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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 <u>https://ec.europa.eu/tools/espd/filter?lang=pt</u> 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 desgin, 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