LIVE INCITE
EMPOWERING PATIENTS. IMPROVING CARE.

Live Incite Q&A no 4, August 2018. Solution Design Phase.

No	Question	Answer
1	In relation to behavior change, do you have any advice on how the collected data can be used to optimize individualized interventions?	Although we assume that individualized interventions will provide better outcomes than standardized (i.e. "one size fits all") treatments, this is ultimately an empirical question. Also, it is difficult to know how the treatment should be tailored to adequately meet specific needs, and thereby have an incremental utility (over the standardized intervention). Thus, assumptions regarding the importance of individualizations should be treated with caution. However, it may be that process targets such as treatment compliance may benefit from a solution that is able to adjust the form and format to meet personal preferences. Again, this is an empirical question that should be addressed as part of the development process. Also, in successful treatments it is possible that the (general) outcome is achieved through different change processes (mediators) for different individuals, or subgroups of individuals (i.e. moderated mediation). A digital, and flexible, treatment format may be ideal to collect data as well as to design micro studies to evaluate the relevance and effects of specific treatment components for different subgroups of patients. Ideally, clarify what type of data that is critical for such analyses, how the solution will collect that data, and how the data will be used (analyzed) and interpreted (i.e. understood in relationship to the theoretical framework) to increase the understanding of a) the utility of specific treatment components, and b) the variability of effects across different subgroups of patients.
2	Could you elaborate on the importance of contextual data?	From a contextual point of view, a behavior is inseparable from its current and historical context, and is defined as the actions by which an organism adjusts to its environment. Thus, understanding a behavior requires an analysis that takes the context in which it occurs into consideration. Therefore, contextual data should be collected, to maximize the solution's ability to understand and change behaviors.

3	How will the possible post-PCP procurement process work?	The process post PCP will most likely differ between countries and regions, an individual decision in each procuring body, and it is too early to determine at this stage. In Sweden for example, the Swedish Public Procurement Law (LOU 2016:1145) is the base for all public procurements. We intend to pursue a possible post-PCP procurement with Stockholm County Council (SLL) as procurement body together with Karolinska University Hospital. If other hospitals in the region will join or not will be decided later. What type and exact timing of a public procurement following this PCP is yet to be determined, but it is likely to be in an open public procurement procedure.
4	Should our solution include medical exclusion critera for using the intervention?	We are looking for a solution that **enables the HCP** to make the relevant medical decisions. We envision a system with flexibility to support different clinical/hospital contexts.
5	From a clinical point of view, should the solution have an ability to be combined with other medical interventions?	For the aspect of sustainability it could be relevant for the solution to have the infrastructure to work as a stand alone as well as in combination with other interventions.
6	What are the benefits of only using a clear theoretical framework as basis for the behavior change programme?	A clear theoretical framework facilitates the use of coherent and consistent behavior change techniques. This clarity allows for meningful organisation and analyses of the collected data. Notably, using a clear theoretical framework allows you to use a wide range of techniques that can be described, evaluated and communicated using a common terminology.
7	Can we assume that behavior change techniques that are empirically supported in a face-to-face format are also effective as digital interventions?	The core principles for behavior change are the same in both face-to-face and digital interventions. Given the novelty of digital interventions it is important to continuously evaluate their effectiveness.
8	When creating the user profiles, could contextual data be combined with data from personality tests?	Any type of data is potentially important, therefore the solution should be able to collect different types of data. However, the utility of the data depends on the solution's ability to organize, analyse and interpret it .

9	Is the solution required/expected to follow a certain semantic standard?	No, the Contractor is expected to explore and address their solution of semantic interoperability and present a strategy within the **area of sustainable consumption, storage and exposure of data**. This could mean looking into standards such as HLR7, including FHIR, and SNOMED CT which are briefly introduced in the Request for Tender Appendix 3, but finding and deciding upon other open, international standards could be equally good.
10	Is there a semantic standard at for example Karolinska hospital that could be used as a guideline for what standard to use in the solution?	No, there is no one semantic standard used all over the hospital. Different systems use different standards or even custom or proprietary methods/terms. SNOMED CT is probably the most used semantic standard at Karolinska and in Sweden.
11	Can we use cloud based data storage or do we need to offer on premises solutions?	At this point in time, there are local regulations that limit the use of cloud based data storage of patient data. In the future, this is likely to change, however the timeframe is uncertain, it may be years after the end of this PCP. It is therefore advisable to be able to provide the solution both with on-premises storage even if you are planning use a cloud as you preferred option. During the PCP however, cloud will serve the pilot well, as we are executing the pilot with active consent.
12	Could you define what you expect in terms of integration during the PCP?	During the PCP Contractors are not expected nor required to integrate solution into EHR/EMR. What is expected are your thoughts and strategy on how to integrate after the PCP in the finalized product, defining which data will be possible for integration and how such integration is prepared, considering use of standards/api´s. Please note that no integrations will be done for the Pilot in Phase 3.
13	What are some key points of interest to include in the presentation of IT architecture?	Two key points within the IT architecture for the aspects of scalability and sustainability are strategies for integration, semantically and technically, and identification of how the solution is affected by changes such as adding a risk factor. Note that when we are talking about scalability, we primarily mean scaling the solution to new care contexts and/or risk factors, not mainly quantitative scaling to more users.
14	Can we assume that FHIR is used in hospitals within a mid-term timeframe?	We cannot guarantee the use of a specific standard and no standard can be assumed to be used at all hospitals/health care providers at this point in time or in the foreseeable future. What can however be stated is that FHIR is a popular standard gaining traction. Examples of the interest and momentum for FHIR are ongoing important IT related projects within SLL, which have required of vendors to adopt FHIR. Further, several large EMR vendors have increasingly over the last years adopted FHIR as a standard for exposing such patient journal data

15	Could you provide us with data on the rate of complications after surgery due to alcohol and tobacco use?	The complication rates are increased with at least 50% for each of the risk factors (risky alcohol intake and daily smoking)
16	With regard to alcohol consumption should the objective be to aim for complete cessation of is there a "non-risk" consumption level that could be good enough?	There is no non-risk consumption level to aim at, if the patient has a risky alcohol intake and thereby an increased risk at surgery! There is no information from ongoing studies about new evidence regarding this. On the contrary, the idea of non-risk consumption is evening out, in general.
17	Could you provide information on the frequency of follow-up and collection of biomarkers by the HCP?	We cannot provide any general information that could be used as a guideline as this varies between hospitals/practices. The solution should be useful for different users in different clinics and countries. Also, clinical routines may vary over time. Thus, we suggest the solution to be developed with flexibility regarding e.g. medical considerations and what types of data to collect, including when and how.
18	Is the classification of complications expected to follow a specific standard?	There is information in the RfT Annex 2 that provides guidance and a standard way to classify complications in general as well as in relation to the core case. We do expect a Contractor to follow and enable the use of standards also in regards to compliication data.
19	Do you as a HCP want to add and/or adapt the content of the soltion?	This cannot be answered on general terms as all HCPs will differ in competences and resources for this purpouse. What is however clear is that we want to know what will be possible to do with and without the involvement of the supplier. It is very probable that addition or adaptation of content will be of interest for the hospitals in the buyers group as we have competence in behaviour change. From a research perspective it is of interest to be able to add and remove components of the intervention to analyse the importance of each component. The evaluation item Modifications is one item where we have intended to clearly signal that we see it as a success factor to be able to independetly (of the Contractor) make modifications to the solution in terms of content and configurations.
20	With patients that are both smoking and have risky drinking habits, should we aim for cessation of both or could we let them choose to focus on one?	From a clinical point of view the choice should in this case always be to quit both. In the surgical context, which is the core case, complete cessation of both of these risk factors is the only relvant aim.

21	What interest can we assume that the HCP will have in following the process of the patient, at what level of detail should information on degree of success be shared during and at the end of the intervention?	This depends on the clinical context, for examplein Sweden, there are counties that do not perform knee/hip replacement surgery if a patient has not quit smoking and risky drinking before surgery and there are reasons to believe that this will become more common. Successful outcome of the intervention could therefore be a pre-requisite to even be put on a waiting list for surgery. This being said the main point of most clinicians can be expected to be of the patient has stoped the risky behaviour or not. There may be some roles that are interested in the patients progress at a more detailed level. So, what is most likely is that this will vary and therefore preferably be adaptable.
22	What limitations are there to the means of communication between the HCP and the patient?	This is defined by local regulations but limitations do exist. For example, in Sweden, you cannot use email to reach your HCP, you use a special portal with two-factor login instead.
23	Do the patients themselves provide any data to the EMR system today, or is it all put in by clinicians?	This depends on the health care system but it is common for example in Denmark and Sweden, that patients fill in a health report before going into surgery planning. This can sometimes be done online and the report is filed into the EMR system. However, a Contractor shall not assume that such information will be accessible as system readable data.
24	Will the LIVE INCITE tool have to allow clinicians to enter complications? As we understand that clinicians will also enter complications via the EMR / EHR during consultation, therefore, will the clinicians have to enter this information twice / in 2 different systems?	The description and determination of and the functionality of your solution is yours to make, however, we do see that clinicians need to be able to enter/tag complication data to a patient in the solution. Yes there might be double entry of complication data, the reason for this is two-fold: a) for the pilot, as we will make no integrations during the pilot, and b) to secure that complications can be correctly tagged in the cases where a procurers EMR does not allow storing or exporting of complications in the manner needed. Please see the Evaluation item definitions for further details. Please also see related Q12 in the Q&A log.
25	When you say you want clinicians to be able to modify the intervention, do you mean modify the intervention on a case by case basis (per patient), or modify for a group of patients (all or subgroup), or both?	We have addressed this issue in the Request for tenders, referring to the need for procurer autonomous improvement of interventions, and the description and determination of and the functionality of your solution is yours to make for instance at group/template and/or patient level. Please see the Evaluation item definitions for further details

26	Which level of clinician involvement is acceptable in order to drive the best results?	There is not general answer to that. It will be up to the different HCP to determine. E.g a balance between feasibility of clinical involvement, patient empowerment and adherence will be of relevance. Please see the Evaluation item definitions for further details.
27	In the tender document you would like to ease the burden on clinicians, what is your preferred option covering patient enrollment: self-enrollment by the patient or have clinicians do this?	Treatment protocols are different from HCP to HCP and it will therefore be up to the specific HCP to determine how to implement the solution in its organizational processes and protocols. We do therefore believe that a solution enabling enrollment flexibly in relation to clinician and patient involvement could be a way to meet different HCP needs.
28	Should the HCP/Clinician make the determination whether the patient should be enrolled for the LIVE INCITE solution or not?	As of today, we foresee within the LI Consortium, the HCP organization would be involved in the determination process. We expect you to define the process which could include roles and activities involved while using the tool.
29	Is it expected that smoking/drinking cessation is recorded at multiple milestones?	You have to describe and determine what is relevant in the context of your solution to be successful, within the peri operative process. For instance when it comes to tracking status; e.g self assessed, externally assessed and/or physical measurements etc.
30	Would it be possible to provide more clarity on "the motivated estimated improvement of E1 over time"? E.g. through projected numbers of patients affected by the behavioural change program. *C5 - Capability – Intervention program optimization: Describe in a summary and analysis the extent to which the solution has the potential for*	We would like you to elaborate on your solutions ability to optimize the intervention programs over time by collecting and analyzing data followed by adapting significant parameters, and what related effect/effects your foresee on “Change patient behavior” (E1).

	continuous and/or major/disruptive behaviour change program optimization, please include and motivate estimated improvement of Effect (E1) over time	