



THE CHALLENGE

Pre-publication, draft version

by the LIVE INCITE team

This document is not a formal part of the LIVE INCITE Request for Tender and PCP. It may thus be used for better understanding of the background to and needs of LIVE INCITE but no content in this document will be part of the evaluation and/or assessment process of LIVE INCITE, unless stated in the coming Request for Tenders.

LIVE INCITE is a Horizon 2020 project*, including Stockholm County Council/Karolinska University Hospital, Bispebjerg-Fredriksberg Hospital, Copenhagen, Clinic Hospital, Barcelona, and Karolinska Institutet, Stockholm

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This document has been produced with the purpose of enabling market stakeholders interested in the coming LIVE INCITE pre-commercial procurement (PCP) to prepare for such upcoming procurement process.

The LIVE INCITE project is completing the Request for Tender documents, but due to unforeseen events we are not able to provide an updated date for publishing of the Request for Tenders. The publishing date will be communicated on the web site ASAP.

We do however have a great understanding for the interest of information from market stakeholders and the wish to be able to prepare possible tender proposal work. Therefore, we have decided to publish background information documents on our website regarding the challenge of LIVE INCITE. We hope that this information may provide interested stakeholders with an opportunity to prepare for the Request for Tenders.

Note that the content of this document is not part of any procurement process and only the content of the later published Request for Tender shall be considered for the procurement.

1. Introduction to the challenge

The long-term subject and scope of this PCP is to improve the clinical outcomes of planned surgeries by reducing identified risk factors for complications such as smoking, alcohol, and obesity through intensive, digital intervention programs supporting patients to change desired behavior.

For the coming PCP, the scope is to develop and pilot a digital solution, focusing on the **core case** supporting the *complete* quitting of smoking and risky drinking, evaluating how successful the solution is to enable this desired behavior change *and* the potential of the solution to support the long-term subject and scope of the coming PCP.

It is our belief that market stakeholders will be innovative and provide different concepts to address the challenge.

2. The challenge

This procurement is for **R&D services** to address the following **challenge**:

The overall goal of LIVE INCITE is to improve health outcome of smokers and risky drinkers by reducing postoperative complications through lifestyle interventions with digital services.

LIVE INCITE thus challenges the market to develop a digital solution for behavior change that:

1. Supports patients to quit smoking and risky drinking before and after surgery
2. Can be applied beyond the core case

The challenge is further specified in the core case and the coming evaluation framework, to be provided with the Request for Tenders.

The unhealthy lifestyles

Overall, unhealthy lifestyles are rather newly identified as important risk factors in surgery.

Especially, daily smoking and risky alcohol drinking add independently to the classic risk factors for development of complications; therefore, they constitute the core case.

Also obesity/overweight, malnutrition and physical inactivity seem to play a relevant role in relation to surgical outcome. Overall, there are many risk factors, which influence the postoperative outcomes. They can be categorized into:

- the specific diagnosis requiring operation
- the surgical and anaesthesiological procedures/techniques and other perioperative care
- the organisation; e.g. evidence-based guidelines, training of staff, quality registries for follow-up
- the health quality of the individual patient
 - co-morbidity, like severe diabetes, and heart, lung, kidney and liver diseases as well as daily functionality and other conditions prior to the operation
 - life styles, such as **daily smoking, risky drinking** (above 2 drinks per day = 24 g ethanol), obesity/overweight, malnutrition and physical inactivity.

Understanding the challenge

LIVE INCITE has the potential to impact many patients with risk factors influencing the clinical outcome. But the risk factors are many and the combinations between them often complex. Further, the identification of risk factors and intensive intervention program are updated over time. Therefore, creating sustainable value relating to a relevant risk factor *and* be able to harness the potential of impacting risk factor behavior in elective surgery is one and the same. Hence, a solution must be developed with the clear intention to be used for multiple and complex types of risk factors and care contexts, being able to adapt to new evidence and knowledge.

A solution which provides a static approach to for instance smoking cessation will not be sustainably successful. A solution which is developed with the insight that it *will* need to adapt to new insights will not only be sustainably successful, adapted with new evidence and best practices for the intervention, for smoking cessation but also possible to scale to other risk factors.

The challenge, and to be accompanied evaluation framework, has therefore been designed as to clearly state this need and intention.

It is however important to define a clear case for the PCP, hence the core use case of daily smoking and risky drinking.

Supporting continuous improvement and increased value

The challenge and solution addressed respectively sought by LIVE INCITE 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. Effect in par with best evidence based practice face to face intensive intervention programs like the Gold Standard program is not necessarily required, even though the project hopes to be able to achieve such over time. Enabling a digital intervention becoming efficient on a comparable basis over time is the reason for evaluating whether a solution enables a continuous improvement.

The importance of a behavior change foundation

The innovative solutions shall be built on technology that is flexible and scalable enough to introduce other risk factors and cover other surgical treatments. One reason for and 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 is both possible and potentially very important. Defining and developing a sustainable and generically applicable intervention engine based on generic behavior change supporting components that will be part of the challenge and included in the evaluation framework in the coming PCP.

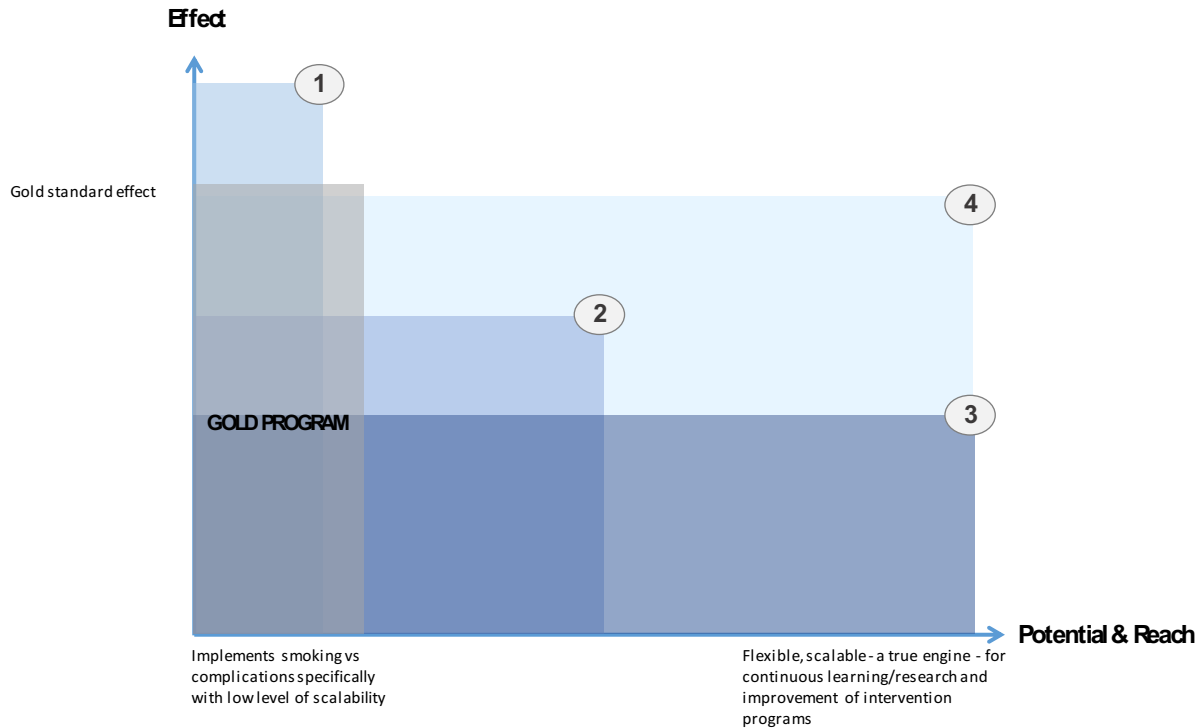
The solution could thus be described as a behavior change tool, configured to include different intervention programs for supporting behavioral change, compliance, and effect in different care contexts and relating to different behaviors in need of change or compliance.

Note that we want all market stakeholders to understand that the LIVE INCITE project strongly believe that a solution should be based on a solid behavior change theory. A market stakeholder having a solution based only partly on behavior change theory should explore expanding such thinking and solution scope.

The below introduction to behavior change represents a framework described by the LIVE INCITE team. For information about behavior change theory we would like market stakeholders to consider when proposing the solution. For more background information see the LIVE INCITE web site (<http://www.karolinska.se/en/int/live-incite>).

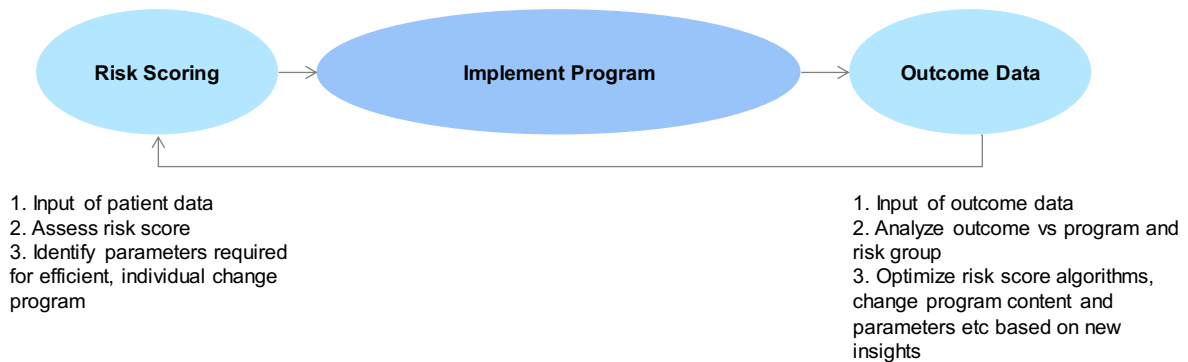
Success by means of Effect times Reach

A successful LIVE INCITE solution leverages the potential for reaching many more individuals than face to face intensive intervention programs. The below picture provides a conceptual description of how effect and reach combine for success.



Picture: Current best practice program (Gold Standard) vs sought concepts/solutions compliance rate and potential/reach.

Conceptual scope of the solution



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

The picture above depicts the overall end-to-end process of the solution, including the crucial continuous learning and adapting feedback and improvement loop we need.

1. We know we need to have system, staff, and possibly¹ patient generated input of data as to be able to asses a risk score, a compliance rate probability, individual aspects related to

¹ If the specific solution includes the patient engaging in self-assessment or other means of providing input prior to the actual start of the intervention.

motivation to change, and thus also be able to choose and configure the right change program².

2. We also know we do this to achieve an improvement of outcomes, in the core use case surgical 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 act upon the new insights in 3, in other words be able to efficiently change parameters in accordance with increased evidence and knowledge.³

The middle part in the picture above – the solutions functionality and features to support and empower the patient to understand and comply to the change program – will be loosely defined by us, aiming at market stakeholder concepts to address it in novel and innovative ways.

Sustainability through flexible architecture and the use of open standards

To facilitate understanding of the importance of a solution enabling implementation in a wide scope, being able to interact with and be an interoperable part of the ecosystem in care providers' overall IT-landscapes, and facilitate the sustainable and flexible evolution for a care provider aligned with new internal and external trends, we have provided some thoughts on architectural issues as well as planning to turn some of those into evaluation items in the evaluation of Solution Quality.

The purpose of the below information is not to define exactly how a LIVE INCITE solution should be designed or developed but to explain the technical and semantic challenges which the success of LIVE INCITE is partly dependent on. The importance of architectural and semantic quality is represented in the evaluation framework.

Capability to learn and adapt

An important principle is the ability to learn and adapt the solution based on results and from new research. Knowledge gained should be used to modify and adapt the incitements process so that the solution becomes increasingly efficient. To accomplish this, it is important that changes to the incitement process can be made by the staff through administration/configuration without requiring access to specialized it-staff or long release cycles.

Capability to handle different risk factors

While it is envisioned that a pilot or test application would focus on a limited set of risk factors like smoking or drinking habits it is important that the solution core structure and information model is based on a generic risk factor so that additional factors can be added as needed. The intention is that a solution can be used in different contexts (like different medical areas or geographical region) where different risk factors might be of interest and new ones might be added or removed over time. Adding and removing risk factors should as far as possible be done by administrators through

² 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.

³ Observe that the optimization based on new insights increases values but makes sense only if the outcome data are validated – as positive over-estimations are well known regarding lifestyles. Results based on poor memory introduce severe bias and may even harm the patients and jeopardize the legitimacy of the IT-solution.

administration or simple configuration so that it is not necessary to involve specialized it-staff or deploy a new software release.

Architectural flexibility

The ability to do add or change the application or logic to meet new major requirements. The ability to make changes and develop new major functionality due to changing requirements or new technology. This covers change that require modification of the underlying application infrastructure or code. Having an application architecture that allows changes to specific modules or layers without affecting the other parts, modules or layers of the application makes changing or adding functionality to the application easier. Adopting open standards is a key evaluation criteria to enable flexible development and interoperability with other systems. This is also important so that different vendors can cooperate by developing different parts of the solution thereby creating a small ecosystem as oppose to having a monolith that depends on one single vendor for all development.

Data export and semantic interoperability

The ability to easily, cost-efficiently, and autonomously export data from the solution to other systems/solutions. It is important that the solution does not result in a data island so facilitating different types of data exports and integrations to and from other systems is vital. While it will not be part of the scope of the PCP it is important that a solution caters architecturally for future possible integrations with for example different EHR systems, BI systems or other systems that are part of the care gives IT-infrastructure. Using well known and open standards for the interfaces is only part of the solution, a bigger challenge is accomplishing semantic interoperability and for that purpose it is important to leverage different health interoperability and semantic standards as far as possible.

This area is important and the future solution presented is expected to show the extent of and quality in exposure of data by using open API's and international, open standards for semantics is evaluated.

End-user application flexibility

The ability to vendor-independently develop new applications based on the data and logic of the platform. As the number of clients and ways for users to interact with a solution continuously grows and changes it is important that there is a separation between the business logic and the user interface so that it is possible to add new clients without having to change the core solution.

We are interested in the use of separation between computational layer and front-end applications by an open, accessible API enabling the development of new applications leveraging the solution platform is one aspect of evaluation.

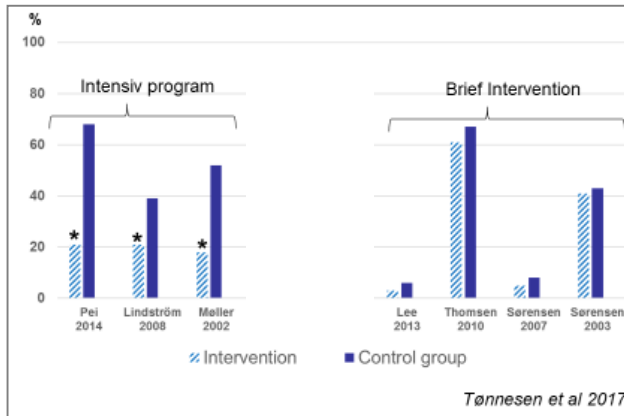
3. Core case description

The core case in LIVE INCITE constitutes digital intervention aiming at reducing postoperative complications by successful quitting daily smoking and risky alcohol drinking for at least 4 weeks prior to planned knee and hip surgery.

Background and impact

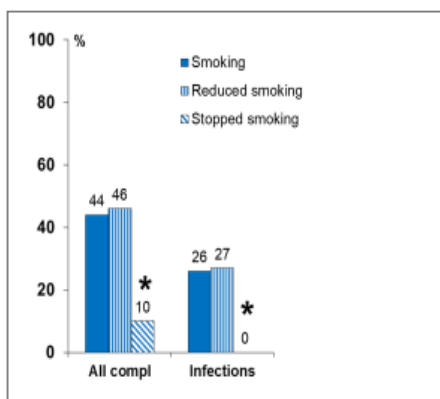
It is well known that life style factors such as smoking and risky alcohol consumption negatively influence health. Also, many studies have shown that they increase the risk for complications after surgery with at least 50% (*Tonnesen H et al 2017*).

Furthermore, high level evidence has been gathered that intensive interventions significantly reduce the development of postoperative complications to about half the level (see the figure below). The reason for their great effect is the 50-60% successful quitting of smoking and risky alcohol drinking at least 4 weeks prior to surgery.



The effective methods are intensive, including at least 4 weekly face-to-face meetings, a patient education program and pharmaceutical support. The less intensive methods (brief interventions, including MI-motivational interviewing) are followed by much lower quit rates and do not impact the development of complications (Tonnesen 2017; Thomsen Cochrane 2014; Egholm Cochrane 2017).

World-wide, lower complications are beneficial for the individual patient as well as for the society at large, as complications are very costly; in average, a complication costs as much as 11,000\$ (www.acs.com).



Interestingly, there is no effect of reducing smoking or alcohol intake, as only complete quitting reduces the development of complications after surgery (see the figure to the left on the lack of effect on complications from smoking reduction) (Møller Lancet 2002).

The core case is focused on the evidence-based clinical results by quitting smoking or risky alcohol drinking that can be measured among patients undergoing planned hip and knee replacement surgery.

The purpose of the LIVE INCITE core case is to facilitate the development of a digital solution to empower patients to completely quitting risk behaviors prior to surgery. The solution should

- allow for individualized interventions and analyses
- follow evidence-based methods for behavior change
- leverage the potential of technology and digital formats to maximize the reach of the interventions.

Desired behavior change for core use case

The purpose of the solution to support behavior change must be viewed in relation to the *desired* behavior change. In the core case, the desired behavior change means *complete* quitting of smoking and risky drinking but for another risk factor, such as for instance obesity, the desired behavior change might not be as absolute.

4. Sustainable success

The challenge will need to be addressed in several ways to achieve success. The LIVE INCITE project has defined four **success components** for a solution, addressing short as well as long-term aspects:

- **Effect** - That the solution leads to and enables the desired outcomes
 - **Capability** - That the solution includes some fundamental functionalities which we have identified as crucial
 - **Feasibility** - That the solution is practically feasible to implement
 - **Sustainability** - That the solution provides the ability to evolve over time
- The solution shall optimize the actual, targeted behavior change defined/configured, in other words have as high behavior change rate as possible, defined by our **Effect Component**.
 - The solution shall as a minimum have a certain set of core capabilities/abilities including functionality with which the interventions can be initiated, executed, and learned from. These overall capabilities are defined by our **Capability Components**.
 - The solution shall be developed considering the many aspects which might prevent an efficient implementation and successful use/value considering all type of stakeholders (patients, clinicians and decision makers), as defined by the **Feasibility Components**.
 - The solution shall be developed with the understanding of the need for continuous optimization and scalability, in other words long-term value and success, as defined by the **Sustainability Components**.