QUESTIONS AND ANSWERS

OPEN MARKET CONSULTATION

Nº	QUESTIONS	ANSWERS
1	In which content is to be delivered to accomplish the "Improve quality of life" goal. Is this just based on delivery information or educational materials? Are contents within this area to be "transformed" into Care Plans we could track?	The solution not only will deal with the **improvement of information and educational materials and skills** but also to improve **self-management** and fulfil with the treatment adherence.
2	Make clearer whether the requested solutions target patient and/or Healthcare professionals and/or Healthcare organisations: who is the customer and who is the buyer?	The final end users are **both chronic pain patients and healthcare professionals.**
3	Is budget per selected supplier or total per phase?	The budget that appears on the market online questionnaire and also on the Tender section on the RELIEF website is related to the **estimated individual budget per supplier at each phase**. See: http://relief-chronicpain.eu/tender.html
4	How could you analyze chronic pain in different diseases?	Following with the outcomes of the validation of unmet needs at Buyer's Group Level, we are focusing **on chronic pain patients treated in Pain Centers Unit** due to the complexity of their treatments. In a later phase of the solution improvements (out of the scope of the RELIEF tender), the solution could be opened to the chronic pain patients treated in primary care or specialists.
5	What type of entity could participate in the RELIEF tender?	RELIEF tender is **opened to all interested entities**, on equal terms, regardless of the size, geographical location or governance structure. There is, however, a place of performance requirement that they must **perform a predefined minimum percentage of the contracted R&D services in EU Member States or Horizon 2020 associated countries**
6	How did you analyze the market? Because needs does not always make a procurement.	At proposal stage a State of the Art was done including a market review to check that the unmet need was not cover by any solution already in the market. In addition, during the validation of unmet needs at Procurer's level, emphasis in the challenges of the unmet needs defined was done: validation of contents and the follow-up of the treatment, as well as in the adherence (self-management), interoperability.
7	What if the solution already exists?	RELIEF is a Pre-commercial procurement tender. This means that bidders must **propose innovative ICT solutions not yet in the market to cover our challenge and unmet needs.** However, the novel solution proposed may combine new and existing technologies to create a really innovative solution. Apart from market research, the preliminary feedback from the Open market consultation activities has shown that no solution already in the market could cover all unmet needs for chronic pain.
8	How do you finance? When will we be paid?	Payments corresponding to each PCP phase will be **subject to the satisfactory completion** of the deliverables and milestones

		established for that phase. **It is not defined yet the specific calendar payment. It will be included in the call for tender documents.**
9	Do you take into account the respect of the budget for each phase?	RELIEF team is not sure about the meaning of this question. Each phase will count with a **maximum budget per offer**. However, the budget included in the financial offers could be lower than established.
10	What do you mean by "prototype"? Beta or advance version?	During Phase 2 of the PCP tender, the awarded entities must **develop, demonstrate and validate prototypes in lab conditions**.
12	Where will the solutions be tested? In the different languages?	The solution must be tested in **all buyers' group facilities** (Spain, France and Sweden). The specific premises per country and languages will be included in the call for tender documents.
13	Will you create a user group? At what time will users be integrated? Have the awarded companies the possibility to contact user group during the different phase of the PCP? How and when to communicate with the buyers group during PCP phases?	Yes, we will create an **expert group for the evaluation and monitoring of each phase.** This expert group will **be formed by different profiles** including healthcare providers and patients. This group will eventually be different depending on the Phase. The communication procedure between expert group and suppliers will be established in the call for tender document. The specific profiles as well as the evaluation procedure will be duly explained in the call for tender materials.
14	Do you have business plan for the solutions who will go until the end of the PCP phase and which will be launch on the market?	A business plan is one of the requirements that suppliers must include in their Technical offers. The **feasibility of the business plan to commercially exploit the R&D results will be assessed as part of the award criteria.**
15	What happen if you realize that two or several proposals are interesting and complementary but need to be united to be selected? Are you going to put the different bidders in contact?	The RELIEF project has created a **dedicated section on our website** where different company can present their organization and see if there is a possibility to submit and common proposal. See more information: http://relief-chronicpain.eu/companiesList.html
16	Is it possible to modify the consortium member between the different phases? For example to add a competence that lacks?	This should not be a problem if you change people in your PCP team. You should ensure that the **place of R&D performance is maintained.**
17	Is it opened to international companies? Is it opened to small companies such as start-ups?	See answer number 5. **RELIEF tender is opened to all interested entities, on equal terms, regardless of the size, geographical location or governance structure**. There is, however, a place of performance requirement that they must perform a predefined minimum percentage of the contracted R&D services in EU Member States or Horizon 2020 associated countries
18	Are you looking/checking where the employments and R&D are realized?	Yes, the **call for tender document will explain the procedure to evidence this requirement**: Compliance with requirements relating to the place of performance of the contract.
19	What exactly are the selection criteria?	The selection criteria are dealing with the **ability to perform R&D up to original development of the first products or services and to commercially exploit the results of the PCP, including intangible results in particular IPRs**. The Buyer's group is discussing the specific criteria that ensure this ability in terms of capacity, materials and equipment that are available to the tenderer for research, prototyping and limited production and supply of the first set of products or services. As well as the financial and organisational structures that are available to the tenderer for management, exploitation and transfer of IPRs and

		for generating revenue by marketing commercial applications of the results **They will be presented in the PCP call for tender.**
20	What are the main award criteria? How will the award procedure be conducted?	After the evaluation of the exclusion, selection and compliance criteria, the evaluation committee will evaluate the tenders against the award criteria. **These criteria will be defined (including weightings and thresholds for each of the three phases) in the call for tender document.** The Buyer's Group is working on them. They will take into account technical quality aspects, impact, price, etc. The award criteria must ensure that the procurer gets the best value for money. It is therefore not permitted to use either lowest price as the sole criteria, without taking quality into account, or highest quality as the sole criteria, without taking price into account. The total technical quality and price award criteria, weightings and thresholds will be defined in the call for tender. We are currently discussing them. In addition, the feedback from the industry will serve us to elaborate the definite specifications /functionalities to be assessed as technical quality criteria. Furthermore, the feasibility of the Business Plan, which is part of the Technical Offer, will be included as one of the award criteria. The procedure of award criteria evaluation will be included in the call for tender.
21	When will the evaluation of the solutions be done?	The **call for tender will include duly explanations about the evaluation process**: - During each phase, contract implementation will be monitored periodically and reviewed against the expected outcomes (milestones, deliverables and output or results) for the phase. - There will be regular monitoring meetings between contractor and the supervisor/monitoring team. How often they will take place, how they will be conducted (physical meetings or remote/online meetings), and what they will involve will be explained in the call for tender.
22	When will we exactly received the financing for each phase? 1 month or 1 year after the validation of the deliverable?	Buyer's group is currently discussing this item (several options: at the end, intermediate payments…)
23	Could you describe Phase 0 and transition to Phase 1?	In **phase 0 the unmet needs are defined at Buyer's Group Level.** After that, the Open Market Consultation is organized to receive the feedback from the industry regarding our common challenge and defined needs. With this feedback the Lead Procurer on behalf of the rest of the Buyer's Group will launch the joint PCP call for tender. Tenderers will have 2 months to submit offers and after an evaluation period of offers the awarded tenderers will sign the contract and start the Phase 1.

24	Is the available budget indicated in the RELIEF phases corresponding to the total of amount per phase or the total of amount per each solution?	The budget distribution that appears in the RELIEF phase's diagram (Workshop presentations) is the total of **estimated budget per each solution in each phase.**
25	What is the expected time to start Phase 4 after Phase 3 ending?	**Phase 4 corresponds to a PPI phase** (the commercial procurement) and it is out of the scope of RELIEF tender. After the end of phase 3 procurers may or may not start with a PPI. Anyway, suppliers have to ensure the commercialization of the solution after a period of time after the end of the tender.
26	Should the solution be designed fitting the situation of the 3 countries of the project?	**Yes, in fact the unmet needs are common for the 3 Public Health Procurers of the RELIEF tender (Sweden, France and Spain).** The different solutions developed must serve to different EU Healthcare Systems ensuring interoperability and transferability. In fact, the solution will be tested in the Hospitals of the 3 countries to guarantee this requirement.
27	Would phase 3 include improvements and test of prototype improved?	**The prototype already validated at lab scale in Phase 2, will be field-tested during Phase 3 in a limited set of field-testing products or services.** The monitoring team of the Procurers will give the feedback to contractors on this field-testing of the products/services and at the end of the phase there will be a Final demonstration of products/services developed during phase 3 (including to EU representatives)
28	In the R&D services, it is included the hours of healthcare procurers?	No, **the eligible cost is taking into account only R&D services cost**. Call for tender includes the planning to meet procurers.
29	What does IPR call-back means?	The contractors will have to **transfer ownership of the IPRs to the members of the buyers group if they fail to comply with their obligation to commercially exploit the results or use the results to the detriment of the public interest, including security interests.**
30	Should the solution be developed in English or in one of local languages of the procurers, in the 3 languages of the procurers?	Firstly, as the solution is developed under EU PCP Tender, the official language is English. In addition, and to facilitate the field-testing, the solution may be designed to be used in the 3 official languages of the procurers (Spanish, French and Swedish). Anyway, this is something that we have to discuss internally. These specifications will be included in the call for tender.
31	What are the main timings since the publication of call for tender and starting Phase A?	The estimated time for RELIEF **call for tender publication is 1st May 2017; however this date is subject to the EC Approval.** After that, the interested entities will have **2 months to submit offers (during May and June 2017).** After deadline there will be a date for offers opening and a period to **evaluate the offers**. Successful tenderers will be notified and will **sign a framework agreement and specific contract for the corresponding phase A. These actions will be done during July and August 2017.** Estimated **starting date for Phase A is 1st September 2017.**
32	Are you going to create an interactive platform putting suppliers together for joint tenders' preparation?	The project has created a **space on the RELIEF website in which all entities interested in presenting joint tenders could find the contact information of other suitable partners** and contact them directly. In order to appear in the table you have to complete the on-line questionnaire: http://relief-chronicpain.eu/companiesList.html

33	Regarding Phase A, will the contractors have pre-established requirements for the 3 procurer's situations?	The defined needs, and following with the OMC feedback, will be turn into common requirements. **These common requirements will be included in the call for tender** to facilitate the technical and financial offers of the tenderers.
34	Are you considering that contractors visit the procurer's premises?	Yes, **Phase A is considering that contractors visit the premises of the procurers to learn about the operational boundary conditions governing the design of targeted solutions.**
35	Taking into account that the budget proposed by phases is not enough to develop a solution that fits with all needs, contractors will have to put in their own money to complete costs. In this regard, the invoices that contractors provide to the Lead procurer, should it contain the price for the whole costs or only for funded costs?	**For every payment established, the contractor must create an invoice for the PCP subcontracting cost** only according to the established budget in every phase. The contractor's invoices must provide: • a price breakdown showing the price for R&D services and the price for supplies of products (in order to demonstrate compliance with the definition of R&D in compliance criterion) • a price breakdown showing the location or country in which the different categories of activities were performed (e.g. x hours of senior researchers in country L at y euro/hour, a hours of junior developers in country M at b euro/hour) (in order to demonstrate compliance with the requirement relating to the place of performance in compliance criterion).
36	What does it mean with "satisfactory" criteria and "successfully" criteria to move from one phase to another?	Payments corresponding to each PCP phase will be subject to the satisfactory completion of the deliverables and milestones for corresponding phase. **Satisfactory completion** will be assessed by an assessment committee according to the following requirements: • if the work corresponding to that milestone / deliverable has been carried out • if a reasonable minimum quality has been delivered • if the reports have been submitted on time • if the monies have been allocated to the planned objectives • if the monies have been allocated and the work has been carried out according to the compliance criteria (place of performance, public funding and R&D definition criteria) • if the work has been carried out in compliance with the provisions of the contract (including in particular verification if the contractor has duly protected and managed IPRs generated in the respective phase) The call for tender document will include more details in these requirements. Satisfactory completion in each of the phases does not mean successful completion. (A PCP could, for instance, be satisfactorily completed even if it concludes that the innovation is not feasible.). Eligibility for participation in the next phase will be subject to successful completion of the current phase. **Successful completion** of a phase will be assessed by the assessment committee against requirements such us: • if all milestones have been successfully completed • if the R&D results meet the minimum functionality/performance requirements of the challenge description (i.e. the minimum quality/efficiency

		improvements which the procurers set forward for the innovative solutions to achieve) • if the results of the R&D are considered to be promising • etc. The call for tender will include the definitive successful requirements.
37	When will payments be made?	As payments are **centralized by the Lead Procurer, the standard procedure of them will apply.** These issues: when payments will be made, information on the amounts of interim payments (if applicable) and/or final payments will be detailed in the call for tender document.
38	Are costs of suppliers being reimbursed?	The **offers include a technical and a financial section in which all tenderers will include the actions taken to develop the corresponding phase and the price breakdown that shows the price for the R&D services.** After satisfactory completion of the deliverables and milestones for that phase, the contractors will invoice the Lead Procurer for the R&D service.
39	The scope of the solution, according to the defined needs, seems not to be developed in a realistic way with timings and budget offered; have you considered that maybe all needs were not covered?	**The unmet needs have been defined and validated according to the main priority areas /challenges of the procurers.** This is our wish list. In addition, the impact of the solution in the healthcare systems and for the patient will also be taken into account. Furthermore, **competitive phases facilitate that procurers could award R&D contracts to a number of competing contractors at the same time, in order to compare different approaches to solving the same problem (needs).**
40	Is every phase related to a TRL level (Technology Readiness Level)? What is the TRL level at Phase A starting point?	**PCP Phases are not defined in terms of TRL levels.** According to ***PCP communication COM/2007/799***, **R&D services can cover research and development activities ranging from solution exploration and design, to prototyping, right through to the original development of a limited set of 'first' products or services in the form of a test series.** Original development of a first product or service may include limited production or supply in order to incorporate the results of field-testing and demonstrate that the product or service is suitable for production or supply in quantity to acceptable quality standards. R&D does not include quantity production or supply to establish the commercial viability or to recover R&D costs. It also excludes commercial development activities such as incremental adaptations or routine or periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements. R&D in PCP phases is split into three phases: • **Solution Design** and feasibility study of the technical, financial and commercial demonstration of the proposed concepts. • **Prototyping** (Develop, demonstrate and validate prototypes in lab conditions). • **Original development and testing** of a limited set of "first products or services.
		The ownership of pre-existing rights remains unchanged by the PCP.

41	How will pre-existing rights (background) be managed?	In order to be able to distinguish clearly between results (foreground) and pre-existing rights (and to establish which pre-existing rights are held by whom): • Tenderers are requested to list the pre-existing rights for their proposed solution in their offers • Procurers and contractors will establish a list of respective pre-existing rights to be used — before the start of the contract (if applicable).
42	Is it possible for joint tenders formed by enterprises and research centers to participate?	Yes, 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.**
43	How will the evaluation procedure be done?	After submission deadline, tenders will be opened and evaluated following the procedure established in the call for tender. An opening committee composed by different members will be established. In addition, an evaluation committee will evaluate the tenders following these steps: • Step 1 Checking whether the tenderer is not in one of the situations covered by the exclusion criteria • Step 2 For tenderers passing Step 1, assessing whether the tenderer has the capacities necessary to perform the contract, on the basis of the selection criteria • Step 3 For tenderers passing Step 2, evaluating the tender based on the compliance criteria • Step 4 For tenders passing Step 3, evaluating the tender based on the award criteria The profiles of the evaluation committee may change in each phase. **How the committee will work (e.g. When and how they will meet), and the process to be used for making decisions at each of the different steps will be duly explained in the call for tender document. The system for scoring, qualitative appraisal and ranking will be also included in the call for tender.**
44	Could a solution only be developed though ICT technology?	The solution should be **focused on eHealth**. However, this solution could also be composed of other non ICT aspects.
45	After the end of phase C, is it possible to move directly to Phase D (PPI)?	**No, it is necessary to start a new procedure of Public Procurement of Innovative Solutions (PPI).** In addition, this phase is subject to EU Procurement Directives. RELIEF PCP TENDER is out of the Phase D scope. H2020 supports PPI projects. In some cases, a PCP project has become a PPI project.
46	How many testing - cycles do you consider for Phase C? Are you considering improvements of the solution during Phase C?	**This issue is under discussion among different procurers. The specific information will be included in the call for tender document.** Field-testing should include readjustments during the period so as to implement a final demonstration of products /services developed.

47	Will the solutions developed have the capacity to be interoperable with different healthcare systems (including the procurers IT systems) or will the solutions be integrated with the IT Systems during phase C? There is a significant difference by capacity of being connected and being really connected.	**The solution must be prepared to be integrated with the Information Systems that support the EHR in the three countries.** It will be mandatory to demonstrate that capacity by mean of some test cases. The security and interoperability standards requirements will be published in the call for tender and will follow international standards.
48	Is it possible to ask doubts or questions during the PCP launch?	**Yes, the project will have available channels to facilitate that potential bidders ask for questions.** **All questions and answers will be published on the RELIEF website.**
49	Is there any register in Sweden for gathering R&D data?	In Sweden one national register exists, called NRS, but it is paper based. This register is focused on rehabilitation of chronic pain. There is no common register for chronic pain in Europe.
50	To facilitate the gathering of data for R&D purpose, do you have a wish list of what type of data do you need?	Information and data regarding follow-up treatments is well received. This information is often not validated and there is a lot of R&D to do in follow-up. There are some validated questionnaires and patient reported out-comes (PRO) that may be used, but this is also part of the R&D that is needed in the process. Demographic data as well as out-come data on different treatments is fundamental for research purposes.
51	What will be the real weight to the contents related to biopsychosocial approach (quality of life, sleep patterns, nutrition, etc.)? And, what about a solution focused on pain prevention?	One of the defined needs is focused on **clinical validation of contents**; taking into account the **holistic approach of the pain treatment trend (multimodal approach),** the inclusion of non-pharmacological aspects are very important. However, this approach in terms of contents and methodologies, therapies etc. must be subjected to validation (at clinical level when necessary and/or by using official references / accepted bibliography). In addition, the opportunity to directly collaborate with clinical experts from the Pain Units could help in this matter.
52	Will the R&D previous experience of the tenderers and also the ability of transferability be taken into account in the evaluation of the offers?	Both aspects are going to be assessed: the technical capacity to carry out the R&D (maybe by presenting previously successful R&D cases) and the financial and organizational capacity to assure they may be able to commercially exploit the solution. The consortium is still deciding the support documents to prove that.
53	What is the Feasibility Study main format for Phase A?	In general terms, for **Phase A suppliers will present a scientific report including state of the art, objectives, methodology, work plan, business plan and budget**; nevertheless it will be clearly explained in the PCP Call for Tender document, indicating deliverables and milestones in each phase.
54	Is it possible to include new companies and/ or entities during the tender phases for implementation, validation, etc.?	Participation in the tendering procedure is open on equal terms to all types of operators from any country. Tenderers may be submitted by a single entity or in collaboration with others. We recommend **submitting the offer by the joint group from the very beginning** because the initial conditions will be the same during the execution of the contract and will be defined in the Framework Agreement.
55	For joint tenderers, can a Research Center be the Lead Contractor?	A research centre can be a lead contractor in case of joint offer because this liability doesn't (and not does) mean that it will necessary be the one who will carry out the commercialisation. **Clear explanations must be given in the offer by the group of tenderers regarding how they ensure the commercialization of the solution, and who will be the organisation in charge of the commercialization.**

56	Is it possible for a company to apply for RELIEF also for EMPATTICS PCP call for tenders?	A call for tender is launched to all interested operators. As far as the **compliance criteria of double funding is fulfil**, there is no problem to participate in both PCP calls. A declaration of honour for absence of other incompatible public funding will be required.
57	This question is related to the confidentiality of information: Could the information given during the PCP phases by contractors be used by another contractor that successfully pass to the following phase?	In no way, this could be possible. All information generated and given during the phases implementation is confidential (this confidentiality is gathered in the Framework Agreement) and under no circumstances the information from one contractor will be transferred to another one.
58	Could explain the R&D results ownership in the different phases of the PCP?	Each contractor keeps ownership of the IPR attached to the results generated during the PCP implementation.
59	In case of reaching the Phase 3, we have some doubts regarding the use of the licenses by procurers, intellectual property rights, patents, exploitation rights, maintenance service models, etc.	The members of the buyer group will have the right to: - **Access results, on a royalty-free basis for their own use** (R&D results; not final commercial solution). So, it is not contemplated the maintenance service of the prototype by the contractors as it is not a commercial solution. In fact, these R&D results that could be the specifications of the solution could serve the procurers to prepare a future PPI. - In addition, the buyers will have the right **to grant (or to require) the suppliers to grant non-exclusive license to third parties for commercially and/or no commercially exploit the results under fair and reasonable conditions** (only for the IPR results of the R&D services under the PCP implementation phases). All costs related to **further deploy and market uptake of the solutions are responsibility of the contractors** (maintenance of IPR: patents cost, etc.)
60	Do you have more information about awarded criteria?	As indicated in the OMC Workshops, there are different criteria for evaluating the offers (exclusion, selection, compliance and award). **Award criteria are related to different themes such as project management, commercial feasibility and RELIEF Challenge (unmet needs), among others.** These criteria have a **punctuation in each phase** based on the level of innovation and fulfilment with the PCP Challenge basic requirements.
61	Is it possible to access to the current Information system at each Unit Pain of the Buyer's Group?	**During phase 1,** each contractor will visit the Hospitals facilities to learn about the operational boundary conditions governing the design of the targeted solutions.
62	Access results for own use involves maintenance service by contractors?	As we are talking about R&D results and not regarding the commercial solution, **a maintenance service is not contemplated**

63	Is it necessary to include the market analysis in the offer?	Yes, the Technical offer includes **the business plan** where the tenderers should include a section describing the market analysis.
64	Does the financial offer includes a maximum quote per subcontracting?	Subcontracting is allowed. However, **must not exceed the 40% of the contract.** Tenderers will identify in the offer who the subcontractors are and which parts of the contract they will deliver in the project in the technical offer.
65	During the period in which the PCP is open for receiving offers, how can tenderers ask for doubts?	The procedure for communication is described in the PCP Tender document (TD1) Section 5.3. **For technical questions related to the use of the eTendering platform,** a specific e-mail and phone number will be available. All clarifications and doubts needed related to **the call for tender (contents) must be submitted in writing via the "messages" section of the eTendering platform** before the set closing date for receipt of clarifications.
66	Is it established a set of preferential technologies to develop the R&D service?	No, any technology that it could be included as **eHealth is welcome.**

Last update: 31 May 2017

This Project has received funding from the European Union's Horizon 2020 Programme under Grant Agreement nº 689476