MARKET SURVEY

LIVE INCITE

Supporting lifestyle changes, improving outcomes of care

Karolinska University Hospital (Stockholm County)

acting on behalf of the consortium of the Horizon 2020 project* LIVE INCITE, including also Bispebjerg-Fredriksberg Hospital, Copenhagen, Clinic Hospital, Barcelona, and the Karolinska Institutet, Stockholm

* funded under the call H2020-SC1-2016-CNECT and topic H2020-EU.3.1.4. - Active ageing and self-management of health

KAROLINSKA

Stockholms läns landsting

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1 Introduction

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 727558.

This open market survey/consultation precede a pre-commercial procurement that is exempted from Directives 2004/18 and 2004/1710.

This market survey reflects only the view of SLL and the project consortium and the Commission is not responsible for any use that may be made of the information it contains.

The PCP tender is conducted separately after this open market survey/consultation and all potential bidders will be treated equally.

SLL will not evaluate or make any selections during this open market survey/consultation.

LIVE INCITE is a 3-year project, funded within the Horizon2020 program and a call[1] for performing a Pre-Commercial Procurement (PCP) for services based on ICT technologies that can empower patients.

LIVE INCITE aims to empower patients by supporting lifestyle changes in order to improve outcomes of care as well as cost effectiveness of healthcare providers. The LIVE INCITE consortium includes parties in Sweden, Spain and Denmark.

Through the use of a pre-commercial procurement, LIVE INCITE aims to challenge and stimulate the market to develop patient centered interactive IT-solutions, enabling care providers to support patients in lifestyle changes related and beneficiary to the outcome of their care process.

We want to emphasize that we believe that the needs which we have identified will require a modern, open and innovative approach from suppliers regarding architecture, technology, use of standards, and user experience in order to meet short needs as well as long-term capabilities.

We also wish to stress that we will enable also for actors without previous health care experience or references to contribute in this PCP as well as be competitive in a possible later public procurement.

1.1 Consortium partners

LIVE INCITE includes the following beneficiaries:

Karolinska Universitetssjukhuset (Lead procurer) in Stockholm, Sweden
Hospital Clinic in Barcelona, Spain

[1] Horizon2020: PCP – eHealth innovation in empowering the patient

Bispebjerg-Frederiksberg Hospital in Copenhagen, Denmark
Karolinska Institutet in Stockholm, Sweden

Karolinska Universitetssjukhuset is acting on behalf of Stockholm County (SLL) in the project.
Bispebjerg-Frederiksberg Hospital is acting on behalf of Region Hovedstaden in the project.

1.2 Purpose with this market analysis and dialogue

LIVE INCITE is a project approved as part of the before mentioned Horizon 2020 call. This call can be summarized as including three core components: IT solution + Patient empowerment + Pre-commercial procurement.

Performing a PCP is the core component of the call. The project is currently in its Preparation Phase, including performing end-user insight analysis and research syntheses but also a market survey/analysis (open market consultation).

The purpose of this market survey/consultationis:

- To describe the overall needs, short term as well as long-term, for LIVE INCITE.
- For LIVE INCITE to receive information about and gain understanding of ideas, concepts, technology, and solutions areas to support the LIVE INCITE need and challenge.
- For LIVE INCITE to get to know the market and type of actors, possibly consortiums, are interested.
- For LIVE INCITE to get ideas and insights needed for defining the best possible challenge in a tender document for a PCP.
- To raise awareness in the market place.

1.3 Disclaimer

This procurement receives funding under the European Union's Horizon 2020 research and innovation programme under the grant agreement No 727558. The EU is however not participating as a contracting authority in this procurement.

Observe that this survey is <u>not a part of the procurement process</u> but one activity in a preparation phase.

SLL will neither be responsible for continuing the overall process described in this document nor perform it in the way described herein or as possibly discussed during this market survey and dialogue.

1.4 Abbreviations

Some abbreviations in this document:

Definition	Meaning
SLL	Stockholm County Council; Stockholms Läns Landsting, the legal entity used in the project, which practically involve Karolinska Universitetssjukhuset.
LOU	Lagen (2016:1145) om offentlig upphandling; the Swedish Public Procurement Law.
PCP	Pre-commercial Procurement (Förkommersiell Upphandling in Swedish).

2 Orientation

2.1 Background

It is well known that health care outcomes in the perioperative care process correlate with severity of disease, operational procedure and co-morbidity. Only recently, it has been proved that also the lifestyle factors of the patient are independent risk factors for a poor outcome after surgery.

In October 2015, a team at the Karolinska Innovation Centre identified an EU call by which the above problem could be explored together with the market in a PCP. Three partners were identified and involved in the application/project.

The thesis that influencing patient life style with the use of relevant, personalized information and continuous monitoring and support for the patient to change and comply to the targeted life style was formed continuously until submitting a proposal to the call in February 2016.

See extract from the proposal in appendix 6, LIVE INCITE Proposal Extract.

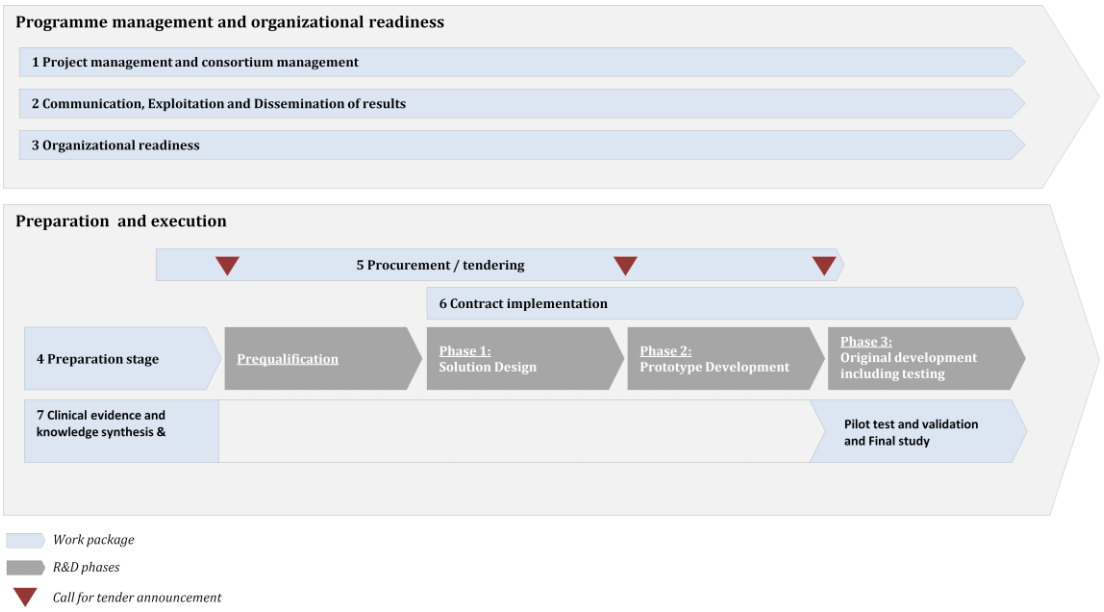
In June 2016 LIVE INCITE was received the highest ranked proposal by the commission and thus awarded the proposed budget.

Following LIVE INCITE in June having been accepted as the number one ranked proposal, formal agreements between the project and the commission as well as between the beneficiaries was signed and the project was started early November 2016.

2.2 Project Overview

The project runs from November 2016 to June 2019. The core project consists of the preparation and execution of a PCP, which will run over three phases.

The project is currently in the preparation stage (Work Package 4 below), which includes performing a market survey/consultation.



Picture 2.2: The overall project plan with seven work packages.

2.2.1 Overall about intellectual property during a PCP

Note: The handling of intellectual property (IP) will be detailed in the later tender document and PCP contract agreement. The below is a non-all-inclusive summary of how IP is likely to be handled.

R&D risks and benefits in the later PCP will be shared between SLL and the supplier in such a way that all parties have an incentive to pursue wide commercialization and take up of the new solution. Therefore, ownership of IP generated by the supplier during the PCP contract will remain with the supplier generating it. Ownership of any supplier background IP will also remain with the supplier.

The supplier will in a PCP contract grant SLL an irrevocable, worldwide, free and non-exclusive license to use the IP generated in the PCP for the purpose of using the results of the PCP con-commercially. Licenses on relevant background IP shall be offered at fair and reasonable conditions. Relevant background IP means the background IP that is essential to the functioning and us of the results of the PCP.

2.2.2 After the project/PCP

This project, as any PCP, does not include an actual procurement of one of the solutions being developed during the project. Rather, the PCP aims a creating a market from which the procurers/buyers group can procure a solution meeting the needs as explored/matured during the PCP.

It is not an obligation of the buyers group to initiate a public procurement after the PCP.

2.3 Consortium

For more information on the consortium partners, see appendix 7.

2.3.1 The Lead Procurer

Karolinska University Hospital (K) has been assigned the role as the Lead procurer for the consortium, and will act as the procurer in the project.

2.3.2 The buyers group

- Karolinska University Hospital (K)
- Hospital Clinic de Barcelona (HCB)
- Bispebjerg-Frederiksberg Hospital (BFH)

2.3.3 Other beneficiaries (Academia)

- Karolinska Institutet (KI)

2.3.4 Third parties

Third parties associated to the beneficiaries:

- Swedish Rheumatism association (associated to Lead procurer)
- Fundació Clínic per la Recerca Biomèdica (associated to Hospital Clinic de Barcelona)

2.4 Budget for PCP

LIVE INCITE has been awarded an EU grant based on the below estimated remuneration to PCP suppliers during the PCP:

Phase	Expected duration	Expected budget	Nr of R&D providers	Maximum budget per provider
Solution Design	12 weeks	300.000 EUR	4-7	75.000 EUR
Prototype Development	25 weeks	1.200.00 EUR	3-4	400.000 EUR
Original Development	28 weeks	1.500.00 EUR	2-3	750.000 EUR

Note that the above is open to change.

Table 2.4: Estimated remunerations to PCP Suppliers

2.4.1 Long-term incentives

It should be noted by interested suppliers for the PCP that each supplier will be expected to contribute own time (invest) in the PCP; to be described in the PCP tender document and evaluated in the qualification process of the tender. Besides formal and legal reasons related to a PCP, LIVE INCITE wishes to find and cooperate with suppliers which have a strategic, long-term rationale and incentive to participate in the PCP.

2.5 PCP in brief

For an introduction to PCP, see appendix 8, PCP in brief.

3 Market Survey details

This market survey and dialogue is a part of the preparation for a pre-commercial procurement process for LIVE INCITE, which execution and content in part will depend on the outcome of this survey.

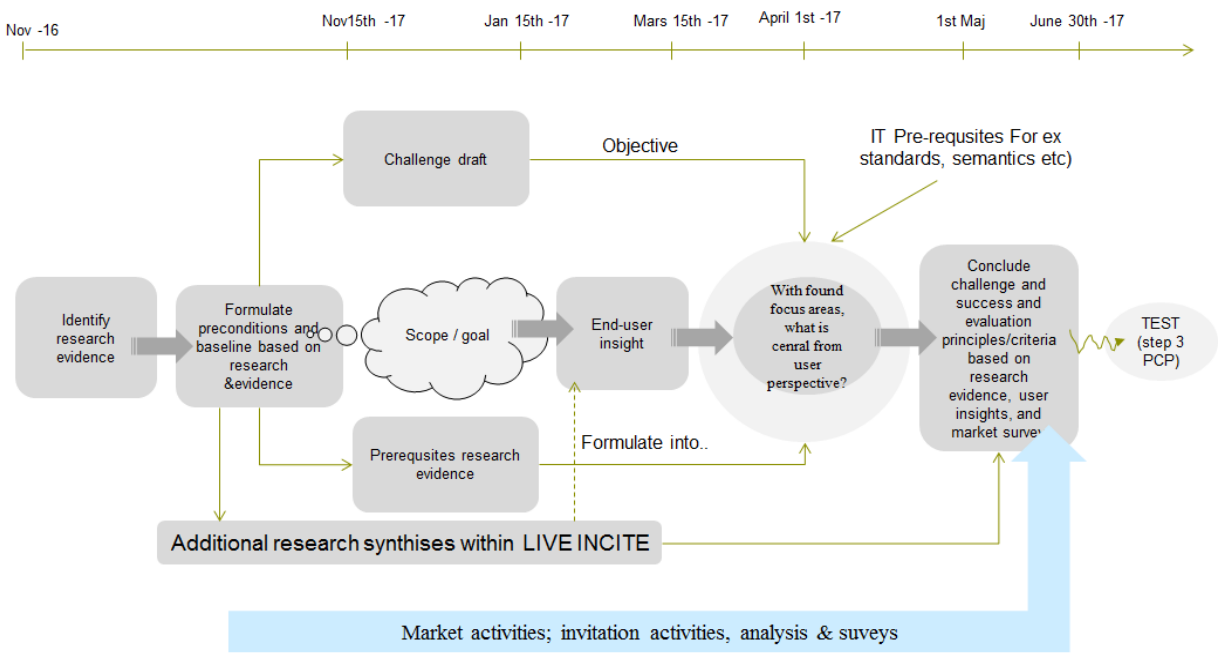
3.1 Issuing organization

SLL, Registration nr: 232100-0016

3.2 Context of open market survey/consultation

This open market survey/consultation is a part of the Preparation phase of the project.

The below picture depicts our overall approach to the Preparation Phase. The aim is to arrive at a point where our insights and understanding of the total[2] needs



Picture 3.2: Overall approach for the Preparation phase, in which the market survey is an important activity. Please note that the dates have been modified and are not correctly stated in this picture.

[2] Needs are often described as known, functional requirements or clinically known overall needs. However, the *capabilities* in a solution look beyond needs which are known and what can be defined and take a long-term look at what the solution should be capable of, which in turn influences *how* a solution is technically designed and developed. LIVE INCITE has started capturing such capabilities through the definition of Success Components, see section 5.

3.3 Important dates for the market survey

Activity	Start	End
Overall analysis of responses and preparation for one-on-one meetings[3]	Apr 15 - onwards	
Open Information Meeting[4]	May 9	
One-on-one-meeting period	May 10	June 22
Estimated Announcement of PCP tender		Sep 30

The above dates and activities are subject to change. Such changes will be published on the same area as this markets survey document.

3.4 Publishing

This material and supplementary information will be published on www.upphandling.sll.se . Ads have also been published on http://www.opic.com as well as a Prior Information Notice (PIN) on TED eNotices (www.ted.europa.eu).

3.5 Responses

- Submitting a response is not synonymous with a supplier or procurer commitment of any sort.
- Material can be supplied by one or several parties together, with one party being the primary contact.
- There should be one contact person clearly stated in the material..
- The material shall be provided in Word or PDF format.
- Observe that we would like you to submit your response to this open market survey both in the online portal www.upphandling.sll.se as stated in 3.4 and by sending a version to the mail address as stated in 3.7.4.1.
- If confidentiality is required please se 3.7.3 below.

3.5.1 What to include in a response

We would like you to address the following areas in your answer, which shall be **no more than 30 pages, excluding appendices**.

As a minimum, we would like you to include the below in your response.

1. **Company presentation** and, if relevant, a presentation of roles in a possible consortium.
2. Your innovative **ideas, concepts, and possible technology/solution areas you deem have potential to address the LIVE INCITE challenge**.

[3] Registration for one-on-one meetings on http://karolinska.se/en/live-incite .

[4] Registration for Open Information Meeting on http://karolinska.se/en/live-incite .

3. Your thoughts on our defined **Success Components**.
4. Your **experiences and ideas of behavioral change** in general as well as related to IT..

3.5.2 Addressing part of the need/challenge

In this document we provide an overview of our need. How this translate to solutions we don´t know but it might be that some suppliers, based on their interpretation of what would be a total solution, feel they could be able to address some of such solution but not all. In such a case we still advise you to respond to this open market survey/consultation. The reason for this is that:

1. You might find yourself engaged in a process which leads to you finding other suppliers to partner up with before the PCP

You will still be able to provide valuable insights to LIVE INCITE and thus support the project in defining the best possible PCP tender.

3.5.3 Q & A

We will answer questions continuously during this market survey (consultation). Since we are focusing on the overall concepts, architecture, and capabilities of possible approaches/solution areas we would like interested parties to refrain from asking detailed questions about functionality requirements for LIVE INCITE (we do not know them yet).

Please submit questions on www.upphandling.sll.se, under the headline “Questions & Answers”. The questions & answers will be published under the headline “Questionnaire” on www.upphandling.sll.se without disclosing the source of the question. The Q&A´s will be available on the project web site on http://karolinska.se/en/live-incite shortly after completed market survey.

For general questions, please use the contact information in section 3.7.4.

3.6 One on one meetings

Suppliers having registered for one-on-one meeting at http://karolinska.se/en/live-incite will be offered to have one on one meeting with SLL.

3.6.1 Purpose

The sole purpose of these meetings is for SLL to better understand ideas and concepts from the market as to build competence and ability to issue the best possible tender document for the PCP.

3.6.2 Agenda

In order to secure conformity in and quality related to the one-on-one meetings the following agenda will be used:

1. Brief presentation about the supplier (5 minutes)
2. Supplier input on solutions that are currently available (5-10 minutes)
3. Supplier´s presentation on innovative ideas, concept and technology/solution areas with potential to address the LIVE INCITE needs
4. Supplier´s approach to our identified success components, as described in this document
5. Supplier´s view on critical success factors for the PCP

3.6.3 Market survey response or presentation material one week in advance

A supplier registering for a one-on-one meeting is requested to send presentation material at the latest one week in advance of the meeting. If such material has not been submitted SLL reserve the right to cancel the meeting on short notice.

SLL expect suppliers to have reviewed and addressed the needs and challenge of this market survey document and be well prepared for the one-on-one meeting. A written response to this market survey according to the content defined in section 3.5.1 will be greatly appreciated and will serve as an approved presentation material. I e, a supplier having responded to the market survey at least one week before a one-on-one meeting will be exempted from sending any more presentation material but only expected to prepare a presentation of the response in time for the meeting.

Suppliers not having provided a written response to this market survey document shall send presentation material in Power Point format with an attached written appendix in Word or PDF covering the agenda items defined above. Such presentation material shall be in English. Submit presentation material – if other than market survey response – by mail to malin.emond@sll.se.

3.6.4 Publication of possible new information

In case of a one-on-one meeting resulting in SLL providing the specific supplier with information not stated in this market survey document, SLL will publish also such complementary information in order to secure transparency.

3.6.5 Findings from one-on-one meetings

SLL expect to gain good insights from the one-on-one meetings (I e verbal presentation of written responses) and will at the latest after the one-on-one meetings period but also possible continuously summarize these insights and make them available on http://karolinska.se/en/live-incite. Such publication will not include detailed information about supplier responses, ideas, and concepts and will respect treatment of confidential information.

3.7 Communication and administration

3.7.1 Responses

We kindly request only written responses to this survey, submitted electronically on www.upphandling.sll.se and by sending a version to the mail address as stated in 3.7.4.1.

On the website you will see a list of current tenders, please select the one named "LIVE INCITE - PCP". When selected, you will have the opportunity to create an account to log in. Once you are logged in you will be able to see all our materials and how to submit your response as well as ask questions.

For technical support please contact;
Peter Ryman
peter.ryman@sll.se
+46707374949

English is the only accepted language for written responses in this market analysis.

SLL will provide all publicly published material in English only.

3.7.2 Confidential information

Documents related to the pre-procurement phase or to any market survey prior to procurement, may be regarded as confidential due to other provisions according to the Public Access to Information and Secrecy Act.

Stockholm County Council will treat any submitted responses within the frame of this market survey, to the extent they contain commercially confidential business information, as subject to confidentiality.

If the Applicant considers information provided during this market survey and dialogue to fulfill the conditions for commercial confidentiality, the Applicant shall submit a request for commercial confidentiality. The request shall detail which information should be covered, and what damage the Applicant would suffer if the information would become public.

SLL individually assesses each request for public information. Note that SLL's decision to treat information with confidentiality can be reassessed and challenged in court.

3.7.3 Costs

Participating parties in this market survey shall bear their own costs related to such participation.

3.7.4 Contacts

3.7.4.1 Administrative issues regarding the survey

Name:	Malin Emond

Phone:	+ 46 (0) 73 745 04 75
E-mail:	malin.emond@sll.se

3.7.4.2 Content issues regarding the survey

Name:	Martina Ahlberg
Phone:	+46 (0) 76 551 90 35
E-mail:	Martina.ahlberg@karolinska.se

4 LIVE INCITE – Developing an Intervention Engine for HealthCare

What is the highest level of patient empowerment in care? One might argue that it would be for a patient to be involved in, and have effect on, the actual clinical outcome of her own care process. By a healthy life style, such patient control and empowerment is achievable.

4.1 Core idea of LIVE INCITE

Research shows that destructive life style factors such as smoking and excessive alcohol consumption are risk factors for complications related to surgery, increasing the risk for mortality, surgery complications, and rehabilitation efficiency.

LIVE INCITE is based on the non-disputable potential in engaging and empowering the patient to contribute to the minimized risk of complications related to elective surgery by changing her life style before a surgery.

However, LIFE INCITE strives not only to solve the above specific care scenario and context but to develop a solution with which care providers can learn, evolve, and execute in how to best support patients in need of complying to a certain behavior in order to improve her care outcomes.

Such a solution is not a smoking cessation application with some scalability potential but a "behavior intervention and support engine". The solution should be able to be configured with smoking cessation parameters and interaction as well as other intervention programs; such capability possible due to the solution being designed based on generic driving mechanisms for behavioral change and the features required for this purpose.

4.1.1 "IT solution"

In this document we refer to an IT solution. By this we primarily mean a digital solution, I e software. However, since the overall need as described in this document include the communication and interaction with as well as perhaps monitoring of the patient in order to support her compliance to a specific intervention program, the total solution might include hardware/devices for f I monitoring. Such concept could thus be a part of the solution, but it is not the focus of this project to innovate new hardware/devices for out-hospital monitoring. Rather, a supplier could and should think about how to include such short or long-term patient generated data in the solution by including or being prepared to include technical interfaces to consume such data. To summarize, each supplier may include such existing hardware/products in its concept – short-term or long-term – but the focus of the innovation in this project is software.

4.2 The need for a solution beyond large, controlled, resource intense program

Research provides clear evidence that patients who manage to comply/adhere fully to intensive pre-surgery program reduce their risks for complications drastically.

4.2.1 Gold Standard: Successful smoking cessation program

The Gold Standard Programme (GSP) is a very successful smoking cessation program[5] and should be learned from in terms of content used and activities performed[6]. However, since the GSP is based on weekly group sessions moderated by a trained expert the potential for scaling into a wider context is limited.

For the project, it is thus important to look beyond the efficiency of programs and identify which "driving mechanisms" best effect behavioral change. With such mechanism identified, we (consortium and the market) will be able to design an efficient and scalable IT solution which provide the level of data and feature richness required to drive self-empowered behavioral change.

So, the intensive intervention programs, such as the GSP, conducted display a high adherence rate and high effect on outcome measures. But, besides of course wishing to increase the compliance rate even more, an implementation of a patient self-empowerment tool must be effective also in contexts where resources are scarce and full-blown intervention programs are not possible to implement, maintain, and scale.

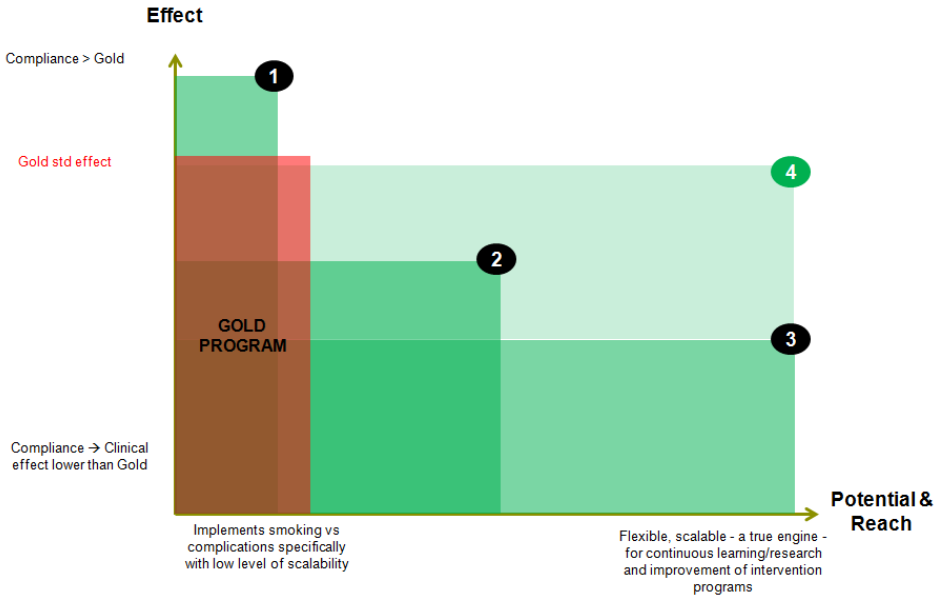
A successful LIVE INCITE solution should thus:

- Be able to be implemented with reasonable effort from a care provider organization and its resources/costs
- Be used by many patients as the support/solution is easily accessible
- Achieve a reasonable high behavior change rate (see picture below)

[5] Four scientific articles on the GSP-programme:
Neumann T, Rasmussen M, Heitmann BL, Tønnesen H. Gold Standard program for heavy smokers in a real-life setting. Int J Environ Res Public Health. 2013 Sep 9;10(9):4186-99.
Rasmussen M, Heitmann BL, Tønnesen H. Effectiveness of the gold standard programmes (GSP) for smoking cessation in pregnant and non-pregnant women. Int J Environ Res Public Health. 2013 Aug 16;10(8):3653-66.
Neumann T, Rasmussen M, Ghith N, Heitmann BL, Tønnesen H. The Gold Standard Programme: smoking cessation interventions for disadvantaged smokers are effective in a real-life setting. Tob Control. 2013 Nov;22(6):e9. doi: 10.1136.
Kehlet M, Schroeder TV, Tønnesen H. The Gold Standard Programme for smoking cessation is effective for participants over 6o years of age. Accepted for publication in Int J Environ Res Public Health.

[6] http://www.rygestopbasen.dk

- Support the continuous learning from data in the solution, possible to transform into improved and/or new intervention programs
- Leverage the anywhere, anytime reach of IT to provide a relevant, ever present support to the patient based on f I the identified risk factor, risk situations, motivational targets, daily life schedule etc of the patient



Picture 4.2: Current best practice program vs sought concepts/solutions compliance rate and potential/reach. Alternatives 2-3 are hypothetical solutions which may still be better than benchmark programsas the enable a higher total effect. Being able to achieve 4 is our utmost goal even though such success must not be achieved during the PCP..

LIVE INCITE seeks to learn from the GSP, and other successful intervention programs, but success will also be measured against ability to implement and reach healthcare effects on a larger scale. A lower compliance than corresponding best practice not-IT intensive programs are likely to be accepted if scalability and high probability to implement is achieved.

Thus, should all solutions prove a compliance rate lower than non-IT-heavy programs, this is not a deciding factor for if an IT solution should be considered or not. We will need to make decisions comparing compliance/effect rates of the PCP solutions with non-IT-programs with how such two different scenarios enable actual, wide-spread and scalable implementation of intensive change programs in healthcare.

4.2.2 Smoking cessation the vehicle, intervention engine the destination

LIVE INCITE is not about smoking cessation for elective surgery patients only but LIVE INCITE is about systematically and efficiently providing patients with a need for behavioral change to be able to comply to and sustain such behavioral change.

By defining and continuously learning about and optimizing how driving mechanism for behavioral change are translated into efficient content, communication, and relevant and timely support for the patient LIVE INCITE wish to explore the potential of an intervention engine.

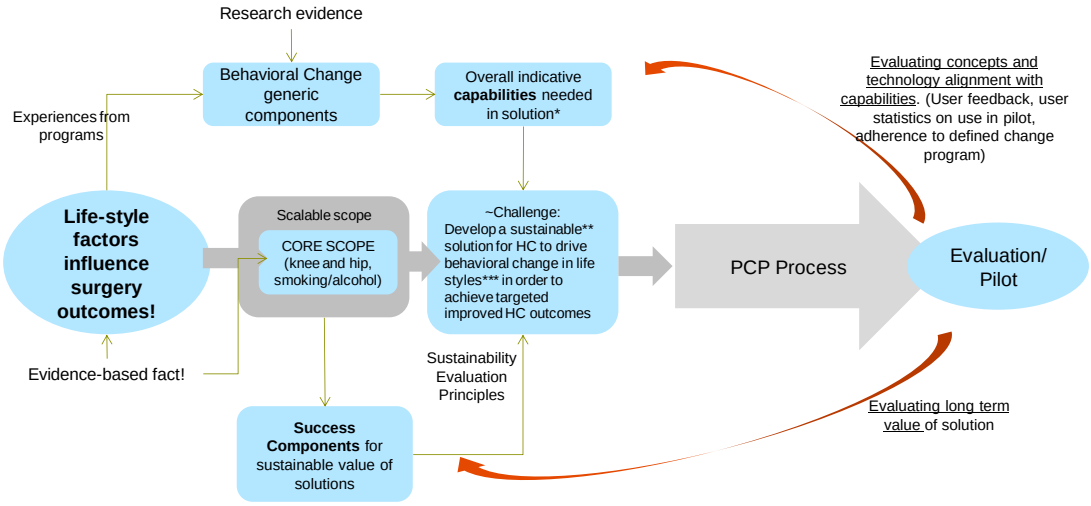
4.3 Our preliminary thoughts on solution scope

The solution can generally be described as one by which we can flexibly and over time, as new research and insights from analysis of data from the solution is introduced, implement the best available support for patient empowered behavioral change which if addressed will improve healthcare outcome.

This PCP is designed to mainly cover risk factors related to smoking and hazardous alcohol drinking and will also incorporate other patient state optimizing needs. Furthermore, for practical reasons it will cover knee and hip surgeries as the clinical case that will be used to evaluate the innovative solutions. Nonetheless, we see that the innovative solutions will be built on technology that is flexible and scalable enough to introduce other risk factors and cover other surgical treatments. One consequence of this ambition is that we see that the translation of behavior change theory into general and configurable features and capabilities of the solution will be important. We believe this will be a primary target of the suppliers, I e developing a sustainable and generically applicable intervention engine based on behavior change supporting components. See the below picture as well as sections 0, 5, and 9 for more thoughts and information in this.

The evaluation of the solutions will account for this generic approach and sustainability issue and it will be monitored throughout the PCP. It is ultimately the capability of introducing clinical knowledge (through e.g. algorithms, forecast calculations, etc.) that is critical for the performance of the innovative solutions, regardless of type of risk or surgery.

The below picture describes our overall approach of defining capabilities to address the whole need and challenge as well as the follow-up.



Picture 4.3a: drafted challenge description

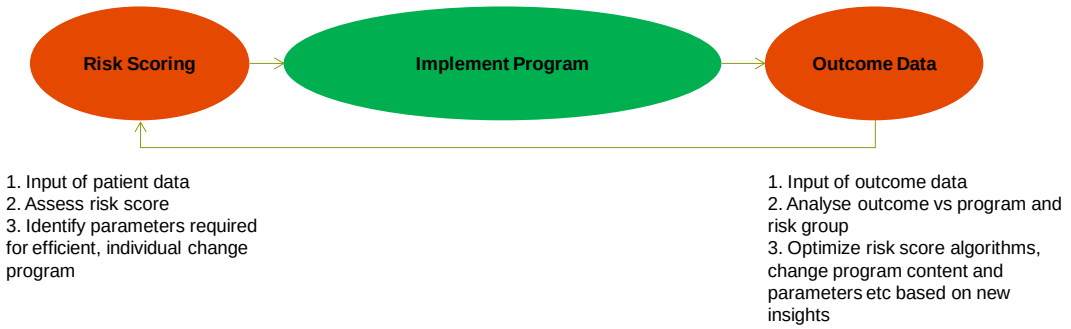
* Identify (input and classification logic) risk group, identify need for support level, program templates with reminders etc, configure individual targets and aids etc.

** As defined by our Success Components, f i scalability, vendor-neutrality, research to clinical use data and configuration loop, degree of self-management vs organizational fit/effort etc.

*** As defined and proven from time to time by current research. In project = smoking/alcohol for elective surgery but also supporting the scalability ambition of implementing other risk factors and care contexts which are possible to address through patient involvement.

In the picture above we have drafted a challenge description:

Develop a sustainable solution for healthcare to drive behavioral change in life styles in order to achieve targeted improved clinical outcomes



Picture 4.3b: Overall conceptual description of end-to-end solution .

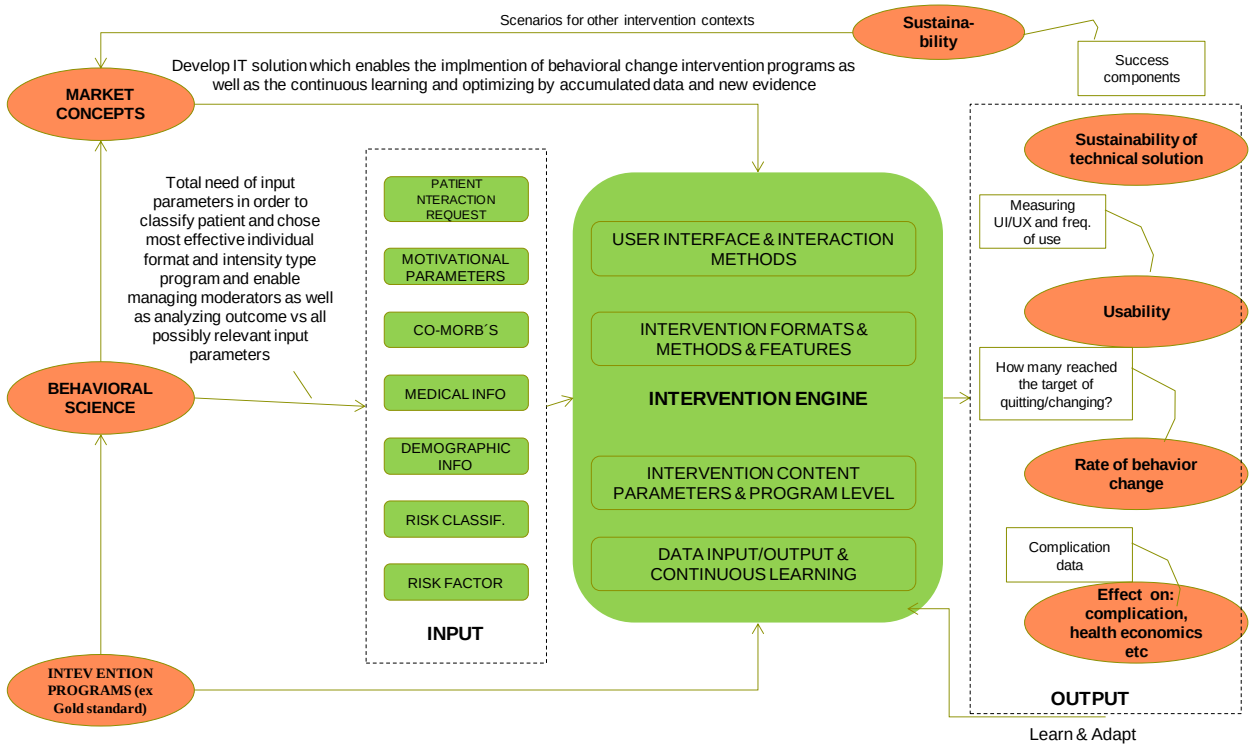
The first and last parts of the picture above make up the critical start to end loop which will be required and probably more defined by us.

1. We know we need to have system, staff, and possibly patient generated input of data as to be able to asses a risk score, a compliance rate probability, individual aspects related to motivation to change, and thus also be able to choose and configure the right change program[7].
2. We also know we do this to achieve an effect of outcomes, in the core use case surgery complications. Therefore, the solution must be able to receive/input data on such defined outcome metrics as to provide us with effect data for a specific patient, program, population etc.
3. 1 and 2 together must be a core of the solution and enable us to analyze and compare risk groups, programs, and outcome.
4. We also need to be able to do something with the new insights in 3, I e be able to efficiently and hopefully vendor-independently change parameters in accordance with increased evidence and knowledge (see section 4.3.1 below).

The middle part in the picture above - the solutions functionality and features to actually and practically support and empower the patient to understand and comply to the change program - will most likely be loosely defined by us in a later tender document for the PCP as we describe generic behavioral change components and thus certain capabilities we believe a solution should include. But it is our hope ***that suppliers will be innovative and bring to the table different concepts for how to reach, communicate with, remind, monitor, and motivate the patient***.

Observe that we believe that the intervention engine should be based and designed/developed on the generic level of behavioral change. The solution could in fact be described as a behavior change tool, configured to include different intervention programs for supporting behavioral change, compliance, and effect in different care contexts.

[7] With "change program" we here mean all the aspects of support to change, f i numbers of contacts, content and subject of contacts, schedules enabling reminders and management of possibly co-morbidities, individual motivational components supporting the patient to stay in compliance etc.



Picture 4.3c: Intervention Engine overall concept.

An intervention engine most likely includes f I data accumulation and analysis for the benefit of continuous learning[8] about risk factors versus outcome as well as efficient intervention methods and content as well as the capability to be configured in terms of when and how to interact with and support the patient.

4.3.1 Optimization cycle

A sustainable IT solution must be built for addressing the fact that knowledge about how to best deliver the right self-management tools for behavioral change will evolve over time. This means that data must be accumulated in the solution as to provide the basis for changing f I templates, configurations etc related to risk groups, template programs, activity schedules etc. The solution must thus enable an optimization cycle of data input versus outcome follow-up and use such analysis to re-configure the solution components.

4.3.2 What might an Intervention Engine look like?

Well, we don´t know and that is sort of the point with a PCP; that we state what our needs are and that you, the market, try to translate those into innovative concepts, suggestions of

[8] 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.

solutions you believe will solve our need. And, that we then commonly explore if those concepts really work by iterating from solution design to prototype to original development.

This market survey and dialogue is a very important part of the entire project. We hope that the market will provide us with ideas and innovative insights of what an intervention engine as we have loosely described the need and potential for in this document might include in terms of components, features, and capabilities. With such input and increased understanding on our side, we hope to be able to more efficiently define the challenge, scope, and pre-requisites for a PCP.

But our experience also points to the need of trying to inform you, the market, as much as possible. That is why we have written quite extensively on our thoughts and included numerous conceptual images in this document. In the next section we will provide such conceptual ideas, in order to inspire you to utilize your knowledge and experience.

4.3.3 Driving mechanisms and active components for behavioral change.

As stated, we are looking for providing intensive intervention to support behavioral change aligned with what research evidence in the relation between f I life style and care outcome states at the time. Due to the nature of continuous change in what we know about such relationships, and thus what to scan for, plan, and provide in terms of support, it is important that the solution be based on what we know, at each given moment, about the driving mechanisms, the active components, behind behavioral change.

See Appendix: Behavioral change in brief for an introduction to driving mechanisms behind behavior change. It is our hope that market actors will try to translate the below into overall needed features in a solution but also provide own insights and thoughts on the area of behavioral change itself, its relevance and best practices in the domain of IT and technology, and ideas on which type of capabilities would support such driving mechanisms.

4.3.4 Experiences as deducted from successful intervention programs

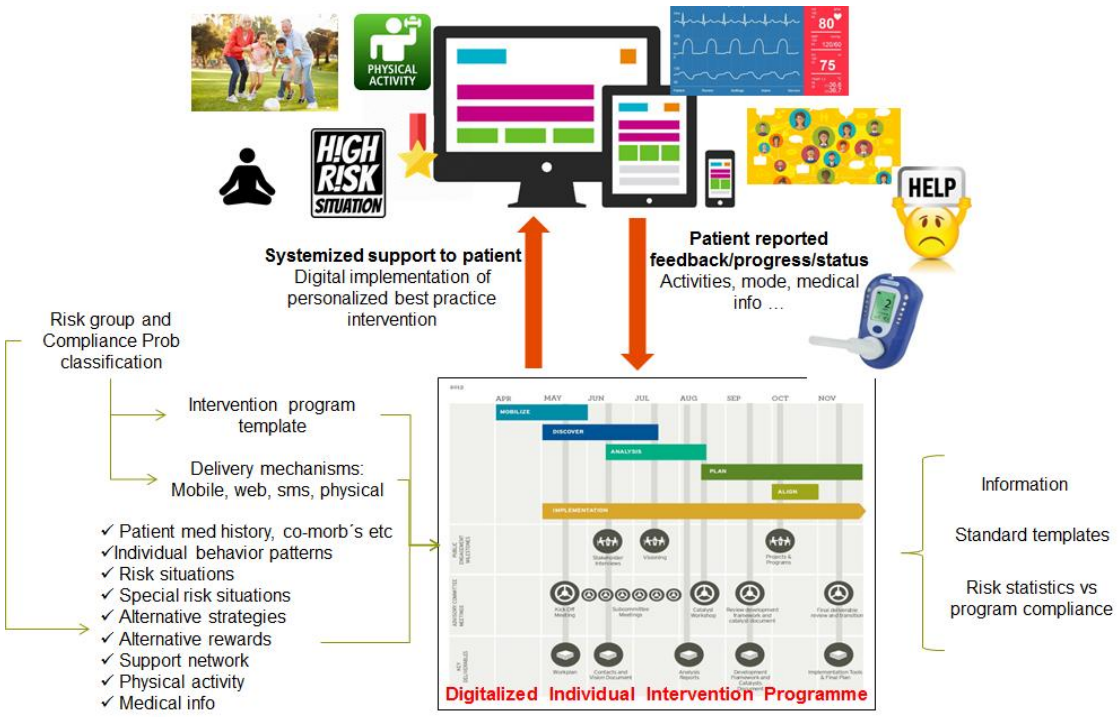
We have mentioned there are some successful intervention programs related to f I smoking cessation. It is of course important to try and learn from those, even though the format and thus likely actual content/methods will be disrupted provided the core IT focus and our Success Components in this project.

One successful such program is the Gold Standard program, as used in Denmark. Exploring the setup, activities, and content used in this program might provide assistance to suppliers in identifying underlying driving mechanism as well as content relevant for the core case in this project. However, bear in mind that the actual format of a meeting intensive program might not be the best approach to address the Success Components as described in this document.

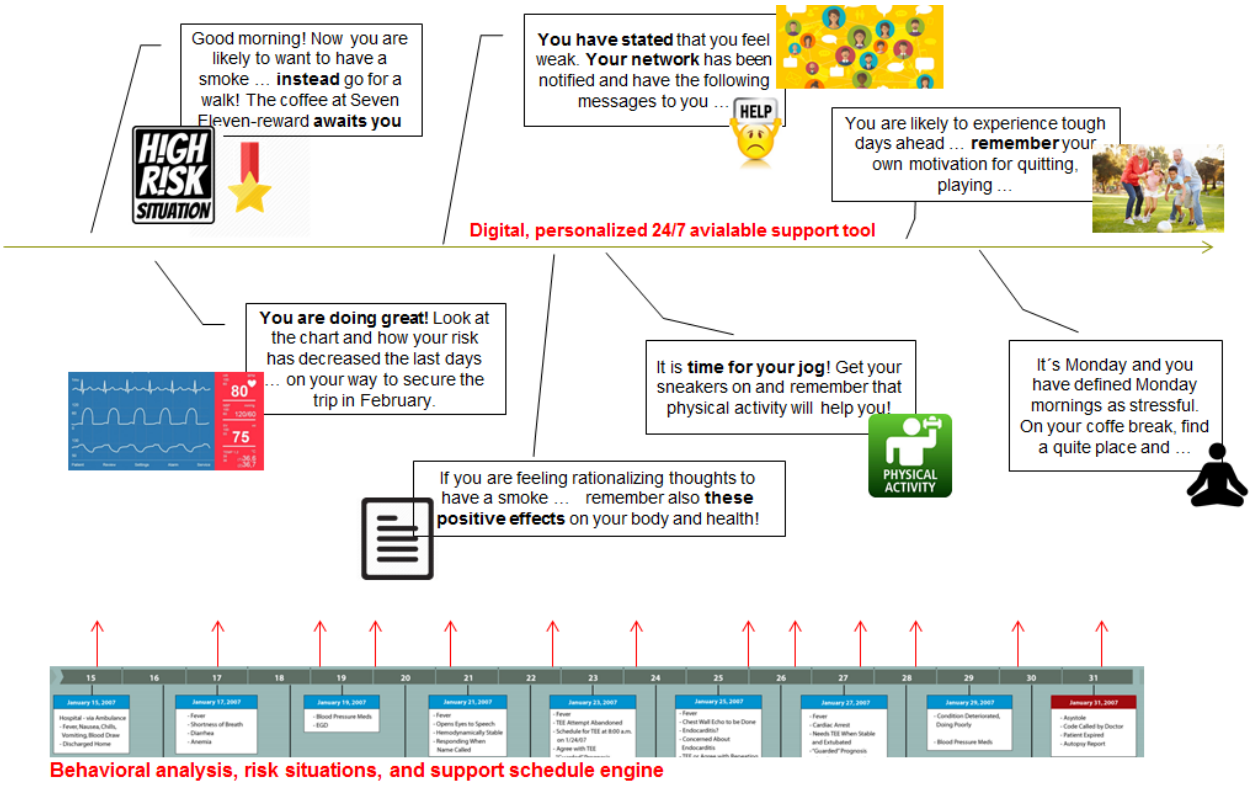
4.3.5 Overall feature ideas

Based on our own preliminary thoughts on what a solution could include, we have stated some ideas about overall features below. We hope to avoid stifling other ideas but feel it important and possibly necessary to at least give the market a hint about what we are thinking about.

The picture below describes an overall conceptual idea about the solutions possible capabilities and approximate scope. **Note though that we will not be expecting responses based on the alignment with the below** but rather wish you see the below as a guide in understanding the type of intervention scenarios and thus capabilities we see as possible. Other approaches to the challenge are equally appreciated.



Picture 4.3.4a: Concept of possible solution, with some sort of intervention engine as a core component.



Picture 4.3.4b: Perhaps, based on input data and self-reported assessments, an individual interactive support guide is created for the specific patient. Preempting risk situations with motivational advice, supplying data updates on how the patient´s own risk scores decrease over time/with the right behavior, and providing alternative strategies might be parts of an automatic, interactive "assistant".

4.3.6 A tool for core case and future care flows and contexts with patient involvement/empowerment

The project scope includes knee and hip elective surgery for patients with risk factors of smoking and alcohol behavior.

However, as stated the project intends to have the market design and develop a solution flexible and scalable enough the enable scaling to other care contexts. Some of these might be as below. It is probable that we will include scenarios for such scaled care contexts in the actual PCP and that suppliers´ will need to describe or possibly even show how such new scenarios and programs would be implemented in the solution.

- Other risk factors (eating habits, snuff, physical status etc)
- Other elective surgery care flows (pancreatic cancer f i)
- Chronic diseases and the long-term self management and –empowerment of them
- Primary care and psychological disorders
- In-hospital ERP program (I e post-surgery before discharge behavior)

4.3.7 Not a black box without moving pieces, please

Technology will change and thus possibilities will arise, f I in how we deliver the intervention and support to the user or accumulate data. A solution should thus be designed and developed with new front-end applications over time in mind, leveraging the data and logic in the core platform/solution or data being perhaps device generated as Internet of Things-trends and e-Health applications and devices evolve.

We will require open interfaces, the use if international standards for syntax and semantics, and a segmented approach to layers and modules making up a solution.

4.4 Evaluation areas for maximum sustainable impact

There are three overall evaluation areas in the project:

1. Functionality & features of the solution
2. Effect of the solution on clinical outcome
    a. Behavioral change: Level of compliance to change behavior according to implemented intervention of the solution
    b. Clinical outcome: The complication rates and statistics for the patients having used the specific solution
3. Sustainability of the solution, evaluated against Success Components

Functionality & features will be evaluated against the capabilities we have defined ourselves as known requirements for a solution but could also include capabilities we have not thought of and the specific supplier introduce in the project. Some capabilities will be mandatory, such as probably that a solution must cover the range from input of patient data/parameters in order to calculate risk group to input of outcome data (f I complications) after the end of the specific patient process and our ability to analyze data as to gain insight into the precision and effect of current risk group classifications, current change programs and patient compliance rates, and how such context has generated which effect.

Effect of the solution on clinical outcome will be evaluated by entering/uploading outcome data (as to be defined by us) and see which solution has lead to which clinical outcome/effect and possibly also statistics on the quality and quantity of use of the solution by the patients/users.

Sustainability of the solution will be evaluated throughout the PCP process by having the supplier document, present, and technically explain how the solution can be adapted/re-configured to meet other scenarios than the core use case.

The scenarios to be defined will together with other *success components* make up the sustainability evaluation aspect of the project.

Being a PCP, the evaluation is not primarily measured against traditional programs and intervention methods but used to compare the different solutions.

5 Success Components

LIVE INCITE has defined a set of Success Components for the solution and they include a focus on long-term capabilities such as the potential to use the same behavioral change framework for many types of intervention programs and care contexts.[9]

The below success components are our preliminary definition of what a solution must be capable of doing beyond what can be understood from studying f I the GSP as well as overall descriptions and thoughts on the *intervention engine* as can be found in this document.

To be clear, a solution which addresses smoking cessation effectively, perhaps incorporating much of the GSP regarding content, will not be sufficient for our ambition. LIVE INCITE shall develop an intervention engine, leveraging a framework of best practice behavioral change knowledge together with continuous best practice in efficient technology, to learn about, define, configure, and deliver to patients in terms of a personal, relevant change and compliance assistance, with which the patient herself can become empowered to change her lifestyle and behavior for greater health outcomes.

Overall, the currently defined **Success Components** of the project include f i:

- Scalability, both technical and business model
- Degree of patient self-management vs organizational resources required
- Total Cost of Ownership, f I maintenance level required, infrastructure requirements, type and implication of devices used, and license costs.

[9] The solution should thus be designed on a higher abstraction level than that for f I the GSP´s content and activities. A smoking risk situation identification exercise/template/activity in the GSP might thus be a generic risk situation component in a solution, possible to configure in terms of what, when, and how for different intervention programs.

Picture 5: LIVE INCITE Success Components per January 2017.

A successful solution must, as examples:

- Be sustainable, I e address the fact that healthcare in general will exist in a state of continuous change, related to internal and external factors, which makes long term capabilities to cope with change very important for success.
- Be developed with the purpose as well as technical and business model flexible and pragmatic capability to be used as a tool to define and implement behavioral change through patient empowerment and IT, I e move beyond the core use case of smoking and elective surgery.
- Be feasible in the eyes of users and take into account different type of patients´ groups as they differ in skill and ability to cope with technology.
- Limit the use of organizational resources, as healthcare is stretched thin in many areas, I e making sure that patient self-management is optimized when the knowledge of care providers are “put into system”.
- Enable the continuous learning in life style interventions, I e ensure that data generated by the solution can be analyzed and new insights are possible to be swiftly and effectively implemented in the solution. This means that data analysis by researchers and the continuous, flexible adaptation of content, ruleworks, and other intervention program specifics based on such insights is a core capability in the solution.
- Take into account the variety of care providers hopefully wanting to use the solution and that infrastructure, IT environments etc will differ. This means that the use of international, open standards for data communication and integration as well as semantic interoperability must be addressed.

5.1 Business and operational agility require flexible architectures and business models

The overall strategic drivers require interoperability and conformity of data as well as an open, flexible architectural design in a solution. We believe that it is of highest strategic value to find a partner (-s) and solution with which we can continuously develop the organization´s capacity to respond to new and future contexts and optimize the support required by the organization to deliver an increasingly safer care. We, as well as any organization utilizing IT as an important tool for operational excellence or organizational development, must have the agility to add new functionality with a flexible solution with which f I new presentation and interactivity interfaces can be added to the solution.

As described in this document, flexibility in and openness of architecture is likely to be an important aspect in our challenge to the market.

6 Appendix: LIVE INCITE Proposal Extract

Note that the below are exact extracts from the proposal, as written early 2016. Since then the consortium has continued to think and collaborate around the evidence and knowledge available and there might be areas below which are not still as valid as when written.

6.1 Introduction

It is well known that health care outcomes in the perioperative care process correlate with severity of disease, operational procedure and co-morbidity. Only recently, it has been proved that also the lifestyle factors of the patient are independent risk factors for a poor outcome after surgery. In the perioperative care, it has been shown that significant reductions in post-surgery complications and rehabilitation can be achieved by introducing individually targeted intensive lifestyle interventions programs. For instance, it has been shown that a 6-8 week smoking-reduction program prior to knee and hip surgeries reduces the risk for complications from >40% to <20% . Similar effects are achieved with the hazardous alcohol drinking case, where a 4 week program reduces the number of complications with 50% after colorectal resection . However, still a very small compliance rate has been noticed, in Europe and outside, where patients take the necessary actions that evidence suggests to improve their health outcome.

Besides smoking and hazardous alcohol drinking other lifestyle factors such as malnutrition, overweight/obesity and low physical activity are relevant risk factors, and if impacted through intensive intervention programs, have a positive effect on health care outcome. As the entire field of perioperative medicine gains more attention, not only with regard to lifestyle factors but overall aiming to optimize the physical and mental state of the patient through the continuum of care, it is evident that methods, tools and practices today are insufficient in several regards. Information transfer and feedback mechanisms between the patient and the care provider are poor and inadequate to stimulate right behaviour in the perioperative situation, both before and after the surgery. Today's solution, both from a supply- and demand side perspective are not good enough to both allow the patient to understand his or her situation and what corrective actions to take, and the care provider to provide individualized recommendations to the patient based on patient's behaviour, information and clinical praxis.

New and innovative eHealth solutions are required to enable impacting and influencing the patient to take necessary actions both prior to and after surgery, as to impact his or her own health care outcome.

This PCP is designed to mainly cover risk factors related to smoking and hazardous alcohol drinking and will also incorporate other patient state optimizing needs. Furthermore, for practical reasons it will cover knee and hip surgeries as the clinical case that will be used to evaluate the innovative solutions. Nonetheless, we see that the innovative solutions will be built on technology that is flexible and scalable enough to introduce other risk factors and cover other surgical treatments. The evaluation of the solutions will account for that and it

will be monitored throughout the PCP. It is ultimately the capability of introducing clinical knowledge (through e.g. algorithms, forecast calculations, etc.) that is critical for the performance of the innovative solutions, regardless of type of risk or surgery.

6.2 Impact

The target problem addressed in our project is, as stated above, is the increased risk for and factual negative effect on complications for patients which smoke, being over-excessive consumers of alcohol, having an unhealthy diet and/or weakened physique due to limited physical exercise undergoing surgery. Research shows a significant increased risk of pre-surgery complications and rehabilitation time for all abovementioned risk factors, as described in section 1.1.

With our project, we want to influence patients which fall into one or several of the risk categories above to change their behaviour and life-style as a proactive measure before an elective surgery as to lower the risk of complications. We believe that the low effect of the current method of general purpose information of the risks can be improved:

- The information being to general, i e there is a lack of individualizing and making the communication centred around and specific for the patient.
- The lack of patient involvement and sense of empowerment and being an active actor in the process, meaning a need for individual patient plans with direct and instant feedback on the risks as the patient follows or divert from the plan. Individuals which set goals and are empowered to and get feedback on progress are more likely to internalize and assume responsibility for such goals.
- The lack of patient support system. A patient having an individual plan for effecting risk of complications where such plan and activities are shared and monitored by family and/or friends are likely to be an important factor for success.

Thus, with the overall goal to improve health quality, in terms of reduced complications during the in-hospital stay as well as rehabilitation period, and following reduction in cost of healthcare, we believe that patient involvement in reducing risk of her own surgery has great potential. Leveraging statistics and analytics to define patient risk groups with suitable individual plans made available to patients alongside capturing activities with modern mHealth devices, providing instant feedback to patient about the effect on risk every and each activity according to plan has, and utilizing modern, intuitive interfaces for patient and relatives/friends to access, input, and monitor her plan and prognosis.

However, the primary focus of the project and PCP will be to leverage the potential of PCP to its fullest, meaning we will activate the market to identify and design total concept solutions it believe can effect to challenge most.

In relation to the impacts sought:

- We will increase the role and the responsibility of the patient and support self-management with our PCP addressing an ICT solution providing the patient with a data- and evidence driven, interactive solution aimed at empowering the patient with insights and feedback on activities improving risk prognosis. The solution – back-end data and front-end use - is entirely focused on involving and empowering the patient in her own surgery process.
- We will reduce the number of severe episodes and complications by involving the patients in reducing the risk related to surgery and increasing the compliance of other recommended actions throughout the perioperative process.
- We will enhance the ICT skills and increase adherence of patients and care givers by leveraging a PCP to create a solution in which the care-givers and patients meet around the patient's individual plan to reduce risk of surgery.
- We will strengthen the evidence base on health outcomes and management of comorbidities as the solution aimed at shall enable a learning loop where outcomes related to the behaviour before a surgery are continuously measured in order to improve the data provided to patients in individual plans.
- We will address the impact to be able to provide early and predictive data about patient disease by using outcome data to inform and influence the patient planned for an elective surgery to start changing her behaviour 8-10 already weeks before the surgery.
- We will reduce the number of unproductive visits to the hospital by continuing to provide information, support, and suggestions relating to life-style during the rehabilitation phase, thus influencing a number of patients to stay on the path of a life-style minimizing risks for after-surgery complications and thereby reducing unproductive visits to the hospital after the surgery.
- We will implement intensive rehabilitation programs at home when appropriate by developing a solution which addresses plan, activities, and patient feedback from the time of surgery being scheduled to the end of the rehabilitation phase, providing patients and care or rehabilitation staff at hospital, primary/home care, or other involved care giver.

6.3 The common challenge

The buyers group challenges the market to develop an eHealth technology platform that enables the individual optimization of patient's physical and mental state in the perioperative care, by enhancing relevant information sharing between patients and care providers while applying clinical evidence to support efficient life style intervention.

The solution should be designed to appropriately address patients' and clinicians' needs of an efficient interaction that ultimately:

1) increases the patient's understanding of its state and what measures the patient can take to impact his or her own health outcome while enhancing transparency and predictability of the care pathway for the patient

2) provides the prerequisites for clinical staff in terms of e.g. coherent information about the patient, analytical support tools and efficient ways to provide feedback to the patient based on his or her behaviour

Furthermore, the solution should have the capabilities of flexibility and scalability to integrate new and updated risk factors and cover other surgical procedures; leverage interactive user interfaces and ease-of-use to stimulate usage; and being interoperable in the sense of leveraging generally accepted industry standards as well as contributing to the development of such.

The suggested common challenges aims to address the unmet need of insufficient intensive lifestyle intervention possibilities to reduce post-operative complications and rehabilitation time. It further aims to enhance the transparency and predictability of the perioperative process where recommended actions for patients in the perioperative process are fed backed based on the patient's self-reported activity. The needs of the buyers group, together with patients' needs that will be represented as a third party in the project, are based on the following discussion about shortcomings in the healthcare today to satisfy those needs.

The perioperative process, initiated by the identification of a surgical need to recovering from surgery, and involving a network of health care actors and providers, is burdened by a set of challenges that prohibits the care providers to optimally provide individualized care while leaving the patients poorly informed, confused and with very little opportunities to impact their treatment outcome and rehabilitation. Incoherent care pathways, lack of modern analytical and interaction tools, non-digitalized information flows and missing data are some of the shortcomings in the healthcare today. As a result, prerequisites are missing for preparing the patient both physically and mentally for the surgery and post-surgery based on the individual profile of the patient. This in turn has a severe impact on treatment outcome and the wellbeing of the patient, where post-surgery complications and prolonged rehabilitation are common outcomes of these shortcomings. At the same time, the increased emphasis on the importance of perioperative medicine suggests that great values can be appropriated. It further suggests that the patient himself has a central role in impacting its own treatment outcomes, by having the necessary information and understanding of his state to take necessary actions along the continuum of care.

Furthermore, care providers are basically left to the hope of patients understanding and acting on the important information, provided as general information, and not asserting their possible influence on patient behaviour by being a constant presence and support in this both surgery outcome related as possibly life altering period. As of today, research shows that most patients do not cope with enforcing the recommended changes in life-style before the surgery and care givers being able to implement a patient-centric solution to leverage data and prognosis aligned with the individual plan and activities alongside a support system including the care giver and patient relatives and/or family throughout the whole care process can have significant effects. Moreover, there is a lack of a holistic overview and follow-up of the patient's behaviour, critical to surgical outcome – on short and long term – across the care flow and care providers. The possibilities to add a patient-centric intersection

for involved actors throughout the care process are great and will be further explored in the proposed PCP.

7 Appendix: Members of the consortium

7.1.1 4.1. Participants (applicants)

7.1.2 4.1.1 Karolinska University Hospital

Sweden	Karolinska University Hospital (Stockholms Läns Landsting)
	KAROLINSKA University Hospital
Healthcare organisation (Public)	www.karolinska.se
Description	**Karolinska University Hospital (K)** is a leading Scandinavian premier health facility and one of Europe's largest hospitals. The hospital has a primary responsibility to deliver highly specialized care and to develop future healthcare in Stockholm County Council but also offers highly specialized care to international patients. The hospital operates in close collaboration with Karolinska Institutet and together they are leaders in medical breakthroughs in Sweden and have produced world-class clinical results within several therapy areas. The hospital's vision is clear – to be recognized worldwide as a premier teaching hospital, leading the way in health science and care. The hospital has about 15 300 employees, 1 700 beds and 1 500 000 patient visits per year where of around 50 000 international patients. At the hospital there are around 2500 employees active within research, 150 professors and 2200 published scientific articles. **Innovationsplatsen (The Innovation Center)** is one of three units under Development and Innovation; the other two are biomedical technology and eHealth & strategic IT. The aim of The Innovation Center is to promote successful collaboration between industry, education and healthcare in the field of medical technology. The overarching goal is to establish a care, intervention and innovation environment that is safe for patients, adds value and is constantly evolving. The Innovation Center has initiated a large number of projects, for example projects focusing on test beds, healthcare at a distance and development of innovation procurement and partnerships. Other current national and EU/international innovation projects include: • eMedic • Integrated multidisciplinary care • eHealth solutions. Karolinska University Hospital is the coordinator of the project and serves as leader for several work packages within this project. Furthermore, K represents the user (the patient), and consequently, has a role in all work packages in the

	project. K has the opportunity through Stockholm County Council, responsible for health care (provider and payer) in the Stockholm region, to have an impact on the whole region's healthcare innovation system. **AnOpIVA and Division of Behavioral Medicine Pain Treatment** The Department of Anaesthesia and Intensive Care Medicine (AnOpIVA-kliniken) at Karolinska University Hospital, Huddinge has Sweden's largest comprehensive anaesthesia-operation service facility with around 20.000 anaesthesias/year and is national and/or regional centre for transplantation surgery, back surgery and cochlea implant surgery. The intensive care unit has the country's highest risk ratio and focuses on severe infections and immunosuppressed patients. The pain clinic has outpatient and in-hospital service and has a focus on spinal cord stimulation. **Legal and Procurement office** The Procurement Division at Karolinska University Hospital signs agreement and implements the purchase at the hospital. The division conducts purchasing and signing of commercial agreements relating to equipment, goods, services and works for Karolinska University Hospital's specific needs. The clients are hospital operations and management, the need for goods and services is the basis for our business. The division collaborates actively with other hospitals in the county and the Stockholm County Council Procurement for coordinated procurement for our common needs. The division has extensive experience of pre commercial procurements and procurement of innovation.

7.1.3 4.1.2 Bispebjerg-Frederiksberg Hospital

Denmark	**Bispebjerg-Frederiksberg Hospital**
	REGION Bispebjerg og Frederiksberg Hospital
Healthcare organisation (Public)	https://www.bispebjerghospital.dk
Description	**Bispebjerg-Frederiksberg Hospital** Bispebjerg-Frederiksberg Hospital (BFH) is a large hospital with 3,000 employees and many different specialties, complex clinical pathways, and diversified groups of patients. It has been undergone successful international accreditation every third year in the decades.

BFH functions as the main hospital for 400,000 citizens from the Municipality of Frederiksberg and the larger part of Copenhagen. It provides special services for a larger catchment area. BFH constitutes the Copenhagen University Hospital together with the other hospitals in the region and the University of Copenhagen (the Faculty of Health Sciences).

BFH has a strong profile in clinical research with 27 research groups, ranging from biomedical research and innovation of new products/treatments over prevention and epidemiology to clinical randomized trials and implementation strategies.
BFH has been leading the majority of the research on smoke-free and alcohol-free surgery to be included in this project.

Department of orthopedics (D-Orth)
D-Orth have integrated research and clinic in a fruitful way. The results from the research group are directly implemented in the daily life – and question from the daily life are often leading to new and innovative research. It is one of the most surgical active departments nation-wide regarding hip-and knee replacement therapy, which is the main operation included in this project. Annually, 6,400 patients are admitted, of which approximately 40% are acute and the rest elective admissions. Moreover, a large ambulatory activity includes about 23,000 out-patient visits per year.

D-Orth has 87 beds in 5 wards and an outpatient clinic as well as a unit of sports medicine, an Institute of sport medicine as well as 8 operation theatres. D-Orth has 3 professors; orthopedics, sports medicine and rheumatology. Also concerning sports medicine the results from athletes at Team Denmark are translated into a program that has been tested among patients and implemented for the benefit of elderly and weak patients.

World Health Organization – Collaborating Center for Evidence-based health promotion in hospitals & health services (WHO-CC).
WHO-CC at BFH was established in 2005, and has been successfully evaluated from the WHO Head Quarter, Geneva. The center integrates research and training, implementation and follow-up for effect aimed at patients, staff and the community as well as the environment.

Clinical Health Promotion is a rather new research field to be developed on the evidence**-based platform. Therefore, WHO**-CC initiates and performs **research;** develop models for implementation**;** and follow-up for effect in many settings. **WHO-CC includes c**linical research that places the p**atient at its center**. WHO-CC create**s** the **top level of evidence (randomiz**ed clinical trials) within Health Promotion related to smoking, alcohol, physical

	activity, diet and nutrition, patient safety and risk reduction among surgical patients, chronic care patients, and patients suffering from mental illness. WHO-CC runs several national and international secretariats, of which the Director is also the CEO/Editor-in-Chief/President. It includes the • International Network of Health Promoting Hospitals with about 800 hospitals from all over the world working on implementation of health promotion • The national clinical database on quit smoking with over 85,000 individual smokers undergoing smoking cessation intervention programs. • Research training for upcoming surgical specialists, PhD-students and other students as well as teaching & training of staff in clinical health promotion • The scientific journal: Clinical Health Promotion as well as the new global scientific society: Clinical Health Promotion Society.

7.1.4 4.1.3 Hospital Clinic de Barcelona

Spain	**Hospital Clinic de Barcelona**
	CLÍNIC BARCELONA Hospital Universitari
Healthcare organisation (Public)	http://www.hospitalclinic.org/
Description	The **Hospital Clínic de Barcelona (HCB**) is a university tertiary hospital located in Barcelona. It is a public institution with a long reputation of excellence in care provision, training and research at national and international level. HCB is a community hospital that employs around 4000 workers (23% doctors, 55% nurses and 22% clerical and other supportive staff). As a Tertiary Hi-tech Hospital, the goals are around consolidating an organisation that stimulates knowledge and its translation to mainstream services, together with an adequate innovation in technology that ensures the development of the most advanced work practices. The priority is set in innovation on new models of organising care provision. HCB has pursued the creation of an integrated care model of service integration aiming at maximising cooperation among professionals, levels of care and institutions. The hospital has a long-standing tradition of research, and is recognised as a institution of reference, both domestically and internationally. A significant part of the hospital's research activities are coordinated by the Institut

	d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS). The research projects are managed and administrated by the Fundació Clínic per a la Recerca Biomèdica (FCRB). The Hospital Clínic also conducts teaching activities at the undergraduate and graduate levels, including the training of medical interns and the continuing professional development of personnel. The hospital is associated with the School of Medicine of the University of Barcelona. Department of Orthopaedic Surgery treat patients who suffer from pain and functional disorders of the musculoskeletal system. Their lines of activity are hip and knee replacement and foot and ankle diseases. This department is the service of reference for a population of 450.000 people. It has teacher accreditation to train medical specialists in orthopaedic surgery, nurses in training and undergraduate students. Their staff is involved in many research activities and they produce different papers in journals of their specialty. Department of Preventive Medicine and Epidemiology has a teacher accreditation to train physicians and nurses in training and undergraduate students. Their lines of activity are health promotion, vaccination, breast, lung and colon cancer screening, nosocomial infection and others. Their staff is involved in many research activities and they produce different papers to national and international journals.

7.1.5 4.1.4 Karolinska Institutet

Sweden	**Karolinska Institutet**
	Karolinska Institutet
Academia	http://www.ki.se/
Description	**Karolinska Institutet (KI)**, founded in 1810, is Sweden's only university especially focusing on biomedical sciences. In addition, KI annually awards the Nobel Prize in Physiology or Medicine. KI ranks as one of the world's leading medical universities, thanks in part to the quality of its research activities, which today account for 40% of all medical research in Sweden. KI has about 4 200 employees (full-time equivalents), nearly two-thirds of whom are female. Some 80% of KI's income is devoted to research, distributed among some 600 research groups covering all medical fields. KI provides excellent postgraduate training with 2 100 registered PhD students from around

	the world who are active in both basic and clinical research. Research at KI has a strong European dimension, with almost 200 project participations within the EU's now closed Sixth Framework Programme (FP6). Of these, KI coordinated 28 projects. KI is a major player in FP7, participating in some 323 projects including 36 as coordinator as well as 31 European Research Council Grants. KI is also a major European beneficiary of funds from the National Institutes of Health in the U.S.

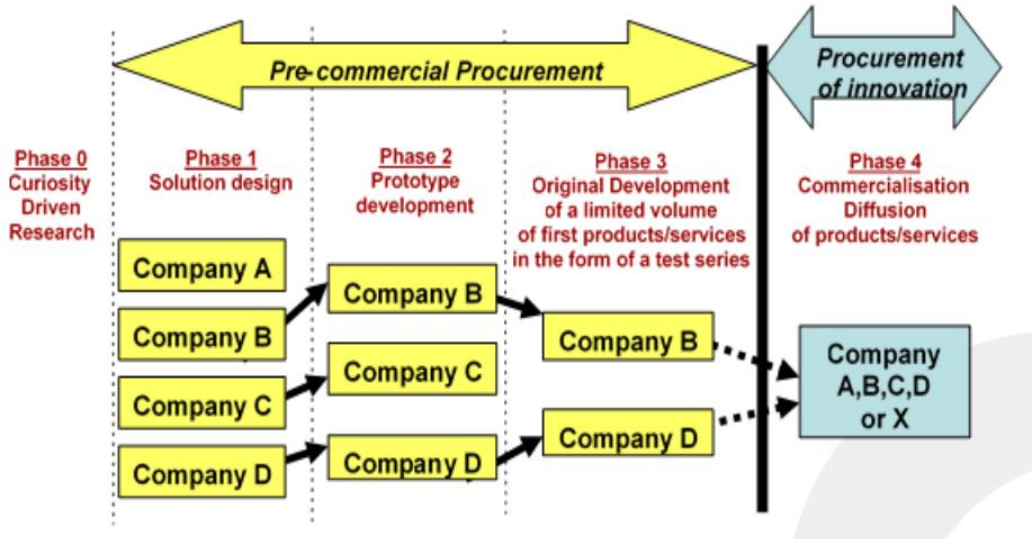
8 Appendix: PCP in brief

Pre-Commercial Procurement (hereafter PCP) essentially refers to the purchase of research and development (R&D) services by the public sector. It is triggered by procurers identifying the need to solve a problem or challenge for which there is no solution available on the market yet. Accordingly, PCP is not concerned with the procurement of existing products or services on the market but with the R&D phase, which involves solution exploration and design, prototyping, up to the original development of a limited volume of first products or services. However, existing products and services could in a PCP be combined and/or adapted as part of a new, innovative solution, thus not excluding the use of existing components to address a PCP challenge.

The PCP instrument enables the commissioning of R&D services, under a staged competitive process, to allow the development of innovative solutions that meet the needs of the PCP procurer. This approach is based on:

1. Risk-benefit sharing according to market conditions;
2. Competitive development in phases;
3. Separation of the R&D phase from deployment of commercial volumes of end-products.

A PCP is usually designed to cover three phases according to the below picture. After the PCP, such contracts and project is finalized and the procurer will decide whether to analyze its insights and learning and enter into a public procurement process. In such possible procurement process following a PCP, any supplier (see X in picture below) may submit proposals; for the avoidance of doubt, also suppliers not having been chosen for the PCP can submit proposals in the public procurement.



Picture 8: Conceptual overview of a PCP process.

9 Appendix: Behavioral change in brief

9.1 Driving Mechanisms & Key Components for behavioral change

9.2 Behavior analysis

In LIVE INCITE, the objective is to empower patients to make necessary behavior change prior to surgery.

Successful behavior change requires an understanding of the problem, i.e. the relation between the dysfunctional behavior and the context in which it occurs. To motivate change in the presence of e.g. pain and distress, it is important that the long term negative effects (DE) of maintaining the dysfunctional behavior is clear to the patient.

A behavior analysis is therefore essential to clarify the specific problem, and constitutes a necessary framework for an individually designed program for behavior change.

For example for a smoker, there might be specific times during the day when he/she is more likely to smoke OR he/she is more likely to smoke in the presence of certain thoughts and feelings (e.g. stress, negative emotions) OR both. If the behavior thus can be related to habits, feelings and daily schedules they can also be turned into a tool for automated support and generated motivational activity suggestions.

"Good morning, Susan! Here is your new risk statistic for complications. As you are on your way to a significant reduction in risk, and thus your value target of xxxx. About this time you feel like having a cigarette. Please bear in mind that … take a good look at the picture of your grandson on the football pitch and remember why you do this. Now, please lay down for your morning visualization. The app will buzz three minutes after you have clicked Start Visualization."

9.3 The need for precision and relevance

Effective and sustained changes in lifestyle and daily habits commonly require more than general instructions, e.g. "eat healthier" or "stop smoking". If the reason for behavior change is clear, and the plan is made (very) concrete, this significantly increases the likelihood of a favorable outcome. Particularly, this accounts for self-help programs with no, or limited, therapist support.

The behavior analysis is, thus, conducted to collect relevant information regarding the individual and the context, in order to present in a clear and individualized way what needs to be done, why and how.

9.4 Compliance

Research shows that positive outcome in behavior change programs are directly related to treatment compliance/adherence. This implies that the patient must be able to alter and

maintain behaviors over time, in the presence of e.g. distress or other challenging circumstances,

It is therefore of importance that the healthcare provider can provide an easily administered tool to facilitate self-management and commitment to the program, also in situations without a high level of social support.

9.5 Motivation and feedback

Motivational factors will increase engagement, commitment to the treatment goals as well as compliance/adherence to the program. Continuous feedback, e.g. continuous reports on the performance in the program may be highly motivating and have a significant influence on behaviors and improve outcome.

This could be accomplished by e.g. a feedback system, in which the patient is being provided with a prognostic result based on the past and current performance.

9.6 Identifying values and goals

Emotional engagement is critical for behavior change to occur. Identifying relevant life values and long-term goals increases the ability to tolerate negative reactions that are likely to occur during the behavior change program. More specifically, assisting the individual in making associations between the target behavior and the long-term consequences is important. Even if the immediate reaction is negative, a strong association with a future positive outcome may be enough to pursue the new lifestyle.

9.7 Comorbidities may need to be addressed

Treatment effects always vary across individuals. One factor that may influence the effects is comorbidity, since such symptoms may negatively influence the ability to e.g. engage in the behavioral change program. For instance, a patient planned for elective surgery undergoing a smoking cessation program might, in addition to the somatic condition, present with a sleeping disorder that decreases the ability to withstand impulses to smoke. It is therefore of importance that the healthcare provider is made aware of, and has the ability to adequately address, also parallel and related behavioral problems.

9.8 Tailored support based on individual needs

For some individuals, general information about the risk for surgical complications is sufficient to trigger life style changes. However, for others, such information will, in itself, not be enough and behavior change requires additional, and more specific, interventions, such as detailed and personalized feedback about own risks and performance, education, or

skills training (e.g. how to cope with distress), modeling or other forms of enablement and support.

Furthermore, individual factors such as somatic or psychological comorbidities may need to be specifically addressed to achieve positive effects.

Thus, analogue to identifying individual risk factors for surgical complications, it is important to also assess risk factors for compliance in a behavior change program. Also, it is similarly of critical importance that such factors can be addressed within a comprehensive behavioral change program.

9.9 Assess, address and monitor possible adverse events

Psychological interventions, including behavior change programs, may trigger negative thoughts and emotions. For some individuals, such negative reactions may be overwhelming and trigger dysfunctional or even destructive behaviors. It is therefore of importance to continuously monitor not just the outcome measures but also possible negative reactions to the program, i.e. adverse events. This provides an opportunity to intervene if necessary, and accounts for e-health programs both with and without therapist support.