

ISBN: 978-91-979215-1-0
www.issuu.com/innoplant

© 2012 — **Product Innovation Engineering program (PIEp)**

Address: c/o Department of Machine Design, Royal Institute of Technology
Brinellvägen 85, SE-100 44 Stockholm, Sweden.

Editors:

Andreas Larsson

E-mail: andreas.larsson@design.lth.se, Telephone: +46 46 222 81 82

Carl Wadell

E-mail: cwadell@kth.se, Telephone: +46 8 790 78 95

Erik Pineiro

E-mail: erikp@kth.se, Telephone: +46 8 790 48 88

Program Director:

Sofia Ritzén

E-mail: sofia@md.kth.se, Telephone: +46 8 790 19 82

The workbook is one of the outcomes from **PIEp InnoPlant**, a research project aiming to improve knowledge about innovation-conducive ways of collaborating between medical technology companies, public healthcare organizations, and academia.

PUBLIC SECTOR PARTNERS

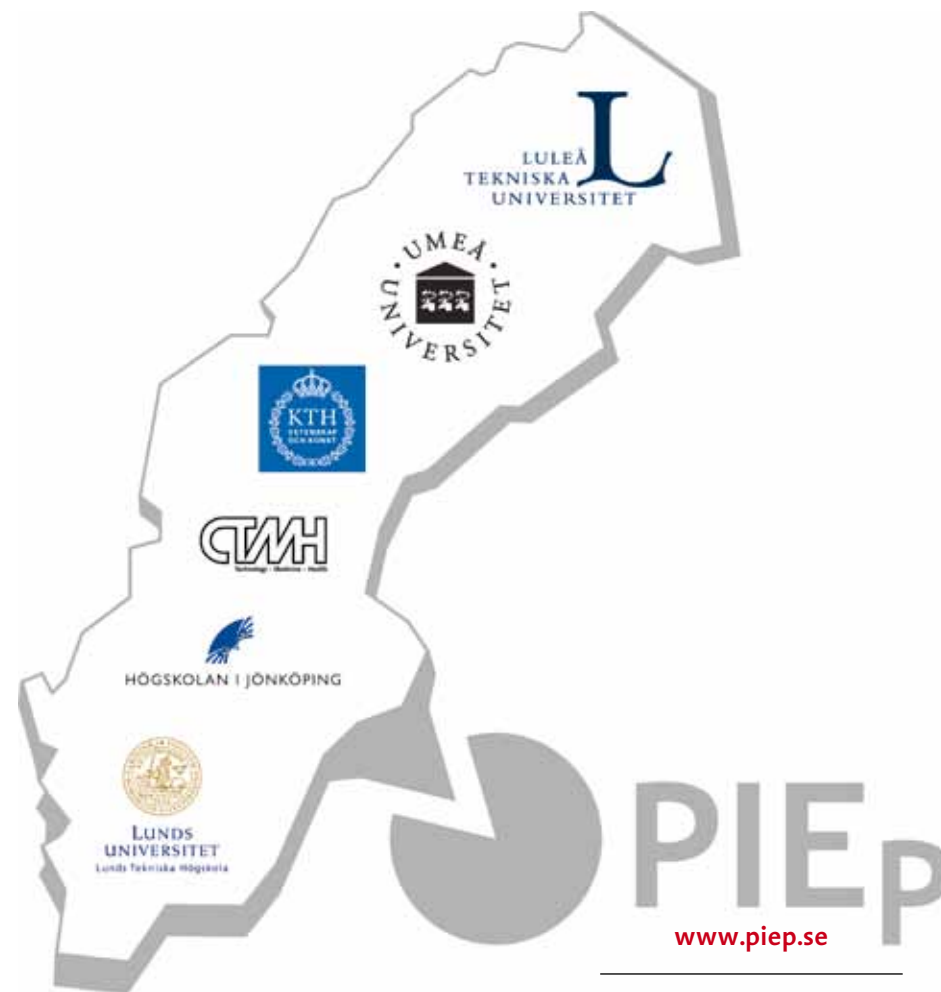
Region Skåne | www.skane.se
Stockholm County Council | www.sll.se

PRIVATE SECTOR PARTNERS

ArjoHuntleigh | www.arjo.com
Getinge Infection Control | www.getinge.com
Maquet Critical Care | www.maquet.com

ACADEMIC SECTOR PARTNERS

CTMH | www.ctmh.se
Lund University | www.lth.se
Royal Institute of Technology | www.kth.se
Södertörn University | www.sh.se



The Product Innovation Engineering program (PIEp) is an academia-based nationwide effort to promote research and education that significantly addresses the urgent need to increase innovation capability in Swedish universities and industrial organizations.

As an established national network, PIEp is working towards a new innovation climate – new knowledge, new professionals, new products, new processes and new businesses.

Contents

INTRODUCTION

pp. 3-5

- * The **origins and purpose** of InnoPlant.
- * The most crucial **innovation challenges** in healthcare.

INNOVATION ECOSYSTEM

pp. 6-9

- * **Stakeholders** in healthcare innovation.
- * **Barriers and benefits** of collaboration.

INSIGHTS & TOOLS

pp. 10-32

- * **Insights and tools** for how to more successfully explore stakeholder contexts, understand stakeholder needs, and co-create solutions with stakeholders in the healthcare innovation ecosystem.

EPILOGUE

p. 33

- * A **roadmap** for innovation.

CONTRIBUTORS

p. 34

- * A list of all **contributors** to InnoPlant and the workbook.

Reader's guide

This workbook is intended as a guide for stakeholders from the public, private, and academic sectors seeking to advance their capability to collaborate in the co-creation of healthcare innovations.

This workbook is not envisioned as a prescriptive and exhaustive “manual”. We recommend that you adapt it to your circumstances, and see it as an inspiration to explore new ways of thinking and working.

The workbook includes a range of practical exercises, examples, insights and practical tips aimed to stimulate dialogue, reflection and learning about how your organization can improve its collaboration with other stakeholders in the healthcare innovation system, to more closely attend to stakeholder needs, and involve a wider range of stakeholders in the co-creation of healthcare innovations.



Collaborative innovation in action (foreground, from left): Annika Olsson (Lund University), Jan Nilsson (Getinge Infection Control), Göran Rydén (Maquet Critical Care).

InnoPlant – a unique playground



Margareta Norell Bergendahl
Professor
Royal Institute of Technology

Per Odenrick
Professor
Lund University

Bertil Guve
Associate Professor
Royal Institute of Technology

InnoPlant is a research and development effort based on the assumption that new forms of collaboration in healthcare can and should be developed to create higher innovativeness in solutions for the future.

A well-known challenge for product and process developing industrial companies is to deepen their understanding of user and customer needs. In practice, perceptions of regulations and rules can hinder a fruitful collaboration, leading to sub-optimizations, inefficiency and, in the end, unsatisfying patient experiences.

PURPOSE AND PLATFORM

The three-year project was established in the Swedish Product Innovation Engineering program (PIEp), with the overall purpose to increase knowledge on forms of collaboration leading to enhanced innovation capability in healthcare innovation.

A three-year duration was critical to allow for observation and analysis as well as exploitation. The focus on healthcare and societal challenges helped us move beyond aspects of technology development only.

Another unique aspect of the setup was the focus on collaborative research. Mixing representatives from the private, public, and academic sectors in a series of network meetings has formed a unique platform, or playground, for learning and sharing of experiences.

THE ROLE OF ACADEMIA

The aim of innovation management research is to increase the understanding of how companies can be managed and organized in order to innovate. In this collabo-

“Mixing representatives from the private, public, and academic sectors in a series of network meetings has formed a unique platform, or playground, for learning and sharing of experiences.”

orative research project, the researchers have investigated different aspects of the participating organizations' innovation capabilities related to collaboration between the stakeholders in healthcare innovation. The research has mainly focused on the collaboration between industry and healthcare and how it influences the emergence of innovation.

An important task has been to formulate research questions that are relevant for the organizations as well as for the academic community and then to plan and perform the research. It has also been important to provide feedback on the research results to the organizations in a way that facilitates effective exploitation.

Moreover, academia has taken on the role of facilitator in the meetings between the different actors with the responsibility of brokering knowledge and experiences from the locally driven projects. The insights gained have been shared, questioned, further explored, discussed and reflected on from a range of perspectives.

By stimulating cross-boundary discussions around healthcare innovation challenges and opportunities, and documenting the learning outcomes, academia has helped shape a playground for healthcare innovation, and new ways of collaborating in this kind of triple-helix alliances, regardless of the application domain.

Healthcare innovation requires system solutions



Photo: Getinge Group, www.getingegroup.com



Carl Bennet
Chairman of the Board
Getinge Group

The general question on how to develop innovation capability is of major importance for an industrial country with world leading ambitions. Medtech industry today is facing a challenging competitive environment, acting on a truly global market. In addition to strong efforts to rationalize current development, manufacturing and deliveries, there is an increasing need for new solutions and innovations for the healthcare sector, leading to better healthcare, good business, and new export opportunities.

MEETING GRAND CHALLENGES

Currently there are grand challenges to healthcare systems around the world. These include ageing populations and developing countries. It is of major importance for companies to understand in detail the future needs of societies and care systems. The time is past when incremental development is enough for sustainable business success.

InnoPlant is an important change project. Industrial organizations, public providers, and actors in care operations have been able to meet in close and concrete discussions that have fostered a learning and goal oriented way of working.

“A strong solution provider will have to propose full product and service solutions and be responsible for upgrades and sustainable deliveries.”

This is an opportunity to open up for creating and testing inventions and ideas in clinical settings and to collect knowledge and experience for better solutions. I would welcome spreading the experiences to many partners in the healthcare innovation ecosystem.

SYSTEM SOLUTIONS

Regarding future demands we will have to work much more on system solutions. This includes organizing, logistics and work procedures for overall better health and environmental economy.

A strong solution provider will have to propose full product and service solutions and be responsible for upgrades and sustainable deliveries.

It is my hope that the PIEp InnoPlant Workbook will be of value for practitioners wanting to increase their understanding of market and user demands for a more dignified healthcare product and service provision.

Healthcare innovation requires collaboration

The healthcare sector is facing great challenges – an increasing elderly population, greater expectations among patients and limited economic resources. New solutions and innovations must be developed to handle this reality in the near future. It will not be enough to make improvements in the processes and technologies of today – new ideas and solutions are necessary.



Bertil Lindström
Director of R&D
Region Skåne



TRENDS AND INNOVATION FIELDS

- Primary care will continue to shorten treatment and rehabilitation, and extend outpatient services. These changes also effect the home care area, which will increase with new and larger patient groups.
- Elderly care is facing larger patient groups with greater expectations and demands but with individually different economic possibilities to realize the facilities needed at home.
- A common healthcare system is emerging in the European Union that will affect the prospects of organization and finance.

These changes must result in new products and services to handle patient care and safety, matching both the individual patient needs and the efficiency needs of a modern healthcare system.

COLLABORATION IS CRUCIAL

As public organizations it is our responsibility to improve the healthcare system and contribute to regional growth and wellbeing. To do so we have to collaborate with private actors when we define healthcare needs and requirements and develop new sustainable and cost efficient solutions.

Improvements can be made within single professions, but the necessary innovations are unlikely to emerge without collaboration with representatives of different perspectives.

“Improvements can be made within single professions, but the necessary innovations are unlikely to emerge without collaboration with representatives of different perspectives.”

A truly innovative collaboration should consist of trustworthy representatives from healthcare professions, users and patients, universities, industry and others with complementary perspectives. We all have a common interest and responsibility to make this happen.

COST EFFICIENT PROCESSES

Moreover, this collaboration should not only focus on the development of single products or services but rather on the development of new cost efficient processes in healthcare. Collaboration in clinical research and development projects requires that highly skilled clinical staff is provided with resources that are effectively used to solve well-defined and relevant problems.

INNOVATIVE CULTURE

Perhaps even more important is to develop a culture and mind-set in healthcare where each and everyone feels that they can take part in developing something that contributes to wellbeing and regional growth. This also means that employees in healthcare feel that their ideas for improvements and new solutions are appreciated and that there are efficient processes to evaluate and develop these ideas that also protect intellectual property rights.

There are legal issues related to commercial law and patient safety regulations that can be interpreted as barriers for a collaborative and innovative culture. All employees in the county and regional councils must feel comfortable with their legal opportunities and restrictions to collaborate with the private sector.

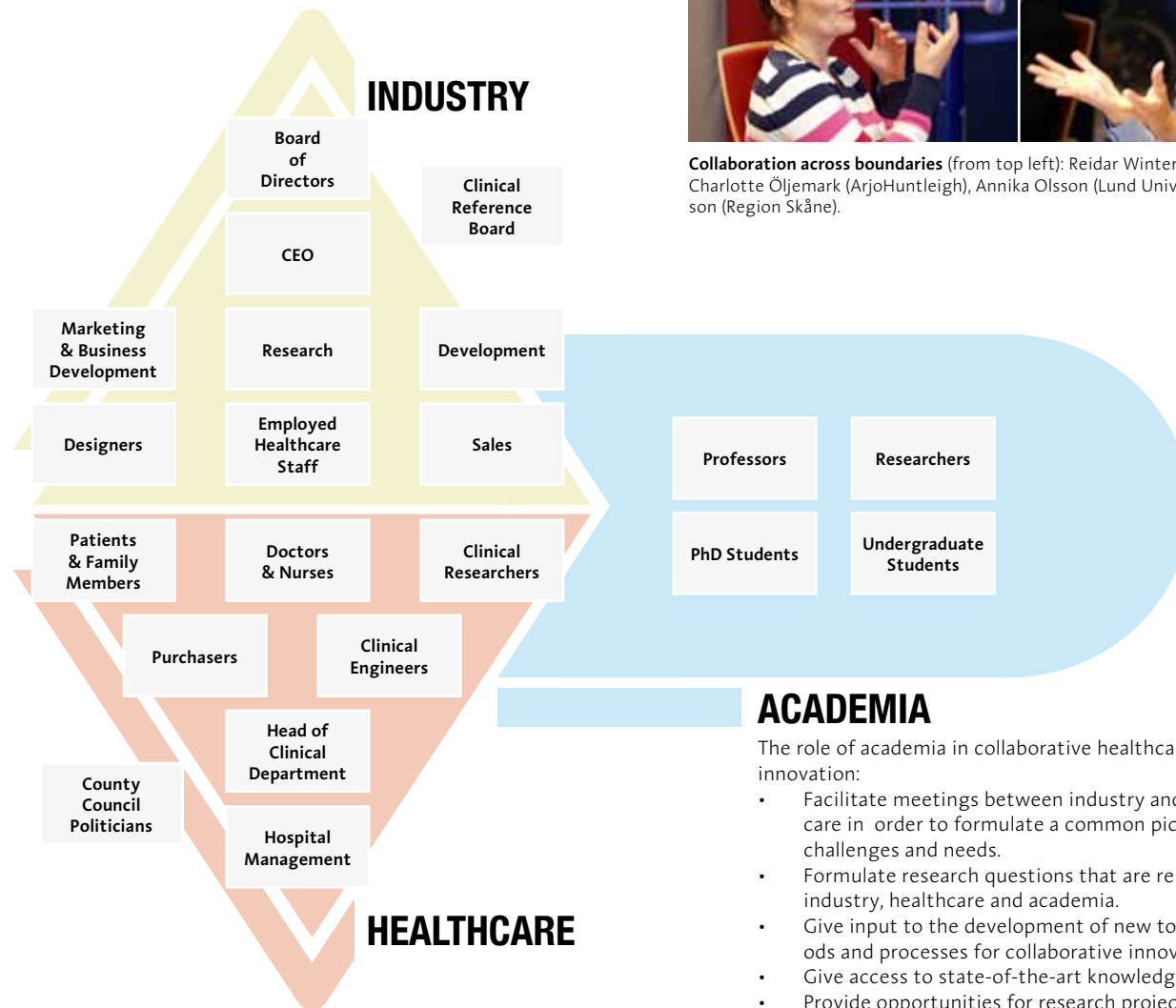


Thorbjörn Ekström
Director of R&D
Stockholm County Council



An ecosystem of healthcare innovation

The figure below presents a schematic overview of various stakeholders in the overall healthcare innovation system. In different ways, each stakeholder contributes to the shaping of innovations. Note that this is not a complete picture. For example, there are supply chains in both the private and the public sector that are implicit here. The InnoPlant project, and this workbook, aim to improve the ability of innovation ecosystem stakeholders to more effectively cross the boundaries between the sectors to achieve innovations.



Collaboration across boundaries (from top left): Reidar Winter (Karolinska Hospital), Charlotte Öljemark (ArjoHuntleigh), Annika Olsson (Lund University), Jonas Johansson (Region Skåne).

ACADEMIA

The role of academia in collaborative healthcare innovation:

- Facilitate meetings between industry and healthcare in order to formulate a common picture of challenges and needs.
- Formulate research questions that are relevant to industry, healthcare and academia.
- Give input to the development of new tools, methods and processes for collaborative innovation.
- Give access to state-of-the-art knowledge.
- Provide opportunities for research projects, thesis projects, and course projects.

Are any stakeholders missing from this picture?

Are any roles different in your context?

Industry stakeholders

Clinical Reference Board

- Provide advice on clinical research and development collaborations to CEO and top management.
- Exploit the networks of the clinical board members in order to access the right clinical environment and build relationships with healthcare.

Research & Development

- Evaluate feasibility in new opportunities and ideas that emerge from healthcare employees.
- Design and perform collaborative research and development projects with healthcare.
- Clinical investigations into clinical practice.

Marketing and Business Development

- Evaluate business potential in new ideas and concepts that emerge from healthcare employees.
- Evaluate the business potential in a collaborative research and development project; prepare for marketing entrance.

Employed Healthcare Staff

(Doctors and nurses who have started working for the industry)

- Use their understanding of the culture in healthcare to support the design and execution of collaborative research and development projects in healthcare.
- Exploit their networks in healthcare in order to access the right clinical environment and build relationships with healthcare.
- Link employees with innovative ideas to relevant clinical knowledge.

Board of Directors

- Set an annual budget that includes long-term goals that require collaborative clinical research and development to obtain sustainable growth.
- Exploit the networks of the board members in order to access the right clinical environment and build relationship with healthcare.

CEO

- Develop a collaboration strategy that supports both discontinuous and more incremental innovation projects to reach both the long-term and the short-term strategic goals of the company.
- Develop good relations to world leading healthcare units within the company's focus areas, in order to jointly develop strategies to face relevant clinical problems and challenges.
- Drive change if the company does not have the right market orientation.

Sales

- Recognize and report back to the company on the customer and user problems with current products.
- Support R&D when they want to set up a collaborative research and development project with healthcare and separate long-term development projects from their day-to-day sales activities.

Designers

- Perform various types of design research studies to understand the values, motivations, obstacles and drivers for the users of the company's products.
- Visualize and materialize ideas and concepts in the collaborative research and development projects.

Doctors & Nurses

- Require a vision and strategy on how to become a world leading clinic.
- Continuously identify problems and challenges in healthcare and generate ideas and conceptual solutions to these problems. Require that there are functions to present these ideas to industrial partners without risking the loss of intellectual property rights.
- Participate in clinical research and development collaboration with industrial partners (research, marketing, designers). Make sure that the time and money dedicated to collaborative research projects are actually used for that purpose.
- Contribute with ideas and suggestions on how to improve the incentives to participate in collaborative research projects with industry.

Purchasers

- Keep updated on collaborative research projects and start planning for the procurement of the innovation as early as possible.

Clinical Researchers

- Are doctors, nurses, physicians, chemists or biomedical analysts who spend time doing research in the clinic.
- Jointly define challenges, needs and problems with companies and formulate research questions.
- Participate in the research design and performance.

Clinical Engineers & Innovation Developers

- Take care of new ideas and concepts developed by the healthcare professionals and test feasibility, IP and give advice on future work such as licensing to an existing company.
- Support companies in the design and execution of collaborative research projects in healthcare.

County Council Politicians

- Develop and implement strategic focus areas for the clinical research and development in the region, focusing on global problems and challenges for mankind.
- Provide resources and incentives to hospitals and healthcare professionals to initiate and participate in collaborative research and development projects with industry.

Patients & Family Members

- The most focal actors in collaborative medtech innovation are all citizens. As patients and as family members we have the opportunity to influence decision makers to provide good conditions for collaborative medtech innovation and also contribute ourselves with ideas, feedback and as participants in evaluations and tests.

Head of Clinical Department

- Create a vision and strategy to become a world-wide respected research clinic in well identified areas and challenges that are relevant to face.
- Invite industry to formulate the challenges and opportunities for collaborative development of innovative solutions (Board of directors, CEO, Clinical reference boards, Marketing, Research).
- Engage the whole staff in the continuous improvement work (for instance LEAN) in order to make the treatment more efficient (doctors and nurses). When there are opportunities for technical solutions, such as IT, involve industry in the discussion.
- Encourage employees to get involved in collaborative research and development projects.
- Develop economic as well as non-economic incentives for the clinic and its employees to become involved in collaborative research projects.
- Involve management and organizational consultancy as well as academic researchers to accomplish the organization's long-term and short-term strategic targets.

Hospital Management

- Provide resource incentives to clinics to participate in collaborative research and development projects and monitor the results carefully.
- Develop infrastructure to manage healthcare professional's ideas and concepts and involve industry in the evaluation and development of these ideas.
- Develop a clinical focus area and form strategic alliances with relevant companies to create world leading clinics. Make these focus areas visible internally and externally.

Healthcare stakeholders

Are any stakeholders missing from this picture?

Are any roles different in your context?

BARRIERS IN HEALTHCARE

Attitudes between healthcare and industry: The traditional relationship between healthcare and industry is of a strict buyer-seller nature. The attitude it creates in both actors is generally not conducive to innovation, co-operation and partnership.

Lack of gatekeepers: A common barrier is the lack of gatekeepers in healthcare that understand the needs of the industry and can support and guide companies when they approach healthcare actors.

Ethical issues: There is a lack of commonly shared ethical guidelines on how companies and healthcare may collaborate in research and development.

Legal problems and liability: Concerns about legal problems and liability risks have a highly significant negative correlation with the likelihood of user invention by healthcare professionals.

Lack of facilities: There is a lack of clinical facilities where industry, healthcare and academia can meet and jointly develop innovative ideas.

Taking care of employee ideas: Idea generation and realization is not a prioritized activity in healthcare. Thus, there is often a lack of supporting structures for healthcare professionals with innovative ideas.

BARRIERS IN INDUSTRY

Not-invented-here mentality: Even though many innovative products have emerged from ideas by healthcare professionals and patients there is a risk that industry sees these ideas as less valuable.

Short-term strategic focus: The pressure to deliver short-term value may result in corporate strategies focused on exploiting the current business rather than on taking risks and seeking innovative solutions through collaboration.

Lack of internal communication: Companies are often good at establishing well functioning selling channels that gather information about their customers' needs. However, they sometimes lack communication channels to distribute this information internally, involving all employees in the process of understanding the customer and improving the offerings.

Lack of clinical knowledge: Companies sometimes lack relevant clinical knowledge, which results in vague objectives as regards collaboration with healthcare representatives.

Lack of windows for input: Companies sometimes lack contact points where they can gather ideas generated by external actors.

BENEFITS

Improved healthcare and wellness: Multisectorial innovation would contribute to a more cost efficient healthcare and a society with a higher degree of well-being. Benefits include higher efficiency, improved patient safety, and better patient experiences.

Improved growth: Fruitful collaboration between healthcare and industry often results in reduced uncertainty in product development which in turn shortens the development cycles and increases the company's chances to succeed in innovation. Benefits include:

- *More innovative patents:* Patents where physicians are involved draw more heavily on scientific knowledge, better anticipate technological trajectories, and are cited more intensively and broadly than traditional corporate patents.
- *Aligned strategies and goals:* Better alignment between actors in the healthcare innovation ecosystem to better meet long-term societal goals.
- *Access to innovative ideas:* Healthcare professionals also generate and develop innovative ideas on their own that manufacturers could acquire and develop further.
- *Smooth testing and implementation:* In order to access the most cost efficient solutions there is a need for close collaboration and clear communication in testing and evaluation of innovative products.

New knowledge creates better healthcare: scientific articles lays the foundation for the deployment of new knowledge in healthcare practice.

Barriers and benefits of collaboration

BARRIERS IN ACADEMIA

Researcher attitudes: Apart from a common resistance to commercialization within the academic sector, collaboration with industry is not always considered a merit in a "publish or perish" community.

Lack of understanding: It is difficult for researchers to deeply understand the challenges of clinical practice.

IPR issues: Research results are often protected by copyright, and many research projects are performed under other types of confidentiality agreements.

Finding the right partners: Who knows what in academia? Where do the academic knowledge and roles fit into the healthcare ecosystem?

Do you see other barriers and benefits?

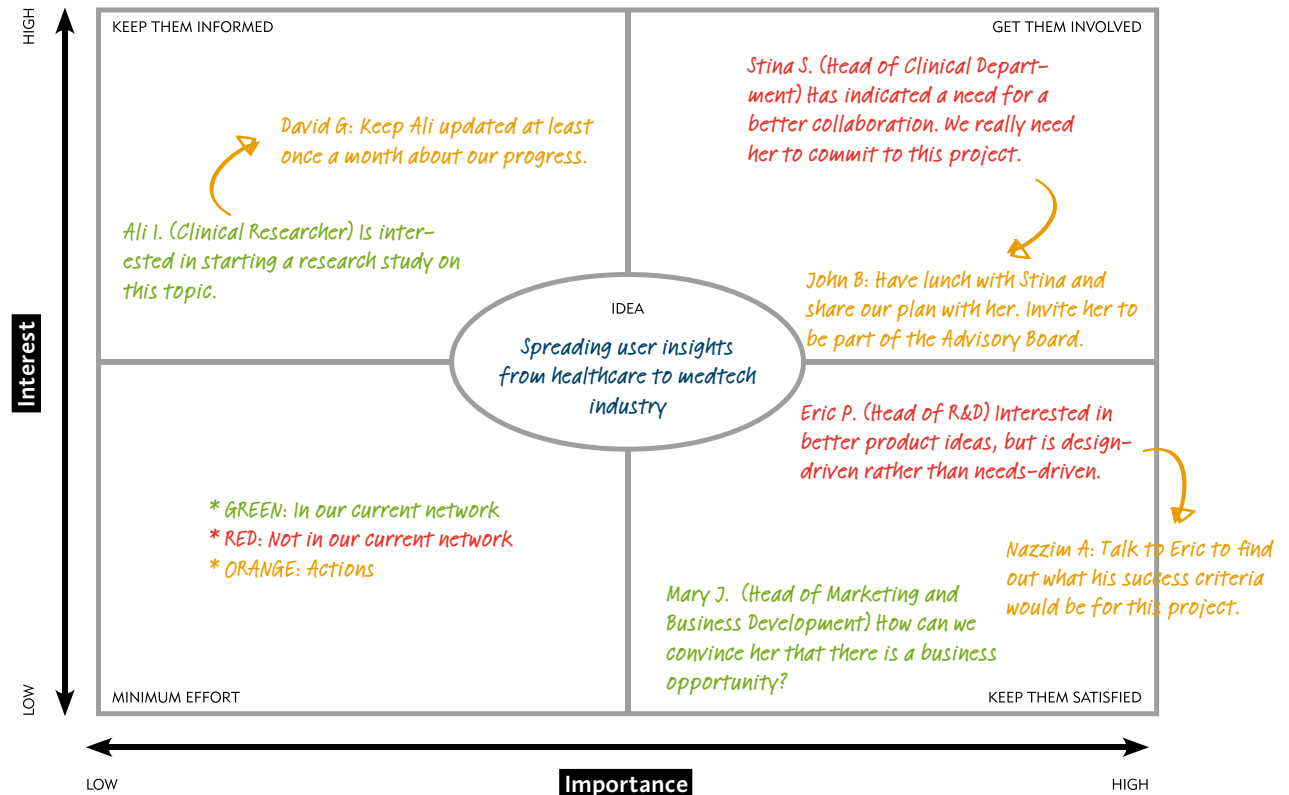
What is preventing or enabling innovations?



Stakeholder mapping

To successfully bring healthcare services to those in need, it is crucial to devise an innovation process that involves the needs and priorities of different stakeholders in the healthcare system – who influences innovation, and who benefits or suffers depending on the outcome? Exploring the contexts of multiple stakeholders in the healthcare innovation system is crucial to success.

A proposal is to use **stakeholder mapping**, firstly, to get a good overview of where we stand and, secondly, to map out how our stakeholder network needs to be developed in the future. Who do I collaborate with today and who do I need to collaborate with in order to get healthcare innovation done?



Instructions: Current Status (As-Is)

1. Identify the idea to be worked with and write the name of the idea in the middle of the template.
2. Identify potential stakeholders by addressing the dimensions suggested in the template and map the result on a relative scale, either using post-its or writing directly in the template. *Interest* = how interested are these people in what you are trying to achieve? *Importance* = how important are these people for what you are trying to achieve?
3. Remember that stakeholders exist inside the organizations as departments, colleagues and managers, as well as outside as customers, users, legislators, etc. Note down the reason for each stakeholder's involvement (money, need of knowledge, curiosity, etc.).

Instructions: Future Status (To-Be)

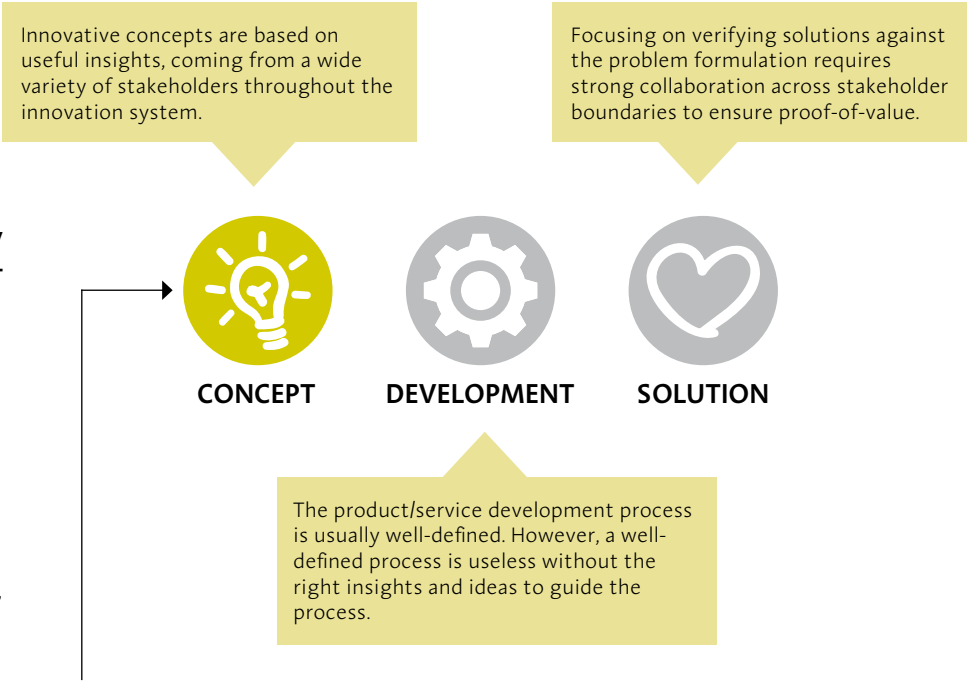
1. Discuss the idea in light of your reflections and observations in the previous step. If needed, refine the idea according to your conclusions.
2. Identify stakeholders needed to get the innovation done who are currently not in your network.
3. Compare the result with the "current status" map and discuss the actions needed to get the new stakeholders committed to your project. Note the actions in the worksheet.

INSIGHT 1

Effective development processes are useless without useful insights

While development processes are usually well-defined, it is absolutely crucial to make sure that you are not only doing things right, but doing the right things.

This statement is well-known, but still the development of a successful concept is often hard to accomplish. One explanation is that creative ideas are suppressed under all kinds of regulations and traditions of an organization. The overall development process to transform great ideas into practical solutions can be described in three steps – *concept, development, and solution* (see figure to the right). Most important for doing “the right things” is the concept. The creation of a successful concept can be further understood in four steps – *insight, problem formulation, idea and proof of value* (see below).



FROM INSIGHTS TO PROOF-OF-VALUE

1. Insight

Insight is the understanding of a cause and effect situation. The innovative ideas flourish where needs are fertilized with new perspectives and knowledge.

This first step is then much about communicating the scenario and its causes to a network of competences such as users, suppliers, manufacturers, scientists and of great importance – people driven by curiosity, enthusiasm and passion. It’s recommended to explore different communication methods to visualize and describe the scenario by pictures, case descriptions, statistics, etc.

2. Problem formulation

From the insight, a problem must be formulated. This requires a deeper analysis of the insights and information from the first step.

This is preferably done with a method that can connect a great diversity of perspectives in order to share views and focus on problem. A workshop theme based on insights has proved to be a successful approach. It is crucial that the problem formulation is verified and accepted by the various stakeholders in the innovation process.

3. Idea

This step is about generating and communicating new ideas for how to effectively address the above problem.

Ideation is an iterative approach to create multiple solution alternatives based on the insights and constraints that has inspired the problem formulation. The process usually involves structured brainstorming and conceptual prototyping to create and evaluate competing ideas. Quantity of ideas is more important than quality, and it is important to make visual and tangible representations of ideas to help others understand complex ideas.

4. Proof-of-value

In this final step, the concept is thoroughly tested in three steps answering three questions before going into the development phase:

- **Proof-of-concept*: Does it function in practice? Formulate a technical file.
- **Proof-of-science*: Does it function in theory? Make a small-scale test, and then verify it scientifically through publications.
- **Proof-of-business*: Is it profitable? Formulate a business plan.

INSIGHT 2

Focus on flows, not products

What flows are currently working poorly?

What are the major bottlenecks? Why?

To implement innovations in healthcare it is crucial to understand how these will be aligned within the larger existing logistic flows (information, equipment, patients, etc.).

When Getinge Infection Control wanted to improve their range of loading equipment they started off by analyzing the customers' flows of sterile goods, not only inside the sterile department but also the flow to the end users and back again. This resulted in a deeper understanding of how important an efficient management of these flows is for the customers' operations. It also became clear that the intensive use of these products makes it important to consider the ergonomics of both the products and the workplace.

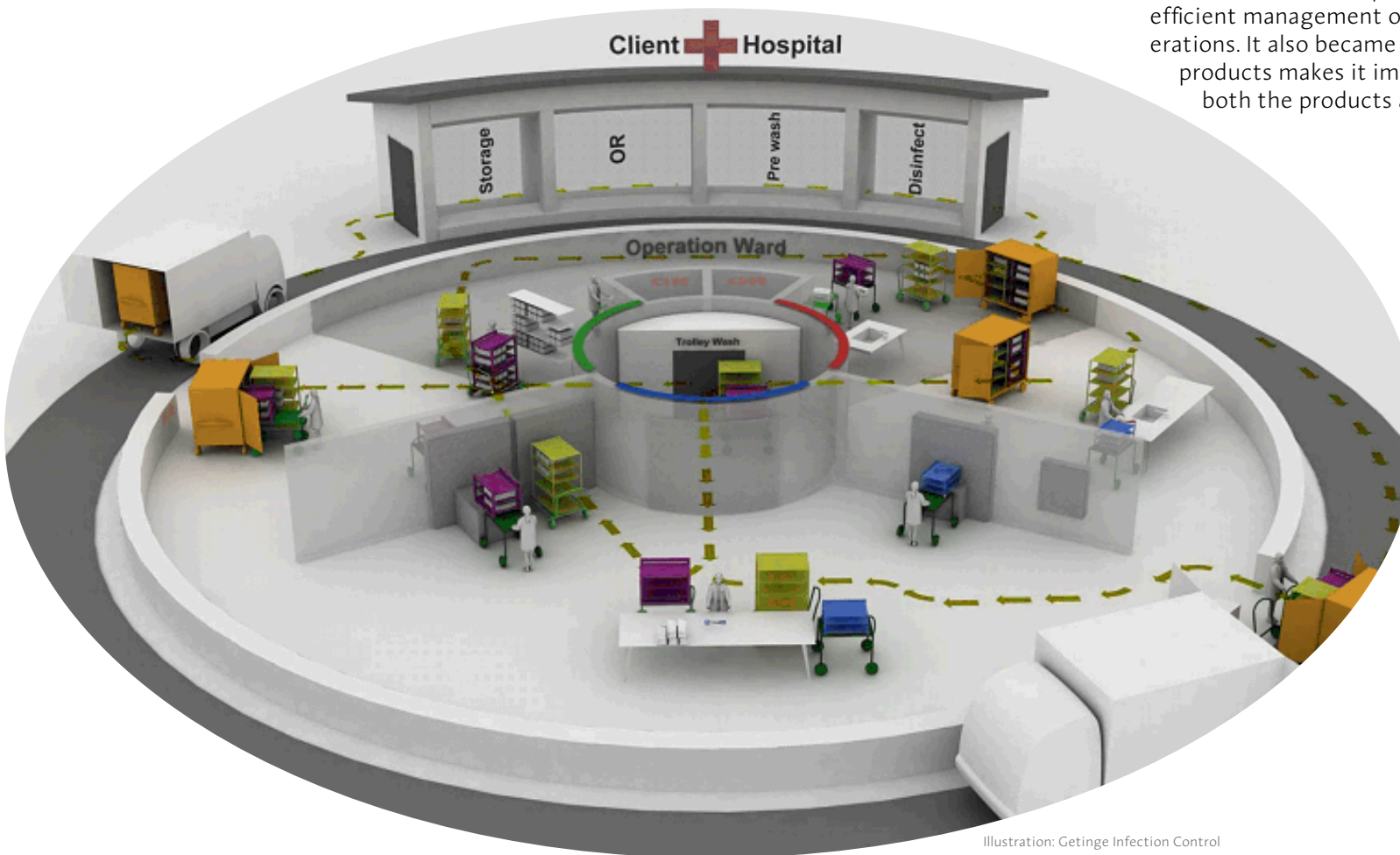


Illustration: Getinge Infection Control



Healthcare is about experiences, not only processes

Innovation in healthcare requires understanding the healthcare processes, identifying bottlenecks and finding more cost efficient solutions. However, one clear insight during the InnoPlant project is that a fundamental, but often forgotten success factor in healthcare innovation, is an understanding of the patient experience.

How can new products and services motivate patients to follow their treatments and make them feel safe?

If we are interested in better understanding a day in the life of a patient, or healthcare professional for that matter, we need to understand that what goes on in the treatment room is only part of the full “patient journey”. IDEO’s CEO Tim Brown takes an example from their project with SSM DePaul Health Center in Saint Louis:

“One of IDEO’s designers, Kristian Simsarian, took on the redesign of a hospital emergency room. Kristian checked in as a patient, video taping every experience – and one of the first things we noticed, watching the tape, was the sheer amount of time he spent lying on his back, waiting on the rolling cot, staring at the acoustic ceiling tiles. The tiles became a symbol of the overall ambiance: a mix of boredom and anxiety from feeling lost, uninformed, and out of control. We could have responded by saying, ‘Let’s make the ceiling tiles more colorful’ or – as many hospitals do – ‘Let’s put televisions everywhere to distract people.’ Instead, we started a series of deliberate discussions about the findings, and those led us to talk about improving the overall approach to ER logistics, so patients were treated less like objects to be positioned and allocated, and more like people in stress and pain.”

It can be difficult to get a good overview of all the different people, activities and objects that play a part in the whole experience. If performing your own patient journey is too big of a first step, why not start with the questions to the left to create a better understanding of the healthcare experience?

“...one of the first things we noticed, watching the tape, was the sheer amount of time he spent lying on his back, waiting on the rolling cot, staring at the acoustic ceiling tiles.”

KEY QUESTIONS

- * What does a day in the life of your patients look like?
- * How do they feel at various points throughout the day?
 - * What people do they meet?
 - * How long do they have to wait?
 - * At what points do they feel undignified, anxious, uninformed, or out of control?
- * How do you create an experience of effective healthcare?

TOOL 2

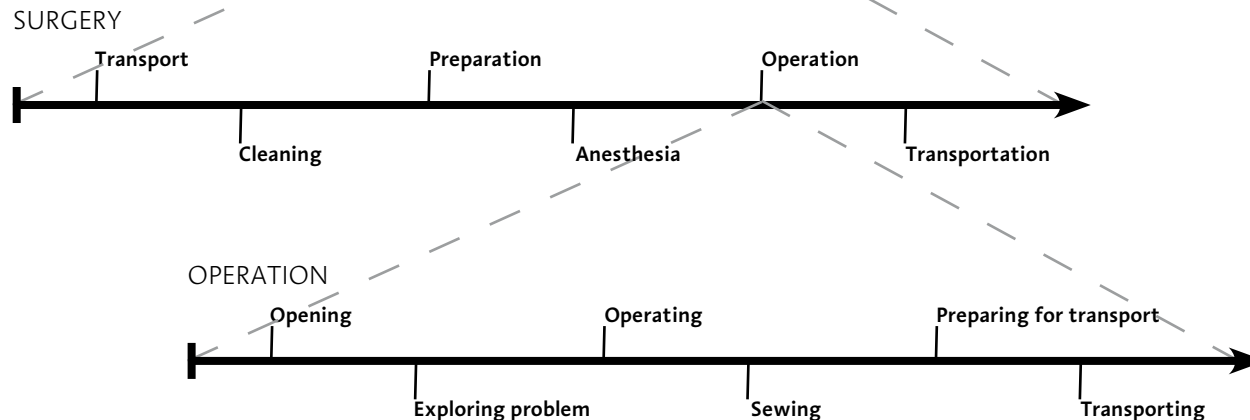
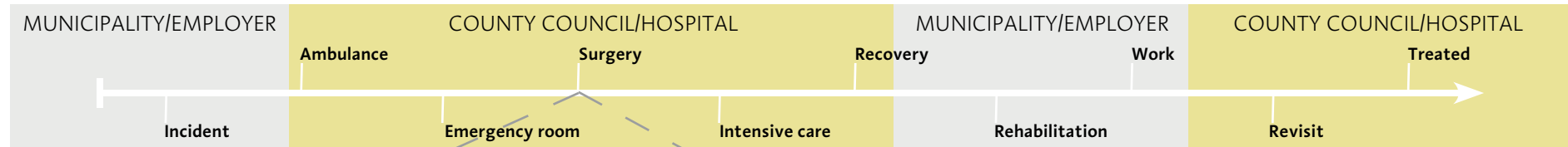
Zoom in, zoom out

Understand your processes, and where you make a difference.

One of the most fundamental aspects of healthcare innovation is to understand the processes related to staff and goods and how they can be improved in terms of cost efficiency, patient satisfaction and time. To map these processes and to understand the potential benefit of an innovative idea or concept, the **Zoom in, zoom out** tool can be used. The tool can also support industry and healthcare to understand the possible risks associated with an innovation, and guide them to where in the process they should focus their resources.

Instructions:

1. Select an overall process or activity that you want to analyze.
2. Draw a timeline, on which you mark critical points or events in the chosen process or activity.
3. Indicate clearly which healthcare innovation stakeholder that is responsible for which event that is marked on the timeline.
4. Identify benefits and risks of introducing an innovation at each timeline marker.
5. Zoom in on a specific part of the overall process/activity timeline, and iterate steps 1-4 for the chosen sub-activity.
6. Repeat the process for yet another level of detail.



KEY QUESTIONS

- * How important is the process in terms of patient satisfaction, costs and time?
- * How and where will the innovation save time, reduce costs and increase patient satisfaction?

TIME



COST



SATISFACTION




 INSIGHT 4

Move beyond lead users

Involving lead users can be crucial for innovation, but it is important to also understand when to involve other user roles and types, and for what purposes. Use the **User Mapping Matrix**, below, to deepen this understanding.

An empirical study involving a Swedish medical technology company and three Swedish hospitals unveiled a need to move away from an archetypical, largely homogeneous view of the user, towards a more flexible, heterogeneous user perspective. The study indicated further that different user types provide very different input, highlighting the importance of clearly understanding when to utilize specific users, and for which specific purposes. In sum, everyone knows that lead users can offer fruitful insights – the secret lies in knowing where in the innovation process these insights make most sense and what other user types are needed to complete the picture.

Make your own **User Mapping Matrix**, which will allow you to get a better understanding of the types of users that you currently involve, and their various roles during the innovation process. This matrix can help you identify areas where you are currently missing certain user types or roles.

Instructions:

1. Make a column for each step of your overall innovation process (the basic phases, not all the details).
2. Make a row called *purpose*, where you fill in the purpose of each of the basic phases.
3. Make a row called *profession*, where you fill in the professions of the practitioners that you currently involve in each phase.
4. Make a row called *user type*, where you fill in the various user types that these practitioners represent.
5. Make a row called *user role*, where you fill in the various user roles that these practitioners represent.

USER TYPES

Requesting users

These users provide input to the innovation process based on their own explicit needs.

Launching users

These users possess a high amount of technical expertise. Often strongly opinionated about the expected functionality.

Pioneering users

These users supply application experience. Often willing to try out prototypes and share experiences with the developers and other users.

First buyers

These users play a more passive role during development, but are the first to buy new products and services after they are launched.

Lead users

These users experience needs still unknown to the public and would benefit greatly if they obtain a solution to these needs.

USER ROLES

Resource

Users in this role provide feedback, suggestions for improvement, and new ideas for products and services.

Developer

Users in this role take active part in the development process for certain periods of time.

User

Users in this traditional role test new products and services to give advice on functionality, design and perceived quality.

Buyer

Users in this role give advice on how to convert potential users into actual users, and non-users into potential or actual users.


 TOOL 3

	IDEA GENERATION	OPPORTUNITY IDENTIFICATION	OPPORTUNITY ANALYSIS	IDEA SELECTION	CONCEPT DEFINITION
PURPOSE	Collecting information	Collecting information	Analyzing synergies	Making decisions	Defining targets
PROFESSION	Nurses, doctors, clinic directors, MT staff, sales representatives	Nurses, doctors, clinic directors, MT staff, sales representatives	Clinic directors	Doctors, MT staff, sales representatives	Clinic directors, MT staff, sales representatives
USER TYPE	Requesting users, Launching users, Lead users	Requesting users, Lead users	Lead users	Launching users, First buyers	Launching users, Lead users
USER ROLE	Resource, Developer	Resource, Developer	Developer	User, Buyer	Developer

Note: this matrix is an example and does not reflect a real case.



Use the right tool for the right job

It is crucial to understand the different types of users and roles related to your product or service. It is also important to know which methods are suitable to engage these different kinds of users. Use the **Methods Mapping Matrix** below as a guide for choosing the right method in the right situation.

Apart from categorizing and understanding the different types and roles of users, it is important to better understand which methods would be suitable depending on the type of user involvement (e.g. direct or indirect involvement of users), the type of user needs (e.g. explicit or implicit needs), the available user study environments (e.g. user workplace, online, etc.) and the fuzzy front-end phase of interest (e.g. opportunity identification, idea generation, etc.).

METHOD	USER INVOLVEMENT TYPE	USER NEEDS TYPE	USER STUDY ENVIRONMENT	FUZZY FRONT END PHASE(S)
VIDEO OBSERVATION	Indirect	Implicit	User workplace	Idea generation, opportunity identification
SHADOWING	Indirect	Implicit	User workplace	Idea generation, opportunity identification
INTERVIEW	Direct	Explicit/Implicit	Company	Idea generation, opportunity identification, idea selection
FOCUS GROUP	Direct	Explicit/Implicit	Company, online	Opportunity identification, opportunity analysis, idea selection, concept definition
SCENARIO ANALYSIS	Direct	Explicit	Company	Idea generation, opportunity identification
DISCUSSION FORUM	Direct	Explicit	Online	Idea generation, opportunity identification, idea selection
IDEA BANK	Direct	Explicit	Online	Idea generation
BRAINSTORMING	Direct	Explicit	Company	Idea generation
LEAD USERS	Direct	Explicit	User workplace	Idea generation
THINK ALOUD	Direct	Implicit	User workplace	Idea generation, opportunity identification
STORYTELLING	Direct	Implicit	User workplace	Idea generation, opportunity identification

Note: There are also composite methods, such as *Needfinding* and *Future Workshops* (see upcoming pages), which make use of several methods on the same occasion.



Make your own **Methods Mapping Matrix**, which will allow you to get a better understanding of methods that might be particularly relevant depending on four important aspects. For example, if you want to understand implicit needs without demanding time and effort from users, video observation could be a good bet.

Instructions:

1. Make five columns. One column for methods, and then one column for each aspect you want to include, e.g. user involvement type, user needs type, user study environment, and fuzzy front end phase(s).
2. Make rows for each user study method that you are aware of.
3. For each method, map what the purpose and/or expected outcomes are in relation to the four aspects.



Needfinding: What do I need to think about?

These pointers about **Needfinding** are based on Michael Barry's class notes from Stanford University, which were published in the illustrated article "Coming of Age of Corporate Anthropology" from *@issue: The Journal of Business & Design*.

1. Cast aside your biases, and listen and observe.

That sounds obvious, but it is too often ignored. When talking to consumers, be an empathic listener, but don't try to argue another point of view, sell them on the product or ask judgmental questions. If a consumer has erroneous views, don't try to correct them. Note the misunderstanding. Let subjects tell their own story, and listen for the things that cause them concern and frustration. Barry quotes the legendary Dale Carnegie: "If you want to find out what people really need, you have to forget about your problems and worry about their lives."

2. Note the contradictions between what people do and what they say.

A homemaker can take you through her laundry routine and tell you how much she loves the detergent, while never noticing that she is using a screwdriver to pry open the box and a stick to stir the granules in the water. Opportunities for innovation lie within the disconnect between action and words.

3. Listen to people's personal stories.

Let them relate their successes and failures. Stories encompass the implicit rules that govern and organize people's lives and reveal what they find normal, acceptable and true. They reveal moral codes, sources of pride, shames, shoulds and should nots. In researching disposable diapers for Kimberly Clark years ago, Point Forward anthropologists kept hearing mothers complain about being asked whether their toddler was toi-

let-trained. Admitting their child was still in diapers made them feel defensive and inadequate. These stories led to the creation of a whole new diaper category – "pull-up" disposable training pants, which became an instant success.

4. Watch for "work arounds".

People make do and work around the shortcomings of products and situations. On a research trip to a hospital, designers at medical cart manufacturer, Modo, noted that a nurse had taped a coat hanger to a cart in an attempt to lift cables out of the way. This not only pointed out a problem with existing carts but provided a possible solution. In everyday life, we all come up with "work arounds", clumsy or clever. Take note.

5. Distinguish between needs and solutions.

Barry cites an example of a wrong assumption: "She needs a ladder." A right one would be: "She needs to get something on a high shelf." If you assume that the only solution is a ladder, then you may overlook the possibility of coming up with an entirely new and revolutionary product.

6. Look beyond the obvious.

If your research entails watching homemakers shop for vegetables or an office clerk operate a copier, the task may seem so routine and familiar that you may feel that there is nothing new to be learned. Boredom and frustration set in. Stay alert. Note everything from body language, surrounding objects, social interactions and distractions, insignificant comments, and sequence of steps to getting a job done. The epiphanies and insights emerge from the nuances.

Excerpt reprinted from @issue: The Journal of Business & Design V1oN1, with permission from publisher Corporate Design Foundation.

"Opportunities for innovation lie within the disconnect between action and words."

1 Cast aside your biases, and listen and observe.



2 Note the contradictions between what people do and what they say.



3 Listen to people's personal stories.



4 Watch for "work arounds".



5 Distinguish between needs and solutions.



6 Look beyond the obvious.



Illustrations reprinted from @issue: The Journal of Business & Design V1oN1, with permission from publisher Corporate Design Foundation.


 INSIGHT 6

Collaborative workshops require building trust

One of the foundations of a successful collaborative workshop is trust. It takes time, but investing into building a relationship of trust yields great returns. Remember that you need people at the workshops to want to share experiences and knowledge.

The pre-work consists of trust-building meetings to reach consensus about the potential benefits for each organization and to identify who is going to represent the organization in a workshop. This trust-building process can take considerable time but is essential for the success and impact of the workshop. The workshop is then approved by scheduling the activity during ordinary work hours and with management in attendance.

In InnoPlant, a workshop was organized that gathered 23 participants from Lund University, ArjoHuntleigh, Region Skåne's Development Centre and Hässeholm Hospital. The theme for the workshop was patient safety and dignity.

Starting from a range of common scenarios and activities in everyday hospital practice, the participants reflected on their own experiences with regard to safety and dignity in their work and in their contact with the patients. Brainstorming was then conducted, where critical situations, proposals and ideas were captured on whiteboards and notepads.

During a break, the material was categorized according to three common topics: mobility, hygiene and communication. These topics were then discussed in relation to possibilities for mitigation actions and development activities both within the hospital practice and in collaboration with companies and universities.

The workshop proved to be a successful approach to gather a multidisciplinary workforce at the hospital with representatives from healthcare, academia, and medtech industry. One important result of the workshop is anticipation of progress. It is thus very important to present fast feedback and actions to the participants. In this case, an information flyer was distributed within a week after the workshop, and eventually presentations of collaboration projects followed.



Collaborative workshop in session: 23 participants from Lund University, ArjoHuntleigh, Region Skåne's Development Centre and Hässeholm Hospital took part in a workshop on the topics of patient safety and dignity.

“The workshop proved to be a successful approach to gathering a multidisciplinary workforce at the hospital with representatives from healthcare, academia, and the medtech industry.”



Future Workshop: What do I need to think about?

“...participants are then encouraged to envision a future without constraints, ending in a set of action points related to each idea’s practicability.”

To bring about change, we suggest you deploy a **Future Workshop** to first reflect on and criticize the actual situation, then dream about a preferable future situation, and finally explore ways to move from the actual situation to the preferred one.

A Future Workshop is particularly well suited for teams that have little experience in working creatively in the development of new products or services. It is a way to share personal experiences of “problems” that participants have encountered in various healthcare situations. Based on a set of critique points, participants are then encouraged to envision a future situation without constraints, ending in a set of action points related to each idea’s practicability.

PHASES OF A FUTURE WORKSHOP

1. Preparation phase

Here, the method, its rules and the scheduled course of the workshop (in accordance with the participants) is introduced.

As a first step, it is possible to prepare the room for the workshop together with the participants (if not already done before). All tables that can separate the participants from one another should be removed from the middle of the room or put outside. Pinboards, paper, pencils, etc., should be available and at hand. The participants should be seated in an open circle to be able to interact and go to the pinboards at any time.

2. Critique phase

This is the start of the workshop. Here, the problem is investigated critically and thoroughly.

First of all, the participants carry out a visualized brainstorming and frame a general and critical question concerning the problem. The critique points are written on small cards. Normally, this is done in groups and in the spirit of brainstorming, where the following rules apply: no excessive discussions, associative linking to already existing ideas, no “killer phrases”, quantity has first priority, etc. The results are written on cards (visualized in-

sights) and grouped accordingly to topics (“clustered”) and the groups are given titles. After this, participants select the relevant points on which they want to move forward.

3. Fantasy phase

After dealing with the problem, the future workshop does not immediately search for the solution.

First, all participants try to work out a utopia, to draw an exaggerated picture of future possibilities. A relaxed atmosphere should prevail in the room and be encouraged by playing games.

4. Implementation phase

Here, the ideas generated are checked and evaluated in regard to their practicability.

If a solution has been found, it is finally written down. Who does what, when, where and how (action plan). This notebook of duties is the logbook for the subsequent permanent workshop (5th phase) – the realization of the solution concepts.

Source: Heino Apel, The Future Workshop, http://www.die-bonn.de/esprid/dokumentel/doc-2004/apelo4_o2.pdf

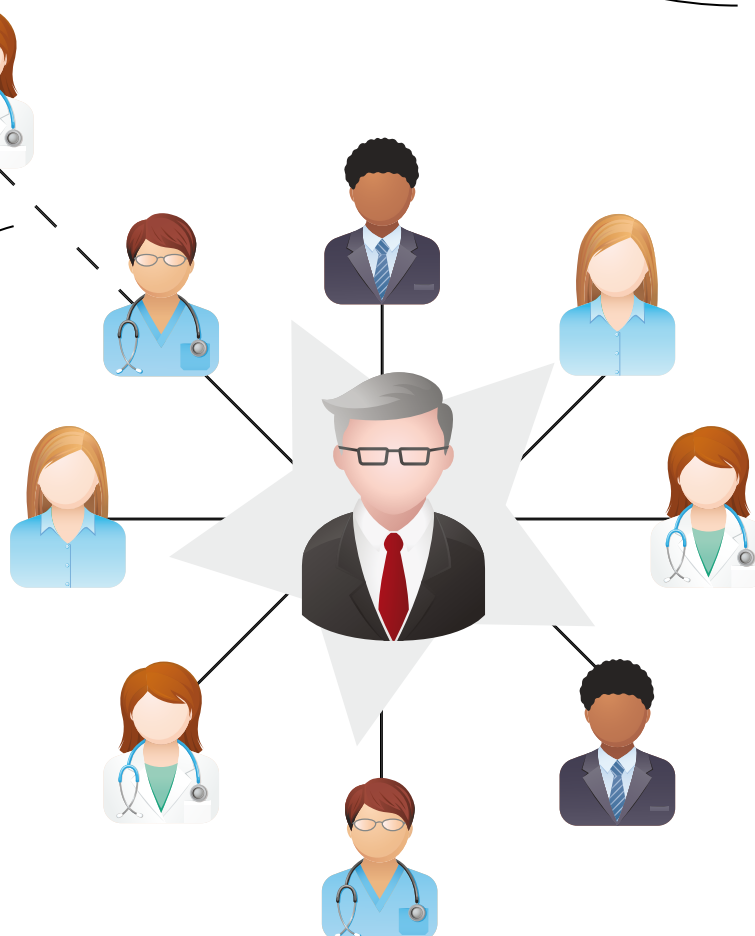
“...there is a correlation between being an idea generation star in a large medtech company and being loosely connected to a large number to healthcare actors.”



Ideation stars are connected

Ideation stars benefit from interacting with a large number of different healthcare professionals.

Ideation stars are those individuals at the company that regularly come up with ideas of great value. Our preliminary research findings in InnoPlant show that there is a correlation between being an idea generation star in a large medtech company and being loosely connected to a large number of healthcare actors.



Loose connections are critical:

When aiming for innovation, we are seeking novelty rather than redundancy. Therefore it can often be useful to gather opinions, knowledge and experiences from people outside your normal circle of colleagues and acquaintances.

Ask your colleagues to refer and introduce you to some of their colleagues and business acquaintances even if you don't see the immediate value of an expanded network.

10 INCENTIVES FOR IDEA GENERATION

116 employees at a large medical technology firm in Sweden were independently asked to rank different factors that influence the generation of innovative ideas. This is what they came up with:

1. Receiving valuable information from end-users.
2. Having time to generate and try out new ideas.
3. Identifying new technological opportunities.
4. Discussing end-users with colleagues.
5. Being appreciated by management for the new ideas.
6. Receiving valuable information from purchasers.
7. Being able to promote new ideas to management.
8. Being skilled at building prototypes.
9. Discussing purchasers with colleagues.
10. Receiving economic compensation for innovative ideas.



Good ideas need facilitation

A growing trend is to facilitate the transformation from ideas to solutions through IT support.

Organizations seldom suffer from a shortage of innovative ideas, but how are you going to support people with ideas and facilitate the transformation from idea to solution?

In order to support, stimulate and encourage an innovative culture, Region Skåne launched a project specifically focusing on innovation a few years ago. The project has resulted in a system to collect, evaluate, support and reward innovations presented by employees in Region Skåne. The process is managed by an innovation board and innovative concepts are eventually commercialized by Innovator Skåne AB.

The innovation process and its steps have been evaluated in frequent seminars. This has been done by listing failure and success factors based on general experiences among a project group with representatives from Region Skåne and Lund University's Faculty of Engineering (LTH). An ongoing case of an IT innovation was followed throughout the innovation process where its founder and several additional key persons in the innovation process were identified and interviewed. To the right are some of the insights that these key persons shared in the interviews.



Success factors

The collection system of innovations (i.e., a website with standardized questions) is frequently used by the employees with a growing potential.

Clear incentives from management.

It is easy to send in ideas for innovations.

All relevant ideas are initially rewarded with movie tickets or books.

It is rewarding to see one's idea come true.

Some of the evaluating theme groups have developed well in their supporting function and give constructive feedback on ideas.

The commercial potential is sometimes quickly evaluated when the intrapreneur meets a company.

One commercialized idea proved to be a success and the products are being used at several hospitals in the region.



Failure factors

Knowledge about the innovation process and the possibilities of support and rewards has not reached full awareness among the personnel.

The employees have low expectations of the system and have to be encouraged to be active and make contributions.

The ideas are lacking in quality – they often present needs but the solutions are not sufficient. The feedback should be faster.

The development costs have to be paid before an idea giver gains any monetary reward.

Some of the theme groups have misinterpreted their role as a supporter of ideas – not creator.

The commercial potential is hard to evaluate in early stages.

The product innovation is not used at the idea giver's hospital, possibly a "not-invented-here syndrome".



Towards challenge-driven idea management systems

Idea management systems in healthcare have mostly functioned as traditional idea boxes where any employee can hand in ideas to solve any problem. A trend that has been identified in InnoPlant is that challenge-driven idea management systems offer new opportunities for collaboration between industry and healthcare. Below are five steps to guide a **challenge-driven idea generation** process.

Instructions:

1. Involve relevant stakeholders from healthcare (e.g., heads of clinical departments, bioengineers, process leaders) and industry (e.g., R&D managers, business development managers)
2. Healthcare and industry stakeholders jointly define a process or problem area that involves considerable challenges for the healthcare ecosystem.

Advice: Ask “Why?” at least five times (i.e. until you have found the core of the problem) regarding the challenge to assure that it is truly relevant to the stakeholders.

3. Establish a mixed evaluation committee, with representatives from both healthcare and industry, to define evaluation criteria.

Advice: Common evaluation criteria are degree of newness, feasibility, user value, etc.

4. Set goals and define the time frame for the idea generation effort.

Advice: Common goals are number of ideas, number of patents, cost reduction, patient experience, etc.

5. Develop rewards, information and education about the system and IP policies.



Insiders have unique advantages

Healthcare practitioners that continuously engage in reflection on their everyday practices are well equipped to discover innovation opportunities that are hidden to outsiders.

A key challenge is how to deliver better healthcare experiences in an increasingly complex and challenging healthcare environment. Part of the answer to this challenge is found in the everyday interaction between patients, doctors, nurses, relatives and all other people that co-create healthcare experiences at a hospital or a primary care center.

If providing better healthcare was all about state-of-the-art medical technologies, better surgical procedures, better IT systems, or more effective medication, the task of innovation would primarily involve people working in research and development (R&D). However, healthcare is not all about finding a cure, it is also about providing care in ways that are not only effective, safe and efficient, but also compassionate. The value of new technologies, procedures and treatments is not only understood in terms of effective treatments, but in terms of how people feel during the care process. Caring is an experience rather than an outcome, and no one knows more about these healthcare experiences than the people that are taking an active part in their co-creation.

There are countless questions that rely on deep knowledge of everyday practices and experiences in a healthcare environment. This knowledge is difficult, if not impossible, to access through interviews or observations performed by researchers or product developers that are not immersed in the environment on a daily basis. Healthcare practitioners that continuously engage in reflection on their everyday practices are well equipped to discover innovation opportunities that are hidden to outsiders.

“The value of new technologies, procedures and treatments is not only understood in terms of effective treatments, but in terms of how people feel during the care process.”

KEY QUESTIONS

Reflect on the things you take for granted, and constantly challenge yourself to think about what could be done differently to enhance the healthcare experience for both providers and receivers of healthcare. A few questions to aid your reflections are provided below:

- * How did the patient experience the procedure?
- * What did the staff experience during the same procedure?
- * What did you like about this experience?
- * What troubled you about this experience?
- * What can you do to make this a better experience for everyone involved?



Hiring users is great, but...

It is common that medical device companies hire doctors and nurses to incorporate them in the firm. Our preliminary findings in InnoPlant show that this policy is mostly beneficial to the firm, but it is important to be aware of its drawbacks.

BENEFITS

- They can use their understanding of the healthcare organization and culture to facilitate and support collaborative research and development projects.
- When there is a lack of access to healthcare they can provide clinical guidance and feedback to their colleagues.
- They may act as change agents within the organization, transforming it to becoming more user-oriented.

DRAWBACKS

- The incorporated user may become the only “voice of the users”, although they only represent the perspective of one user.
- The company may rely too much on the incorporated user’s external network in the search for information and new opportunities.
- Being a well-functioning incorporated user requires a lot of flexibility and reflection regarding their role within the company, especially when it comes to critical decision-making situations, where several perspectives have to be considered.



Identify who knows what about your customers

To utilize the full innovation potential of a medtech company, it is important to consider how information about and from healthcare professionals is disseminated and exploited between employees within the company.

Research findings from InnoPlant show that different types of customer knowledge are handled in totally different ways within companies. For instance, people in a company may have frequent conversations about the end-user's needs and requirements, whereas there are much fewer conversations about, for instance, the purchaser's needs and requirements. This may influence the type of ideas, concepts and business opportunities that emerge and are prioritized. One problem is that people do not know "who knows what" about certain stakeholders in the organization. For this purpose an **Internal Crowdsourcing** method can be applied (see tool to the right).

Research findings from InnoPlant show that **ideation stars** (i.e., people who frequently generate ideas that become valuable to the company) are more efficient in the way they access end-user and customer knowledge than non-ideation stars.



The aim of **Internal Crowdsourcing** is to further understand who is knowledgeable about different customers within the company and to access their knowledge effectively.

Instructions:

- * Let all members of the product development team list five people who they consider as the most knowledgeable about certain customers and end-users.
- * Contact the top 3-5 people and invite them to a meeting. Also ask them to list who they know that are more knowledgeable than themselves in the company about the stakeholders of interest.
- * When there is a group of 5-10 people, a meeting can be held to discuss how they think your ideas or concepts will satisfy the needs and requirements of the different stakeholders.

Questions that you may want to ask the people include whether they think that the new product in the end will:

- 1) *reduce or increase the unit cost per treatment.*
- 2) *expand or reduce the treatment population.*
- 3) *reduce or increase the risk of complications for the patient.*
- 4) *require repetitive use or eliminate the need for further treatment.*
- 5) *improve or complicate the patient's quality of life.*

Remember that internal people only are proxies for real healthcare professionals and patients. They cannot replace actual interaction and testing with these stakeholders but save time by providing fruitful directions for future validations.



How to prepare yourself for observations at the clinic

Perhaps your company has established an innovation agreement with a hospital, or perhaps you work at a hospital and you have been offered some time “off” to find improvement areas. You are now going to spend a few days *in situ* identifying needs.

At the Center for Technology in Medicine and Health (CTMH, a KI, KTH and SLL co-operation) we run a clinic-immersion innovation program called Clinical Innovation Fellowships (CIF). This tool is meant to introduce you to four fundamentals we have learned about observing and identifying needs in clinical practice.

CHOOSING A FOCUS

As one of our fellows said after his clinic-immersion: “Just looking around won’t take you very far”. You need to have a clear idea of what kind of problems and situations you are interested in. Make sure you write down a list of parameters before you start the observation, for instance:

- **Internal Organization:** Are you going to be interested in problems related mainly to the organization of the clinic, such as internal communication, motivation programs, human resources? If you find, for instance, that meetings are run inefficiently, is this a need you are going to pursue?

- **Intraorganization:** Are you going to be interested in questions that have to do with the clinic’s relationship with other groups in the same hospital? Are you interested in the kind of needs that may arise in the communication between surgeons and anesthesiologists? Or in the communication between the emergency service and internal medicine?

- **Technological areas:** Should your attention be focused on the kind of problems that can be solved through mechanical solutions? Or electronics? Or software? Or through new materials? Bear in mind however that a given need can probably be solved satisfactorily with different technologies.

- **Size of the problem:** Are you only interested in problems that have a certain return potential? Or perhaps you simply want to strengthen a certain area, regardless of the possible market or the possible savings for the hospital.

IMMERSING YOURSELF

Clinics are very complex entities, where you find many different specialized professions working under strict safety constraints and in collaboration with other similarly complex and specialized groups. Every problem you might observe has a number of different perspectives: the same problem may be very differently viewed by the doctors than by the nurses, or the patients, or the relatives, or the clinic administration, or the cleaning service, or the technicians, or the management. Be sure to allow yourself the time to immerse in the everyday of the clinic and to understand as many perspectives as possible.

TELLING A STORY

Have your own story ready to be recounted. You have to be able to explain what you are doing there in no more than 30 seconds since everyone will be curious and expect a story, but no one has the time to listen to long explanations. Why are you there? For how long? What do you expect from your observations? And also, how will the whole process affect them? What do

you need of them right now, right here, and what would you hope your results might offer them?

KEEPING A DIARY

Don’t forget to dedicate at least 30 minutes every evening to writing a diary. Fill in the gaps you left when you logged down observations during the day, and make notes about what you would like to focus on the next day. Once you’re back to the clinic, things happen fast and continuously, you need a structure to guide you through the day and make decisions about what you want to see and hear.

Acknowledgements: The text above was written based on interviews with three former CIF fellows: Sjoerd Haas, Johan Tegin and Anna Thies.

FACTS

The Clinical Innovation Fellowships (CIF) is a joint KI-KTH-SLL program (Karolinska Institute, KTH Royal Institute of Technology and the Stockholm County Council) run and organized by CTMH (Center for Technology in Medicine and Health). The goal of the project is to (1) strengthen Stockholm’s cluster for clinical innovation, (2) create new clinical innovations (devices and services) and (3) educate future clinical innovators. See more information at www.ctmh.se.



Simplified pre-clinical prototype studies are needed

There is a strong need for a simplified process for early-stage testing of medtech prototypes in clinical practice. A proposal is to test proof-of-concepts in the first two stages of the overall validation process: 1) testing on a small group of healthy individuals, and 2) testing on a small group of patients, to test the product function, usability and design. When it is time for validation of a larger group of subjects, the Medical Products Agency's (Läkemedelsverkets) rules for clinical investigations of medical devices should be applied as usual.

The rules concerning clinical investigations for medical devices, issued by the Medical Products Agency, can be seen as too encompassing in the very early phases of medical device design and development. The medtech industry is in need of a simplified instrument, based on self-assessment, in line with the National Board of Health and Welfare Regulations (Socialstyrelsen, SOSF 2008:1) on the Use of Medical Devices in the Healthcare System.

The natural demands on such an instrument is compliance with the critical requirements in the Medical Products Agency's Medical Devices Directive (LFVS 2003:11) in combination with a smaller exposure towards humans, confined to the activities within a single clinic. Thus, high patient safety is ensured at the same time as the medtech industry is given the opportunity to more effectively, in collaboration with healthcare providers, develop new medical devices. Governmental requirements on transparency and traceability are met through documented self-assessment and the Medical Products Agency's rules are then applied formally when clinical investigations are needed for larger subject groups.

With the intent to raise Sweden's innovative capability, the medtech industry and its professional association are recommended to initiate a dialogue with the Medical Products Agency about a simplified, self-assessment process that is harmonized with the National Board of Health and Welfare's Regulations (SOSF 2008:1) on the Use of Medical Devices in the Healthcare System.

REQUIREMENTS FOR A SIMPLIFIED PRE-CLINICAL PROTOTYPE STUDY

Pre-clinical prototype studies for medical devices shall, via self-assessment, meet the requirements for CE marking as governed by the Medical Devices Act (SFS 1993:584). The prototype in such a study does not require a CE mark, but should, if possible, have an identification number and a Swedish manual.

Manufacturer responsibilities:

The manufacturer needs to make sure that all documentation for design, manufacturing, use, and evaluation is accessible to the Medical Products Agency. The manufacturer shall attest, using a similar form as in Appendix 1 of SOSF 2008:1, that the prototype in applicable areas meets the critical requirements of the Medical Products Agency.

Healthcare provider responsibilities:

The healthcare provider needs to make sure that there are no higher demands set for the prototype's safety and applicability than there are on CE marked products, and that there are certain routines in the management system with regard to the pre-clinical study – similar to the routines for self-assessment of medical devices.

Clinical department manager responsibilities:

The head of the clinical department needs to state the purpose, scope and timeline of the pre-clinical prototype study. Further, he/she needs to confirm the risk, according to the National Board of Health and Welfare's handbook for patient safety. If the manager sees a need for an ethical review, he/she is responsible for getting such permission. The manager shall also, in writing, confirm that the pre-clinical prototype can be tried on human subjects, and make sure that subjects are provided with adequate information about the prototype and its use, so subjects can agree to taking part in the study with the understanding that there is traceability to the department and the patient.



Platforms for collaboration

INNOVATIONSPLATSEN, KAROLINSKA UNIVERSITY HOSPITAL

Innovationsplatsen officially opened its doors on January 1st 2011, with the goal of developing and coordinating Karolinska's contacts with the business community, particularly in the medtech field. Ultimately, the aim is to run R&D projects in collaboration with the medtech industry to achieve greater patient safety, new methods of treatment and more efficient care processes.

Innovationsplatsen coordinates and creates contacts between partners in the business community on the one hand and Karolinska's various departments on the other. All of Karolinska's departments, both in Solna and Huddinge, will be accessible for collaborations with corporate actors, provided that these collaborations fall within the scope of Karolinska's goals and its formal and legal competence.

If the collaboration project calls for it, Innovationsplatsen brokers and facilitates contacts between the Hospital's departments and other parts of the Stockholm County Council.

Through Innovationsplatsen, Karolinska enables access to patient documentation, care chains and care processes, infrastructure equipment and hospital staff of all categories, including leading experts.

Innovationsplatsen works to strengthen the triad Healthcare – University – Business in all the collaborations that it initiates and supports. This means a constant drive to broaden collaborations between Karolinska and the business community to encompass Karolinska Institutet, the Royal Institute of Technology (KTH), and other universities and university colleges.

Platforms for collaboration (cont.)

REGION SKÅNE

Region Skåne's internal innovation work is decided by the Regional Executive Committee, and is focused on finding good ideas among the organization's staff – ideas that can lead to effectivization and improvement of Region Skåne's activities. The internal innovation work is led by Region Skåne's Innovation Group, which receives staff ideas and makes decisions about how to best develop and manage those ideas. Below are three companies that are fully owned by Region Skåne, with the objective to support the development of innovations within the region's healthcare system.

Innovator Skåne AB

Fully owned by Region Skåne, Innovator Skåne's purpose is to support the development of innovations coming from within Region Skåne. It is built on the idea to facilitate and support development of innovation projects, support the establishment of new companies and license collaborations that can be created around inventions, and to manage the innovations that the companies own.

ClinTrials Skåne AB (Skåne Medical Research Centre)

ClinTrials Skåne, fully owned by Region Skåne, offers an infrastructure for clinical research and trials within healthcare, making it attractive for companies and researchers to conduct clinical trials. The company is based on the idea to facilitate and support companies from the pharmaceutical and medical technology industries to conduct clinical trials within Region Skåne and its medical practices.

Skåne Care AB

The company, fully owned by Region Skåne, develops and performs healthcare export activities, including management, customised training programmes and services within the healthcare area. It is based on the idea to, by itself and in collaboration with other partners, perform healthcare development on an international healthcare arena.

Medical simulations as innovation facilitators

At **Practicum - Lund/Malmö Clinical Skills Centre**, healthcare staff and students participate in training programs to attain clinical skills. The objective is both the training of manual skills and of teamwork and communication with relation to patient safety. However, simulation capabilities can also be crucial to facilitate collaboration on future innovations.

For example, Practicum has the capacity to offer the manufacturing industry a unique opportunity to explore how medical devices support or hinder the interaction between staff and patients in realistic healthcare situations. The patients at Practicum are simulators, so regardless of the trial results patient safety is never at stake. The product developers can use simulations to get valuable insights about what is working well and what needs to be improved in a certain use situation.

For example, this can be achieved by allowing a selection of staff members or care teams to test a prototype. The test can be video-recorded and healthcare staff interviewed after the test so they can share their experience and reflections about the prototype. The developers can very easily adjust the prototype based on the feedback, and quickly perform new tests with the improved prototype.

The Skills Centre offers the following simulation environments:

- Full-scale patient simulation with a number of patient simulators, adult as well as pediatric and infant models
- Simulators for manual clinical skills such as endovascular, laparoscopic, endoscopic and eye surgery simulations

Simon – one of the full-scale patient simulators

Simon is a full-scale patient simulator. The major benefits are that *Simon* both talks and reacts as a patient would. He can have various medical conditions and be given different physiological profiles or complicating primary diseases.

The staff members that are going to practice or test a certain situation with a new medical device, receive background information about their patient. Then, pre-defined scenarios are run, such as an operating procedure where a complication arises, or a trauma case. Those practicing or testing on the patient simulator perform diagnosis and treatment on the “patient” just as

“The patient is a simulator, so regardless of the trial results we can never hurt a patient. The product developers can use the simulations to get valuable insights about what is working well and what needs to be improved in a certain use situation.”

they would in a real situation, using injections, IV drips and other actions. They receive information via the medical devices that are attached to the simulator model. Everything that happens in the room is video-taped and all treatment procedures are registered and saved in the computer. After a practice run, there is a debriefing session. It is possible to repeat the exercise or further improve it as needed. Only fantasy sets limits for how *Simon* could be used for collaborative product development by industry and healthcare stakeholders.

Pediatric simulations

Simulations are also very useful in educating healthcare staff in taking care of newborn infants with asphyxia (oxygen deprivation). In these courses, teams that are to handle these situations are trained in a realistic, simulated environment using infant simulation dolls.

The education is based on hands-on training in realistic cases where the infant is the center of attention. The importance of organization, leadership and communication is highlighted. The exercises are video-taped and followed by feedback and discussion.

Endovascular simulations

Atherosclerosis can occur anywhere in the vascular system, and an important treatment method is angioplasty. This involves mechanically widening a narrowed or obstructed blood vessel through the use of balloons, often combined with a stent, which is a permanent placement of a small wire mesh tube to help prop the artery open and decrease the chance of it narrowing again.

With the help of simulators, specialists-in-training can get valuable practice in these procedures, without having to risk harming patients and without having to use animals or cadavers in the training or testing process.



You and your partners belong to different cultures

Collaboration projects that include participants from different areas (healthcare, medtech industry and academia, for instance) come with an added difficulty: cross-cultural communication.

We need to keep in mind that some central concepts do not mean exactly the same for all participants: “user”, “innovation” and “result”, to name a few. Also, ideas that seem specific to researchers might, to healthcare practitioners, be experienced as detached from reality.

DIFFERENT TIMELINES

One of the most problematic aspects of this kind of cross-cultural collaborations is time. Three years is a short time span for a researcher whereas it might be long for a healthcare practitioner and next to imponderable in the corporate world. The following excerpts from interviews with participants in the project are revealing:

Academia: Three years is sufficient for a project like this; it’s a normal length for a research project. You can’t do much in a shorter time. Maybe it should be a couple of years more so that there is more time to test other things.

Industry: It’s hard for us to work on such long term; three years is a long time and this is really a challenge to InnoPlant since time gets

so fragmented as you work in parts and it becomes secondary. And when such a long project is not clearly defined it gets even harder. We understand that the researchers want to study the process, but in our world it gets difficult; innovation is a vague concept and it’s easy to lose focus in such a long term project.

Public healthcare: We have a more protected environment and we don’t suffer the same time pressure as industry does. At the same time we can feel that it is a little too long and too quiet between the encounters. There is a cultural difference here; we want more action and academia wants to turn every rock over to make the project last the whole time. There are different views on action and reflection within the project.

DIFFERENT GOALS

Cross-cultural collaboration must also deal with the problem of differing goals. This requires a profound discussion of every participant’s presumptions, practices and expectations.

As participants in InnoPlant have pointed out in interviews, the main interests of each group diverge; companies seek economic profit, researchers create knowledge and the public healthcare sector administers healthcare.

Academia: This is a project of change involving learning; it has to take time [...] It is important to create a time and a space beyond the ordinary everyday practice [...] We also have to consider that it’s important for us to publish results and create knowledge.

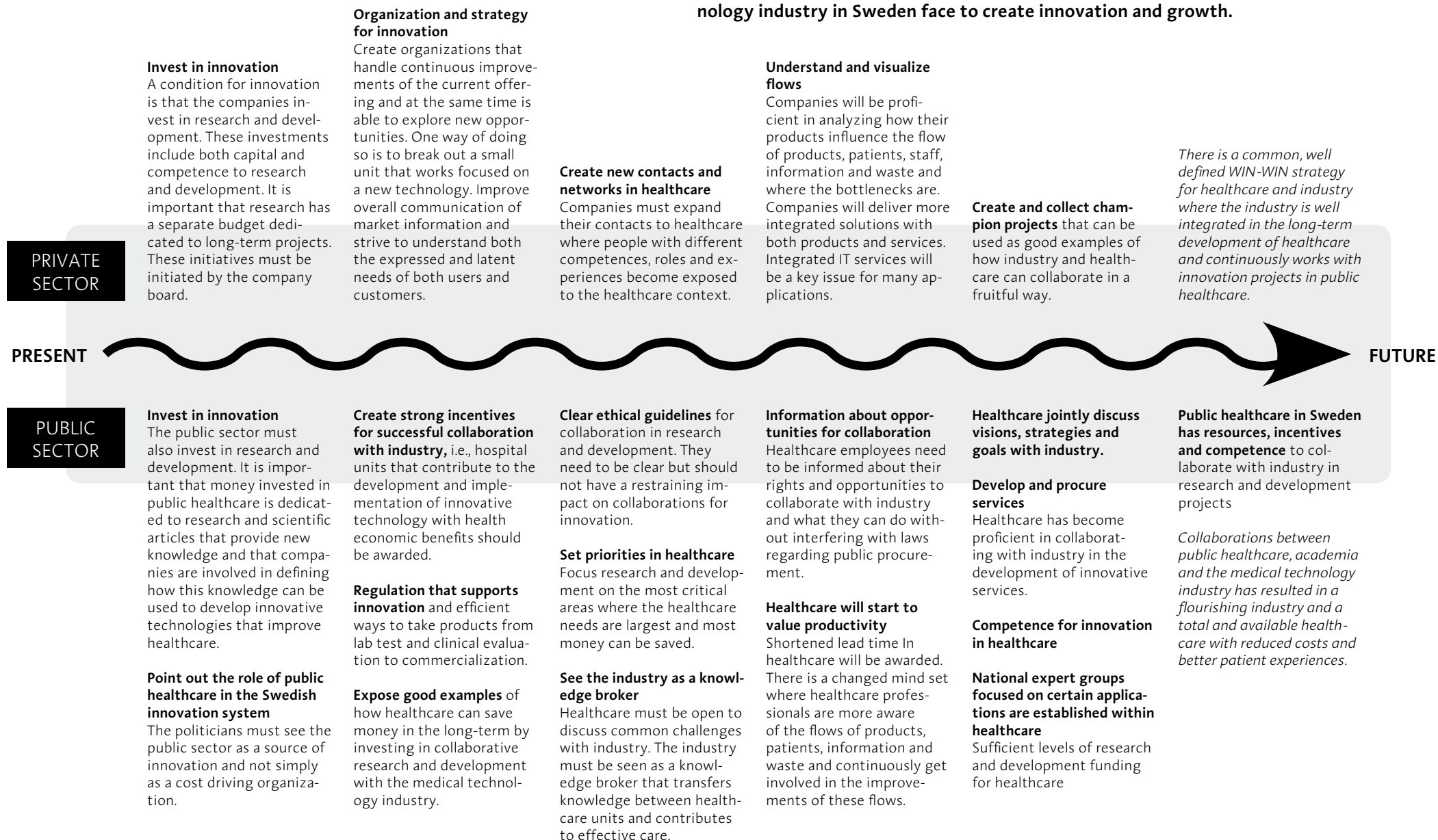
Industry: From the beginning, the purpose was very ambitious. It is hard to see what we can change and how we should measure it. It becomes more of a research study, but maybe that’s fine, as long as it is about constructing knowledge; perhaps it isn’t that important to get explicit results.

Public healthcare: There has been little discussion on concrete things and much on theoretical things, sometimes a bit too abstract. The project has been marked by a silent conflict as the academic partners pulled back, wanting to study the process rather than taking part in the cooperation. There was also a conflict at the beginning as the industry regards us as customers.

So remember, you and your collaboration partners come from different cultures and speak different languages. Every hour spent at the beginning formulating the group’s expectations will pay itself back during your collaboration.

A roadmap for innovation

Within the InnoPlant project, roadmaps were developed to create a shared understanding of the challenges that the healthcare and the medical technology industry in Sweden face to create innovation and growth.



CONTRIBUTORS TO INNOPLANT

Region Skåne | www.skane.se

Jonas Johansson
Bertil Lindström
Stig Wiinberg, Innovator Skåne AB

Stockholm County Council | www.sll.se

Thorbjörn Ekström
Björn-Erik Erlandsson
Kristina Groth
Reidar Winter

ArjoHuntleigh | www.arjo.com

Mikael Berg
Hans Lingegård
Alex Myers
Zlatko Rihter
Charlotte Öljemark

Getinge Infection Control | www.getinge.com

Jerker Funnemark
Jan C Nilsson
Peter Palmqvist
Klas Rudbäck
Christer Ström
Magnus Ufvenfeldt

Maquet Critical Care | www.maquet.com

Ulf Andersson
Dan Rydberg
Göran Rydin
Jens Viebke

CTMH | www.ctmh.se

Bertil Guve
Erik Pineiro

Lund University | www.lth.se

Susanna Bill
Mikael Blomé
Andreas Larsson
Annika Olsson
Per Odenrick

Royal Institute of Technology | www.kth.se

Jenny Janhager Stier
Margareta Norell Bergendahl
Carl Wadell
Gunilla Ölundh Sandström

Södertörn University | www.sh.se

Jenny Ingridsson
Mats Lindqvist



Investing in your future



EUROPEAN UNION
European Regional
Development Fund



www.piep.se