should integrate with the source systems from each country and to estimate costs and plan, may we assume that the integration can be based in HL7 standard normalized for all 4 counties? Otherwise, what are the specifications for this integration in each country?

A: The approach to integration with procurer systems is to be described by the tenderer. To meet award criterion "Soundness of the approach to integration" (TD1 Section 5), the proposed approach to integration must be described in Tender Application Technical Section TD6, Sections 1.2 and/or 1.3. Assumptions made by the tenderer in estimating costs and planning execution of Phases 2 and 3 should be described. In respect of existing systems, reference may be made to TD2 Section 2.2.

ID: 68; Submitted on 14 February 2018

Q: Given that “the Shared Care Plan shall be able to make use of (read) relevant patient data from the existing systems infrastructure of the four procurers”, kindly confirm if the source systems have an authorization feature where the patient can accept or deny sharing information with ProEmpower?

A: See the response to question with ID68.

ID: 69; Submitted on 14 February 2018

Q: Please clarify if a patient with high scores, at initial assessment, of emotional/mental state using Goldberg/Joslin test will be enrolled in the system or not (UC2 of TD2).

A: Which patients are recommended for enrolment in the system is to be proposed by vendors in line with their approach to diabetes management and the requirements in the Challenge Brief on this and related issues. Actual enrolment will take place at the discretion of the specific healthcare organisations and healthcare professionals responsible for the patient concerned.

ID: 70; Submitted on 14 February 2018

Q: At UC9 of TD2, who is expected to develop the training material/course for Peer Mentors?

A: Training material and/or a training course for the peer mentoring process are to be delivered by the tenderer. Note that in respect of a process model for UC10, it is stated that: "The ProEmpower system should support the peer mentoring process as best as possible. This aspect is left open and the corresponding process model will be defined once suppliers offer concrete suggestions."

ID: 71; Submitted on 14 February 2018

Q: In paragraph 3.4. of TD1, it is mentioned that for phase 3 “Submission of an ethics application for phase 3 is to be in time for punctual start of the pilot”. Is the preparation of the file and submission a responsibility of the Pro-empower vendors?

A: Yes.

ID: 72; Submitted on 14 February 2018

Q: Regarding the Medical Devices, that could be necessary, in the document

tttps://ec.europa.eu/docsroom/documents/17921/attachments/1/translations/en/renditions/native , it's mentioned that "The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." However, on the document Challenge Brief page 15, we can find the necessity of having a medical device to collect some data in order to have the automatically or semi-automatically measurement of some data like Heart rate, Steps (physical activity).

Can we conclude that it is really necessary have a medical device associate to the project, in order to respond to all requirements?

A: Whether or not devices or software deployed by a vendor in response to the ProEmpower challenge fall under medical device or other regulations is the responsibility of the vendor to determine. The procurers expect that the developed solutions will address their needs and requirements as captured in the challenge brief document (TD2). It is possible that different tenders will have different approaches.

ID: 73; Submitted on 14 February 2018