THE GAME PLAN

For Development and Innovation within Public Healthcare

By Tomas Borgegård, Stefan Persson, Erik Mårtensson Djäken and Tomas Gustafsson

THE GAME PLAN was developed in collaboration between Karolinska University Hospital, Region Stockholm, Västra Götaland Region, Region Västerbotten and Region Skåne, within the Swelife project, Sweper, with support from the Swedish National Agency for Public Procurement.

Authors of the report:
Tomas Borgegård, Center for Innovation,
Karolinska University Hospital, Region Stockholm
Stefan Persson, Innovation Skåne, Region Skåne
Erik Mårtensson Djäken, Innovation Platform,
Västra Götaland Region
Tomas Gustafsson, Innovationssluss Västerbotten,
Region Västerbotten
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Illustrations: Karin Olu Lindgård

Sweper is a national initiative to improve and support opportunities for the Life Science sector in Sweden to access and use data.[1]

THE GAME PLAN is available for download on the Swelife website: swelife.se.

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Introduction

The present document is intended to serve as a brief introduction and instruction to THE GAME PLAN.

THE GAME PLAN was developed with the intention to clarify how development and innovation within public healthcare may be pursued in collaboration between different regions in Sweden and with the private sector. It visualizes how to, efficiently go from an identified need, all the way to implementation, utilisation and dissemination – without distorting the competition on the market. THE GAME PLAN is largely based on prior knowledge, experience and lessons learned, condensed into a 'two-pager', which should be easy to bring along to meetings as support for both operative and strategic discussions – fold it up and put it in your back pocket or quickly pull it up on your phone or screen.

The Swedish Government's Life Science strategy concludes that:

> *"Sweden is to be a leading Life Science nation. Life Science helps to improve the health and quality of life of the population, ensure financial prosperity, develop the country further as a leading knowledge nation and to realise Agenda 2030."*[2]

To achieve these objectives, the need for collaboration between all actors in the Life Science sector – that is, the companies, higher education institutions and public actors at municipal, regional and state level which, through their activities, contribute to promoting human health[3] – is emphasised; but also with an understanding of the complexity of collaborations between different actors. Collaboration and coordination within and between regions, public authorities and other public actors are also highlighted in the strategy. Vinnova's report "Innovation Power in the Public

Sector" states that innovation within and in collaboration with public authorities plays an important role for the development and growth of society[4]. Public sector revenue accounts for almost 50 per cent of the Swedish GDP and procurements amount to more than SEK 700 billion/year[5].

> *"Public sector demand can be an important driver of innovation. Demand from the public sector activities is often manifested through procurement."*[4]

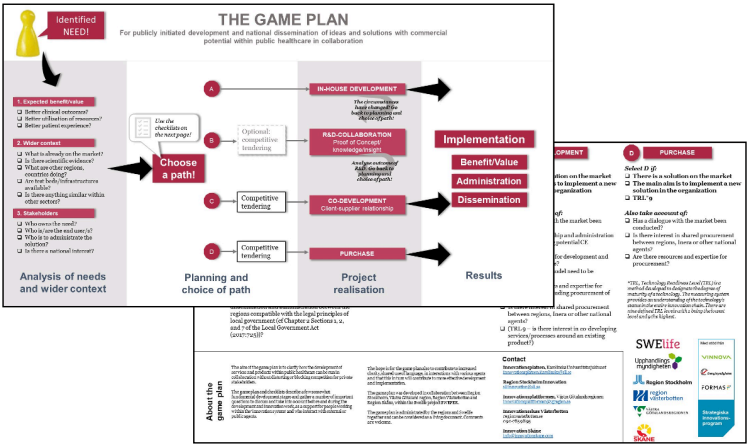
The report further highlights several barriers for innovation within the public sector: time and money but also a "lack of knowledge on how to actually do it"[4]. Leadership is considered critical to successful innovation work, as is the need for support for a more structured and systematic way of working with innovation from idea to implementation[4]. The report also emphasises the importance of avoiding the "project trap", that is, developing solutions that only facilitate specific project deliveries, but which are not possible to implement and introduce into regular practice after the project is completed.

The National Agency for Public Procurement highlights the possibility for several actors to carry out innovation work jointly within the scope of a procurement. Procurement may be a condition for the innovation work to reach the finish line, i.e. implementation and utilisation of a new solution. And, procurement should be considered at an early stage of the innovation project. This can be done by intertwining the innovation and procurement process based on the specific conditions for each project[4].

These reports summarise well the many challenges that public healthcare, as well as the Life Science sector, are facing, and where improvements are needed. At the same time there are clearly many steps being taken in the right directions. For example, innovation platforms, innovation hubs and innovation centres are more regularly teaming up with purchasing departments in order to fully utilise procurement as a tool for the innovation work. Also, more transparent and thorough discussions are seen at an early stage of the innovation process in order to better understand and analyse the specific needs of the organisation as well as the most relevant innovation strategy to adopt. In addition to THE GAME PLAN there are already numbers of guidelines and reports available[6,7], with similar scope, and the hope is that THE GAME PLAN will provide yet some additional values and aspects to this available collection.

The GAME PLAN – Instructions

THE GAME PLAN, designed as a 'two-pager', was meant to be comprehensible and easy to use on its own. Nevertheless we could see the need for a short report or instruction manual to highlight its various components.



THE GAME PLAN – easy to bring to discussions with internal och external participants.Download at Swelife.se.

Analysis of need and wider context

THE GAME PLAN can be used when public healthcare (or other public organisation) has identified a need, problem or challenge that requires a solution.

A structured way of working with identification and analysis of organisational needs is of great value and can in many cases be stimulated by interactions with external actors like industry and academia. Increased knowledge of the opportunities and solutions that exist outside of the organisation itself is of great importance when conducting the analysis of the identified needs.

The first part of THE GAME PLAN focus on the 'Analysis of need and wider context' and has been divided in three main categories:

1. *Analysis of expected benefit/value.* What are the expected clinical values with regards to patient outcome and experiences as well as organizational?

2. *Analysis of wider context.* What is the state of art, what is already available or close to the market, on-going research, and what synergies and lessons can be obtained from other sectors?

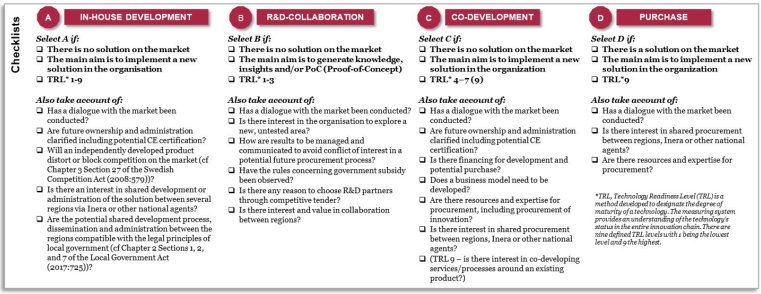
3. *Analysis of Stakeholder.* What should ownership, administration, and dissemination look like, as this may vary between research, development and innovation-initiatives?

All begins with a need that needs to be understood.

Planning and choice of path – Checklists

The next part of THE GAME PLAN focuses on planning and how to choose the right path, or strategy. Note that THE GAME PLAN does not include internal organisational development or academically driven research and development.

Choosing the right path requires a well-executed 'Analysis of needs and wider context', which should include an open and broad dialogue with external actors like industry and academia[8]. To help choosing the most appropriate path THE GAME PLAN contains checklists for each path, which highlight important aspects to consider. The answers to the questions may vary depending on the project and the context, but the questions themselves



The checklists.

can provide a good indication of which path, or strategy, is most advantageous.

Some general key questions from the checklists are:

- Is a relevant solution to the identified need available on the market or not?
- Is the main purpose to explore different potential solutions and to gain insights within a specific area related to a need, or to develop and implement a solution to the identified need?
- What technology readiness level (TRL) have the potential solutions reached, in cases concerning technological development? See Table 1.

If these questions can be answered with reasonable certainty, there are good conditions for choosing the right path and delving into the more specific questions on each checklist.

Project realisation – In-house development

This part of THE GAME PLAN describes in more detail the different possible paths, or strategies, for 'Project realization'. First; 'In-house development' refers to the development of potential innovations within one's own organisation. This path may lead to implementation of the solution and assumes that ownership and owner responsibility (possibly regulatory responsibility) are managed within organisation's internal activities. In-house development may be considered if the conducted 'Analysis of need and wider

Table 1. TRL levels denote technical maturity. TRL = Technology Readiness Level. Originally developed by NASA, but adapted to different technologies. In the table TRL levels for medical technology.[16]

TRL1	The basic principles are explored and documented. A medical technology application and technology are being investigated.
TRL2	A technical concept is being developed. Different hypotheses, research ideas and experimental experiments with the aim of showing function are defined. A basic understanding of the potential of technology, material or process exists.
TRL3	Active development has begun, e.g. hypothesis testing, data collection, identification and evaluation of critical techniques and components. Verification of important functionality and / or components is carried out at an early stage (Proof of concept) in the laboratory environment.
TRL4	Active development of subsystems is ongoing. User requirements are investigated and verified. System solutions are investigated and integration of different subsystems into relevant lab environments has begun.
TRL5	Further development of selected technologies and components. Verification of system solutions and processes in relevant laboratory environment and / or in animal experiments. The important product requirements are known and verified. Preparatory work regarding the classification of equipment from the appropriate regulatory authority.
TRL6	A working prototype has been developed and the function verified. The regulatory process has begun. Production technology is investigated and clinical testing for safety may be necessary.
TRL7	Customer verification and / or clinical verification is in progress with a complete prototype. Final product design fixed, product tested and 0 series produced. Regulatory work such as CE marking or Pre Market Approval - PMA is performed
TRL8	The product, service or process is ready for launch. The regulatory work is approved. Production is ready to start.
TRL9	Launch done. "Post-marketing" studies and any further development projects start.

context' shows that solutions to the need are not available on the market and that the market does not show interest in developing a solution for this need.

Administration, ownership and, not least, dissemination of proprietary in-house developed solutions can be challenging. Among other things, the rules and restrictions on sales activities of public entities laid down in the Swedish Competition Act and Local Government Act must be considered.

In cases where national actors and infrastructures are available – such as the Swedish Inera[9] or the Regional Cancer Centre (RCC) platform INCA[10] – these can be an alternative for managing and disseminating solutions of national interest.

In some cases, market conditions may change during ongoing in-house development, so that actors on the market starts to show interest in the development of relevant solutions. In such cases, a renewed analysis should be performed, and a new path or strategy should be considered.

In cases where public organisations do not want to take ownership of the solution, ownership may be transferred to the employee(s), through dispensation. In a report, the Swedish Association of Local Authorities and Regions (SKR) have summarised important legal issues in innovation[11].

Project realisation – R&D collaboration

Research and development (R&D) collaboration refers to collaboration between public healthcare and actors within the Life Science sector, with the goal of generating new knowledge and insights, and testing ideas. R&D collaboration does not directly lead to ready-made, marketable and implementable innovations in healthcare.

The main rule is that the project results generated is not only accrued or paid by the procuring public authority and has a focus on acquiring knowledge rather than a final solution. It is important to be able to prove that collaboration really concerns R&D and if this is the case R&D collaboration is exempt from procurement legislation. However, sometimes it is still advisable to carry out a procurement to select and secure the most competent R&D partner, and to ensure an open and transparent process. And procurement can be used as in the case 'Pre-commercial Procure-

Collaboration is good! It should go fast! Now there is money! And there are many crashes; but we learn from our experience and collect the grains of gold.

ment' (PCP) as a policy tool when a public procurer would like to stimulate R&D activities within a specific area.[17]

There are clear advantages to engage in this type of R&D collaboration during exploration and early development. Close collaboration between healthcare and private actors ensures that eventually the right solutions may be developed and offered on the market, based on the knowledge and insights generated from the project. Furthermore, it is relatively easy to start R&D collaboration projects and a relatively large portion of public funding goes towards stimulating R&D collaboration. However, collaboration also presents complexity and difficult challenges for the actors involved, for example to agree on common goals and expectations as well as signing formal agreements.

Wrong expectations of the outcomes from R&D collaboration too often result in projects ending up on the so-called "project graveyard". R&D collaboration should preferably be executed within the TRL span 1–3, have a clear project plan and a signed agreements between the actors involved, as well as have a clear delimitation in time.

Project realisation – Co-development

The 'Co-development' path, or strategy, refers to collaboration between public healthcare and actors in the Life Science sector regarding the development and implementation of products and services following a public procurement, also referred to as 'Public Procurement of Innovation' (PPI).[18]

Co-development includes joint activities for development and implementation, of solutions not readily available on the market. The actors involved contribute with necessary unique skills and roles, and their responsibilities are clearly defined.

To ensure that co-development is the right path or strategy to choose, a thorough analysis of the wider context, ie business intelligence and market analysis is required, and a broad market dialogue is recommended. It is important to understand if solutions are available or not on the market, but also that the market is sufficiently mature, so that development of a final solution is possible.

Requirements for co-development procurement should be formulated in terms of functions of the solution which would solve

the identified need, as well as skills and capacity of the potential industry partner and supplier. Since co-development depend on the contribution of all involved actors it may be possible to develop business models, agreements and contracts that reflects the respective contributions to the work.

The number of examples of co-development projects following procurement is increasing in several regions in Sweden, and the dissemination of experiences from these is of great value to the entire Life Science sector.[12,13,14] Co-development is optimally carried out within TRL span 4–7, but in some cases co-development may be linked to further development of existing products or development of associated services, in which case it falls under TRL 9.

Project realisation – Purchasing

Purchasing refers to procurement when the 'Analysis of need and wider context' shows that the market actors can provide solutions to meet the identified needs.

Also, in this scenario, it is good, at an early stage, to conduct a dialogue with market actors through, for example, meetings and external refferal.[15] And it may also be appropriate to consider formulating as many requirements as possible in terms of function, rather than issuing detailed mandatory requirements.

Results – Implementation – utilisation – dissemination

The final part of THE GAME PLAN concerns the 'Results'. Obviously, results generated from development and innovation projects and processes may come in many forms. THE GAME PLAN mainly focuses on results in terms of implementation, utilisation and dissemination, since it is when implementation has been achieved that the real values of the innovation can be realised, for the different actors involved but also for society at large. Implementation of new innovations is in many cases a comprehensive and complex activity that goes far beyond just, for example, technical instal-

It's never too late to do the right thing, but it's not always easy ... Check out the GAME PLAN*, it can help…*

lation or integration of a solution. The effects of new technology or other innovations often entail changes in working methods and organisation. Knowledge, particularly in change management, is of great importance, and ensuring, at an early stage, that the development work is firmly rooted at all relevant levels within the organisation is crucial.

The issue of dissemination of solutions, products or services, needs to be considered early in the development and innovation process. If several organisations within or between the Swedish regions have similar needs, there may be an opportunity for a joint procurement. If the idea is to develop solutions in-house, regulatory and legal constraints and opportunities must be carefully analysed in order to ensure dissemination of solutions. Obviously, there may also be great value in the execution of various development and innovation projects, even if they do not lead all the way to implementation and utilisation, as the work contributes to a more solution-focused and flexible way of working and possibly a culture that promotes innovation.

Conclusion – Reflections

Going from an identified need to a finally implemented, value-creating solution with the potential for wide dissemination is no easy journey. THE GAME PLAN draws parallels between development and innovation work and a strategic game – not a simple game of dice with a high degree of chance, but rather a complex game with certain basic rules of conduct, but also great flexibility and room for creativity. A game where a player will not be able to go from start to finish on its own, but rather where many interactions and a lot of cooperation and collaboration is crucial.

THE GAME PLAN has been presented and discussed with representatives from all parts of the Swedish Life Science sector, and has been well received: "It provides good clarity", "We want to make a deal faster", "Avoid running pilot-project over and over again", "Procurement is difficult and slow", are some of the comments from different actors.

An interesting discussion was with representatives from public funding bodies – those with perhaps the most powerful tool for controlling the direction and creating incentives for development

and innovation. How can the public funding (or private for that sake) release the power of demand driven innovation? How can funding be effectively tailored to ensure that roles are clarified, and conflict of interests are minimised while at the same time encourage collaboration and create real value? When is it relevant to fund R&D collaboration and when should incentives be created for procurement and co-development?

THE GAME PLAN is intended to serve as a tool for all actors to lead strategic and concrete discussions about innovation work in an easily accessible and clear way. Why, and not least in specific terms: How do we drive development and innovation so that everyone wins?

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Notes

1 https://swelife.se/projekt/sweper/
2 En nationell strategi för Life science, Regeringskansliet 2019
3 En nationell strategi för Life science, Regeringskansliet 2019
4 Offentlig verksamhets innovationskraft, Vinnova Rapport VR 2019:14
5 http://www.statskontoret.se/globalassets/publikationer/2018/offentlig-sektor-i-korthet_2018.pdf
6 Utveckling på Upphandlingsområdet Trendens 2017 https://www.upphandlingsmyndigheten.se/globalassets/publikationer/trendens_2_2017_1dec_webb.pdf
7 Första Innovationshjälpen Innovation Skåne; http://www.innovationskane.com/wp-content/uploads/2018/07/InnovationSkane_lathund.pdf
8 Upphandlingsmyndigheten – Tidig dialog internt och externt: http://www.upphandlingsmyndigheten.se/omraden/dialog-och-innovation/dialog/
9 http://www.statskontoret.se/globalassets/publikationer/2018/offentlig-sektor-i-korthet_2018.pdf
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12 Hedman Rahm, L., Hedman, P. och Bruse, L., 2019. Utvärdering 10 projekt inom innovationsupphandling. https://www.upphandlingsmyndigheten.se/globalassets/omraden/dialog-och-innovation/rapport-utvardering-10-projekt.pdf
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14 Fallprevention Region Skåne; https://kfsk.se/halsaochsocialvalfard/wp-content/uploads/sites/4/2015/02/170831-Region-Skane.pdf
15 Upphandlingsmyndigheten – Tidig dialog internt och externt: http://www.upphandlingsmyndigheten.se/omraden/dialog-och-innovation/dialog/
16 https://www.vinnova.se/globalassets/utlysningar/2016-05340/omgangar/trl-trappa-mt4h-samt-trl-swelife.pdf872789.pdf
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