

	<b>Q&amp;A LIVE INCITE Open Market Consultation</b>	
	The below questions and answers were received and published during the spring 2017 as part of the open market consultation.	
<b>No</b>	<b>Question</b>	<b>Answer</b>
1	<p>Is it possible to add additional members or subcontractors in a group of partners as the PCP is progressing and additional learning is generated? If yes, what is the process for this? If no, please explain why not?</p> <p>For the LIVE INCITE project, are there particular requirements for companies and partnerships to join? What about SME's and large international companies? Are you demanding offices in Sweden, Denmark and Spain?</p> <p>For the market survey response, is there any required or preferred format (word or PPT)?</p> <p>How much market and problem assessment did the consortium do for in-depth understanding of the problem? When and how will this be shared?</p> <p>Would it make sense spending additional and significant time and effort to deeply understand the problem with the 3 consortium partners? The assumption is, that all parties will benefit from an in-depth problem understanding during the PCP process. However, this may shift effort and time spent towards PCP phase 0 and phase 1, while benefitting everybody in phases 2 and 3.</p>	<p>The details of the PCP process and eventual possibility to supplement a consortium along the way will be detailed further on.</p> <p>We have no particular size or location requirements for companies to join the PCP. However, the majority of the work by the supplier shall be performed in EU Member States or associated countries.</p> <p>Word or pdf format required for the response.</p> <p>As the consortium was created, the members pooled their common and long experience from the health promotion and research area together with a market assessment based both on the many touch points of the consortium researchers. We expect to learn more and detail our total assessment during this market survey and other project internal activities. We will not release any more information during the market survey but compile all information until the PCP tender.</p> <p>We are open to activities during the first phase (solution design) being spent on the problem and we might come to such conclusion during the preparation phase.</p>

2	<p>Can you please elaborate in more details the estimated remuneration to PCP suppliers during the PCP?</p> <p>How do you envision remuneration for collaborative partnerships with consultants, IT companies and NGO's?</p>	<p>We have defined a total maximum budget per phase of 300 keuro, 1200 keuro, and 1500 keuro per phase. We will decide if to issue fixed remuneration per excepted supplier/consortium or bid based, in both cases though bids will be evaluated on a best value for money basis, with total contribution per bid being taken into account (i e a supplier's/consortium's own contribution). In case of a bid including several parties, such consortium will make one bid together and, if choosen, receive one budget and distribute such between themselves.</p>
3	<p>Can you please clarify the last date for submission (uploading of documents to participate). On the SLL Webpage it says: Last date to participate: 6/22/2017 11:59:59 PM GMT+1But in the updated material for the market survey it states:3.3Important dates for the market survey: Overall analysis of responses and preparation for one-on-one meetings Apr 15 - onwards.Open Information Meeting May 9What is the actual last day for submission?</p>	<p>If you are planning to participate in either the Open Information Meeting and/or a One-to-One meeting and wish for your response to have input on them (especially the one-to-one meeting) , which we hope and believe you will, we would like to have your respones at the latest one week before such event start. If you however don't expect to participate in any form of meeting the last date i June 22nd.</p>

4	<p>You state:</p> <p>"We have no particular size or location requirements for companies to join the PCP. However, the majority of the work by the supplier shall be performed in EU Member States or associated countries.</p> <p>I assume this includes UK also after Brexit or will we not be allowed to have one of the three partners in our consortium to be based in UK? The other two partners are based in Sweden.</p>	<p>You may have parties in non-EU countries. The directive only state that the majority of the work shall be performed in EU Member States or associated countries. The UK may very well be such associated country but even if not, it will be feasible to perform some of the work in the UK. The full extent and consequences of Brexit are yet to be defined and we will follow the guidelines and advice as it becomes available from the Commission. The exact distribution is not defined nor will be until possibly in the PCP tender.</p>
5	<p>Regarding the IPR, can you please share a tender template contract document (or parts of it), which is addressing the handling of intellectual property (IP)?</p> <p>This is helpful for partnerships that are currently in the process to be formed and who want to align themselves on the consortium's thinking around IPR. Thanks!</p>	<p>The PCP tender document including Framework Agreement, which will include definitions of how IPR is handled, will be produced later in the process. At this point, we can only provide the description as stated in section 2.2.1 of the market survey document. If further detailing is done during this open market consultation, we will make such available.</p>
6	<p>We noted that third parties are involved in the consortium. We like to know: - to what extent they will participate in the R&amp;D activities and whether suppliers can or will have to interact with them especially in design and pilot phases. - whether it is possible for suppliers to work with other (additional) parties, especially other associations representative of patient groups.</p>	<p>The linked parties are involved in the process in different roles but supporting the respective partners in the buyers group, • Swedish Rheumatism association (associated to Lead procurer) • Fundació Clínic per la Recerca Biomèdica (associated to Hospital Clinic de Barcelona) Mainly the linked parties involvement refers to formulation of the challenge presented in the Tender documentation and support the evaluation activities. The R&amp;D suppliers can work with any associations and parties, to set up any suitable cooperation, with partners they find appropriate.</p>

7	Do you expect the suppliers to run prototype development (phase 2) and the piloting/testing (phase 3) with all identified clinical partners in the three countries? Will this require each solution to be prototyped and piloted in 3 languages?	Our intent for both phases, subject to possible change until the tender, is suppliers for the prototype phase shall develop the prototype in english and demonstrate such protptype development continuously at sprint demos. These sprint demos will be held in Stockholm plus video, demonstrating the current state of the prototype in/from the suppliers own development/staging environments. For the pilot, the "feild tests"/pilots will be run on three sites with estimated 40 patients per site. The language will need to be in the native language per site (i e Swedish, Danish, and Spanish). The supplier shall ensure that the solution can thus be run on each site in the specific language. However, we will not evaluate how such multi-language ability is enabled, only that the pilot can be run successfully in the three sites. LIVE INCITE can facilitate such translation to swedish/danish/spanish by reviewing supplier translated files but the supplier shall perform the translation as part of the contract.
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We would also like to clarify the following information from the market survey document you have downloaded:

On page 21 and footnote 8 we state: “By ‘continuous learning’ we do not primarily mean automatic, machine learning or some kind of AI capability in a solution but the ability for our researchers to analyze data from the solution and (!) be able to use such new insights to actually and autonomously re-configure/optimize intervention programs.”

This information should not be interpreted as that we do not believe that a data driven approach with application of modern technologies for machine learning, AI or similar could be a vital part of or primary approach for a solution. We are aware that the continuous learning related to individual behavior and activities to support when and what to support the patient with during an intervention program as well as the retrospective manual or automatic/machine-driven learning and adaptation of interventions might be very important and successful to achieve the goals.

With this clarification, we would like to stress that we do not exclude nor require a data driven approach.

9	<p>LIVE INCITE - MARKET SURVEY (Coming Pre-commercial procurement) Question: To what extent is the target population of Life Incite binding? Are for example IT-applications to improve healthy lifestyles in a school-based setting still within the scope of Life Incite? We would like to share our knowledge on behavior change strategies in children to further develop IT-applications. This knowledge could on the long term also be applicable to an adult patient population, but certainly not on the short term?</p>	<p>The target population for the core use case (elective surgery) are patients. However, since we want to address the need to support changed behavior for patients with risk factor life-styles with generally applicable behavior change knowledge, in order for us - procurers within health - to be able to scale the use to new risk factors and care contexts and for the supplier to have the best possible market potential. We do see it as very interesting if you are achieving behavior change in other populations. Whether it is possible to transfer such knowledge right away - i.e. develop a solution and explore the potential during the PCP based on this knowledge - or have it be one input and consideration we can of course not say. A PCP is intended to explore new, innovative ideas and transferring this your experience/knowledge to a solution concept and prototype (built yourself or in a consortium perhaps) is perfectly viable as an approach. But, to be clear on the target population question, LIVE INCITE will during the PCP target patients in the elective surgery setting with risky life-styles which need to be changed but a solution could be based on knowledge/assumptions from other populations.</p>
10	<p>Does the PCP only focus on the two mentioned risk factors (alcohol and smoking)?</p>	<p>These are the two core risk factors, but the solution can also include other factors in the future.</p>
11	<p>Can the suppliers skip the RFI but still attend the tender process?</p>	<p>Yes, the RFI is not a pre-requisite for participating in the Tender. This is however a unique opportunity to develop the solution as well as the process to reach the solution together. We value your input on the upcoming process.</p>

12	What is the time plan for the different phases in the PCP?	Phase one is 2,5 month starting the feb 1st 2018. Phase two is 5,5 months starting mid June 2018 and the phase three is 8,5 months starting Feb 1st 2019.
13	What is the goal with the Tender process?	To stimulate the innovation and development of a solution meeting our needs and challenge. The aim is also to be able to leverage the insights gained during the process and the innovated solutions to enter a possible procurement post-PCP.
14	For how long and where will the test be held?	The tests will be conducted in phase three. At the moment the current sites for testing is Barcelona, Stockholm and Denmark, but there could be more or other sites due to the number of patients. We estimate that approximately 30-60 patients/solution will be involved. Please notice that this is an estimation and may change in the future.
15	Will the number of patients be enough to evaluate if the solution is scientific?	No, but the PCP is not a research project and need not be scientific in its conclusions. We believe the number of patients will be enough to evaluate and compare the solutions, which is the purpose of the PCP. Solutions might post-PCP be subject to scientific trials/studies in order to be relevant for procurement but that is outside of the scope of this project.
16	We interpreted the PCP as focused on small and middle-sizes suppliers. Will large suppliers not be able to participate in the tender process?	Any supplier meeting the exclusion criteria is subject to win the contracts. We have no restrictions on size and welcome all type of suppliers but have stressed that also (since this is not always the case) small to mid-size companies should engage.
17	What are the thoughts regarding ownership of the IPR of final solution? Who will own it?	The supplier will own the IPR but our aim is to construct the framework agreement so that we, in the buyers group, do not have to pay for the solution twice, for instance licencing fees that we have been part of developing. We will gladly take input from the market regarding this area.

18	How will the IPR of the suppliers be handles and be exploited by the suppliers them selves?	The are EU regulations stating that if a suppliers has not exploited their solution commercially within 5 years from the end of the PCP, we as a buyer group will have the right to the IPR. All suppliers will be requested to describe how they plan to commercialize the solution; such business plan work process will be evaluated throughout the PCP.
19	When 2-3 suppliers are left in the last phase, they are competitors. How will you handle the condidentiality during the process?	We will execute phase 3 as separate/supplier parallell tracks, trying to leverage as much of the resources as possible, f i regarding local support staff and patient recruitment processes. We, as care providers, continuously work with many competitors on site in production or project mode and are used to secure the required and relevant confidentiality.
20	Will you combine solutions from two different suppliers during the process?	At this point each supplier/consortium shall be able to address the full challange on its own and that such capability shall be described and be evaluated during the first tender process. The level of flexibility to modify components of or parties in a consortium as well as for us to so suggest between phases in being reviewed but most likely such flexibility shall not be anticipated.
21	You mentioned that you do not want a vendor specific solution, is that totally excluded?	We want to secure as much authonomy and flexibility as possible but understand that companies depend on profit and need to have ownership and that some sort of dependency will be necessary. The core issue is flexibility over time for the procurer - where f i the use of standards for data communication and interaction/integration is one aspect - and we will most likely have that as one of several evaluation criteria but it does not rule out that a supplier can address the issue of flexibility in

		several ways, even with traditional vendor lockin.
22	Will you provide us with data for example patient data?	<p>It is difficult to foresee which type of data every possibly winning concept might require for the PCP and it might be that we need to adress specific data requirements during phase 1-2, i e in preparation for "possible" phase 2 and 3. Phase 1 will not require any data at all and phase 2 will most likely work welll without other data than the fictive and demonstrative that the supplier can provide itself. It is for phase 3 and the pilot/field test that we will need to deliver data. As stated, we do not know which data a supplier will require but we do beleive that the solution should not be integration intensive and that suppliers should take the feasibility aspect of implementing the solution into consideration and thus also define concepts which are as non-dependent as possible and data requirements possible to supply manually if important. F i, if behavior analysis is to be done in a first stage for a specific solution then of course patient data and history would be relevant but the solution could score well by enabling or even pre-defining as default that all such background data is to be filled in by the patient as part of such self-assessment/behavior analysis step. That said, it is our intent to provide basic example patient data for phase 1 and 2. For phase 3 we will look into the feasibility of enabling real integration</p>

		<p>to patient data in each specific hospital being tested or if we will state that such data will be defined and manually created outside of a hospital EHR/patient journal, f i as part of the recruitment process and an SLL provided database or if we will require such data collection manual process to be provided by each supplier. To summarize, we will define this in the tender and at this point of time we believe that the project and (!) a widely implemented solution would benefit from minimizing requirements on EHR/journal data and try to strive for self-sufficiency. Therefore, the best guess at this time is that we provide basic example data for use in phase 1 and 2 - possible to connect to and/or download from a SLL database - when phase 1 is started and stipulate on suppliers to secure a manual input process of the data needed for the appr 40 patients to be piloted on each solution. The feasibility and sustainability in integration in a latter stage - if a concept/solution requires such in a real production setting post-this-PCP - will be evaluated but not necessarily by doing in phase 3.</p>
	<p>What is the business opportunity?</p>	<p>We have shown the scalability opportunities, that we believe are substantial. Approximate numbers indicate that out of 18 million planed surgeries in Europe, 2,7 millions annually, are preformed on smokers. Smoking is a evidence proved risk factor impacting complications. That is just one risk factor.</p> <p>We believe that there are good solutions and that the business opportunity depends on how well we can create a business model together during the PCP process. The business opportunity is likely to be more described in the tender.</p>

	Will there be a health economic perspective in this process?	Yes. We are presently working with that now.
23	How will the solution be intergrated in the current healthcare system, hospital care and GP?	We do not know since we at this point do not now what type of solutions, and thus extent of process/organizational integrations, will be proposed. We will have to (to the tender) strike the balance between having the solution be feasible to be implemented (i e not require substantial integration with the HC system) and its possible dependency on just such HC system integration.
24	From which stage is the solutions supposed to intervene the patient life style change?	In our core case the focus is 6-8 weeks before the surgery, at the time of operatin planning mots likely, but in a scalable solution it could be substantially longer. But developed the right way, we beleive we can focus the PCP on the intervention starting at the time of operation planning (some 6-8 weeks ahead of operation) and continuing for a minimum of 30 days after surgery.
25	Who will buy the solution?	The aim for LI is that care provider in each country decides where in the care process the solution will be purchased. If the solution can have additional buyers it is up to the supplier to define and explore that.
26	Is this aiming at life style changes or/and also at patient empowerment?	This solution is not supposed to monitor other health conditions or a general well-being solution, it focuses on life style changes that has an impact on the care processes and usage defined.
27	Should the solution be able connect to the responsible physician at the hospital?	If you/a supplier beleive that is necessary for an effective and sustained behavior change it could but we, at this time of the preparation process, do not stipulate such connection. It should ne note that we plan to evaluate the Feasibility and Sustainability of concepts/solutions, in which solutions being effective with a minimum of use of hospital/care

		provider (always scarce) resources will be one evaluation item.
28	Is technical monitoring included?	This is up to suppliers to define as part of their concept. It can be included, could be an interesting way of getting patient data in real time. Not mandatory. Take a look at the Horizon 2020 project Nightingale: <a href="http://www.nightingale-h2020.eu/">http://www.nightingale-h2020.eu/</a>
29	Who will store and own the data? Both in the PCP and in the final solution.	It is for the supplier to recommend in their solution.
30	There is a budget for the three phases – what are the thoughts of this in regard of the evaluations?	There will be a best value for money overall evaluation principle used, i.e. that we weigh and value both the quality of bids and the price to conduct a phase. The details of such remain to be specified however.
31	You suggested earlier that companies can work together in a consortium, is it mandatory describe the composition of included companies?	Yes, in the tender it will be. You may have parties from non-EU countries. The directive only states that the majority of the work shall be performed in EU Member States or associated countries. The UK may very well be such associated country but even if not, it will be feasible to perform some of the work in the UK. The full extent and consequences of Brexit are yet to be defined and we will follow the guidelines and advice as it becomes available from the Commission.
32	Do consortiums with companies from different countries have some sort of advantage in the tender process?	No
33	How will the bidding be designed?	Pricing, content and own contribution will be valued somehow, but the evaluation criteria has not yet been set.

34	Will money include the evaluation or only product development?	The supplier shall perform all of its explicit and non-explicit activities to secure complying with the framework agreement and phase specific contract and delivery and will be compensated with the agreed remuneration, contributing own time as well.
35	Are there anything in the Horizon 2020 project stipulating levels on suppliers contributions?	No, but we will have own contributions as one aspect of the evaluation.