SHINE Project –
The manual on propelling innovations in regional healthcare systems in the North Sea Region

How the healthcare domain can be innovated from the inside out

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The manual on propelling innovations in regional healthcare systems in the North Sea Region: the summary

This report is one of the main deliverables of the SHINE project. SHINE is an acronym for Shared value creation in the Healthcare economy through INtegrated business modEls. It is an Interreg North Sea Region project (NSR). Within the SHINE project, researchers aim to study and realize regional healthcare economies in the NSR, these include, amongst other countries, Denmark, Belgium, Norway, The Netherlands, the UK and Scotland. In order for the healthcare sector in the NSR to profit from innovative ideas, and to create new opportunities for innovation in these regions, it is essential to learn from existing models and best practices with regard to innovation, across sectors and countries. Therefore, this report aims to be a handbook for regional ecosystems. One of the central issues under investigation in the SHINE project is how we can increase valorization of products and services that stimulate health & healthy living, how different stakeholders involved in the healthcare economy can be supported, and identifying and improving the role of specialized healthcare suppliers is in the process of healthcare innovation. The report consists of five chapters that are the result of extensive literature studies and field work, including case analysis and a breakdown analysis of regional economies.

The overall aim of this report is to support innovation in the healthcare economies of the NSR regions. Hereto, the report proposes a pragmatic (non-systematic) exploration of current innovation models and theories that may apply to the healthcare sector in general and to regional healthcare economies or ecosystems (Chapter 2), an in-depth analysis of the current healthcare landscape in three regions in the NSR (West-Flanders, Scotland and South-Holland) (Chapter 3); an inventarisation of exemplary cases of innovations in regional healthcare systems (Chapter 4), an in-depth analysis of essential building blocks for innovation in healthcare systems and recommendations for the application of these building blocks within the 3 selected regions (Chapter 5), and a final conclusion (Chapter 6).

Contents

1. Purpose

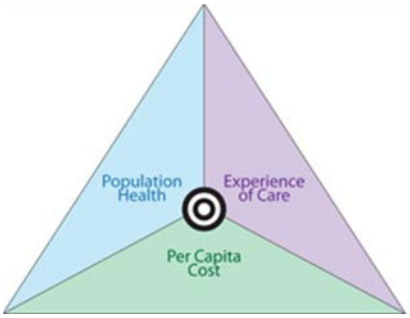
1.1 Innovation in Western society is changing faster than ever

Over the last 5-10 years, we have seen a tremendous change in how products are developed, systems are implemented, and technology is engineered (1). A major driver of this change relates to how new products, services and technological developments are funded (2). For instance, products, services and technology are increasingly funded either by private funds and/or by the crowd (3). Another driver of change is the setting in which innovations are created. The development of products and technology increasingly takes place in ecosystems surrounding small enterprises, startups, and spin-offs or spin-outs of existing companies (4). Such ecosystems consist of various stakeholders, including investors, mentors and potential customers, as well as certain facilities such as physical office space, web-facilities and networking opportunities (5). Such an ecosystem allows for more flexibility and speed in the developmental process, freedom of creation, a direct relationship between developers and consumers, which altogether lead to an accelerated level of innovation in our societies (6). The new innovation paradigm significantly differs from the previously established research- and development processes. Traditionally, development processes took place within R&D departments of large companies, rather distant from customers and (local) SME. Additionally, the availability of many products and services used to be driven by government- or industry-demands. End users and consumer-demands hardly played a role.

1.2 Innovation in healthcare is changing too

The traditional development process is still particularly present within the healthcare sector. In most Western countries, the healthcare sector is largely funded by the government through taxes, and partly by consumers who contribute to the system through their insurance policies (7). This process allows for linear innovation to take place at a moderate pace and with considerable limitations regarding developmental creativity, funding and implementation (7,8). In practice, we see healthcare costs have been rising since years, due to healthcare privatization and inflation but also due to the ageing population and a rise in number of people with chronic diseases. Luckily, we have also seen an in increase in quality and client perception. However, in recent years the costs have risen too fast and the costs and benefits have not been shared equally among stakeholders. Some gain more, where others lose too much or gain too little. This makes the healthcare systems and solidarity in health vulnerable. As a response, we now see healthcare systems, on local, regional and/or country level introducing “triple aim” (13).

Three aims that need to be met coherently and in cooperation by all local partners involved in the healthcare system: improved population health, improved experience of care and decreased per capita cost. This creates a new perspective for innovations in health.



Another change in perspective has been introduced. Especially related to the ageing population and increase of lifestyle related, chronic diseases. These trends have placed emphasis on the question: “How can we prevent or reverse diseases or how can we adapt and self-manage them when they are not preventable or reversible?”. This perspective led to the introduction of the new definition of

health “as the ability of an individual to adapt and self-manage in the face of physical, societal or mental challenges” (14). This new definition aligns very well to all new opportunities technological innovations are offering to personalize products and services for health and wellbeing and allow for timely support.

1.3 Healthcare innovation ecosystems are not yet meeting expectations

Over the past years, the context of Western healthcare in general has transformed, with new roles for professionals and consumers (patients) (9). For instance, in the North Sea Region (NSR), which includes (parts of) Norway, Denmark, the UK including Scotland, Belgium including West-Flanders, Germany, the Netherlands, and Sweden, significant changes have been made in the structure of health insurance systems (9,10). The most radical changes include the (partly) privatizing of hospitals and the introduction of new types of health insurance policies. And with the introduction of Triple Aim, shared values are more under debate in healthcare. Innovations that render both economic value and societal value. Michael Porter of course also introduced value based healthcare, where all activity in healthcare processes should add value to what matters to the patient or consumer.

With these changes, both professionals and consumers in healthcare were to be empowered in their choices for innovation and use of healthcare. For instance, hospitals may compete with other facilities by specializing in certain areas of expertise. Also, consumers may choose which types of care they would want to pay for, to a certain degree, in exchange for reduced healthcare contributions.

Although the extent of these changes within the healthcare system differed between countries in the NSR, they were all predominantly driven by economic change, the hypothesis being that the healthcare sector would flourish, both in productivity levels and in economic benefit and self-reliance. These and similar developments can be viewed in the light of a diminishing social welfare state within Northern-European countries, and the introduction of a less patriarchic social system. These systems emphasize an approach that includes more responsibilities regarding health and (work) participation for each individual under its care.

Also, more specifically, it was expected that redesigning funding of healthcare could stimulate the development of innovative products, services and technology from the inside out, as opposed to traditional developments conducted by tech or service companies outside of healthcare. However, since then, the expected acceleration of innovation processes in healthcare has been marginal, at least compared to other sectors in which the sector’s structure and funding procedures have been re-invented (11).

1.4 This report discusses how regional ecosystems can improve

In order for the healthcare sector in the NSR to profit from innovative ideas, and to create new opportunities for innovation in this region that create shared values or Triple Aim, it is essential to learn from existing models and best practices with regard to innovation, across sectors and countries. Therefore, this report aims to be a handbook for regional ecosystems.

This report is one of the main deliverables of the SHINE project. SHINE is an acronym for Shared value creation in the Healthcare economy through INtegrated business modEls. In is an Interreg North Sea Region project. SHINE aims to study and realize regional healthcare economies in the North Sea Region (NSR). One of the central issues in the project is how valorization of products and services stimulating

health & healthy living can be stimulated, by supporting the different stakeholders involved in the healthcare economy, with a special focus on healthcare suppliers.

The report is developed to support innovation in the healthcare economies of the NSR regions. The overall goal is supported as we map obstacles, opportunities and examples of innovation in healthcare in the report. In the following chapters, we explore several generic models for innovation, extract building blocks and key elements for innovation processes in the health domain, we provide a regional analysis of Scotland, West-Flanders and South-Holland to map opportunities for innovation in their health domain, we analyze and discuss exemplary cases of innovation in the healthcare domain in these regions, and we provide recommendations for stimulating innovation in each of these region. As innovation processes in the healthcare domain are young, growing and expanding rapidly, this report does not provide a blueprint for innovation in each region. Rather, it aims to inspire stakeholders and entrepreneurs that look to innovate within the healthcare domain within the NSR region.

In closing, with the report we propose a pragmatic (non-systematic) exploration of current innovation models and theories that may apply to the healthcare sector in general and to regional healthcare economies or ecosystems (Chapter 2), an in-depth analysis of the current healthcare landscape in three regions in the NSR (West-Flanders, Scotland and South-Holland) (Chapter 3); an inventarisation of exemplary cases of innovations in regional healthcare systems (three examples in Chapter 4, additional examples in the Annex), an in-depth analysis of essential building blocks for innovation in healthcare systems and recommendations for the application of these building blocks within the 3 selected regions (Chapter 5), and a final conclusion (Chapter 6).

2 Models for innovation

2.1 Innovation models are changing

The business model of the traditional innovation process where large companies develop new products in their own R&D lab is no longer successful. The enormous pace of technological developments and disruptive nature of innovation leads to an on-going demand for new products and shorter product life cycles. If we close our eyes and think back to hospitals and healthcare a few decades ago, we can easily understand the enormous effect that technological innovation has had on healthcare. But innovation over the past years has not been limited to technological innovation. We also see major social and cultural innovations. The importance of these innovations and the velocity at which they are developed will only increase in the coming years. In this chapter, we will introduce a model that fits to this new nature of innovation. And explain how it goes beyond the traditional models of innovation and how regional ecosystems can support it. We start with a short description of the meaning of technology, innovation and valorization.

Technology is a frequently used term. Today 'technology' is mostly associated with complicated machinery. Yet, tools to make everyday life easier are of course ancient. As the availability of technological innovations increased, simultaneously countries in the NSR and their citizens have become dependent of technology. This is also true for the healthcare sector, where we see an enormous amount of high-tech for complex processes in e.g. operating theatres. Moreover, new easy-to-use technological products are being developed for everyday health (-care), such as wearable health devices including smart watches.

Essentially, technology is about products that combine knowledge with identified needs or opportunities to improve lifestyles. From this perspective, innovation driven by demand is incorporated in the innovation process. Yet, we also see that technology is pushed from its autonomous possibilities, i.e., purely in the interest of technological advancement. Also, the revenue model for a certain technology can push market access. For example, in the pharmaceutical sector, where it is often debated whether the cheapest and most useful product is placed in the market.

Innovation goes beyond the core development of a product and its technology. Innovation is about how the technology is renewed, updated or improved and especially about how the technology is embedded in society to impact and progress use and results. An idea can be ever so brilliant, if it is not used successfully, we cannot call it an innovation. And the more it is used, the more successful the innovation is.

The commercial exploitation of new knowledge and innovations is called valorization. The SHINE project is about valorization of innovations in the healthcare economy, with emphasis on shared benefits for all partners involved in the innovation process; particularly healthcare organizations and other public organization, as they are often left out of valorization. To support such partnerships and valorization, it is important to take a closer look at models for innovation, as well as barriers and facilitators for healthcare innovation.

2.2 A model offering a new perspective on innovation in health

It is clear that, in order to propel innovation forward in the healthcare sector within the NSR, we could use a new perspective on innovation in health, for two reasons. First because healthcare costs keep rising and technology and innovation play a part. Second, because the perspective on health is changing, due to new scientific insights. In this chapter, we introduce the Cyclic Innovation Model, which offers such a new perspective (12).

The former innovation models most often perceived innovation as a linear process. That is, first something is invented, and then it is tested and adjusted, then made and finally sold with sufficient return on investment. During the last decades, however, we have seen velocity being introduced in this model, as well as market pull. Yet we also see that current society is diffusing the model and making it more non-linear. We see more open and non-sequential innovation.

Here, we introduce the Cyclic Innovation Model (CIM) by Berkhout et al (12). One of the main differences between the traditional linear model for innovation and the cyclic model, is that the traditional model describes an innovation process driven by technological developments (referred to as 'technological push'), while the cyclic model incorporates the increasing demand of customers and the development of new networks around innovations (referred to as 'market pull'). In the cyclic model, the potential customer can be involved in the innovation process from the start, while in the linear model, a product or service will go through numerous rounds of refinement before it reaches the customer. The cyclic model of innovation fits very well into the general increase of innovations that occur outside traditional R&D facilities. That is, the model describes an open process where various stakeholders and resources can catch on throughout the innovation process. Moreover, it resembles the reality of many innovative ideas nowadays, where a network and environment starts to evolve around such an idea, with many parties looking to contribute to, and profit from, the innovation. Also, the model describes several types of activities that go hand in hand with the type of innovation that is required, for instance applied research matches with technological innovations.

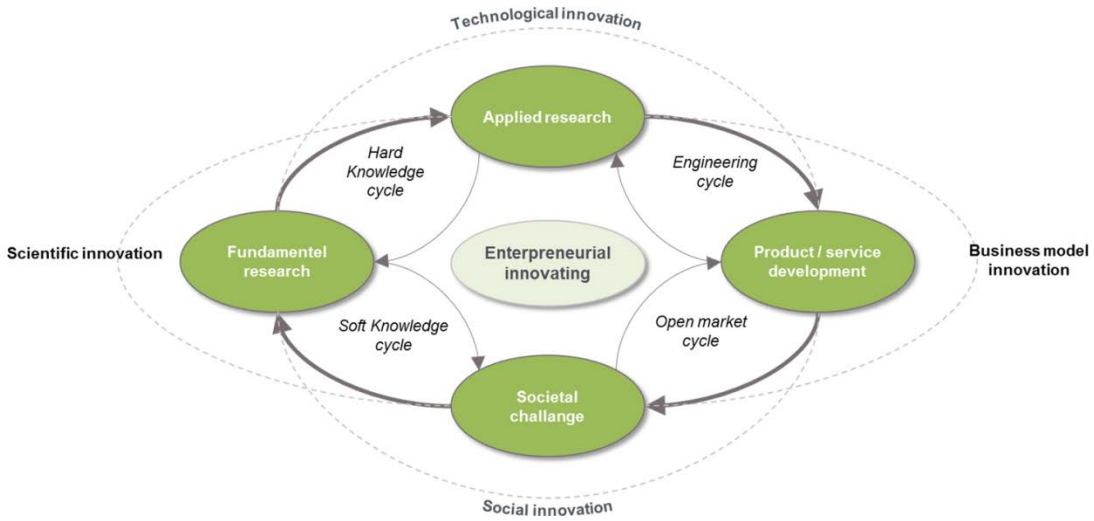


Figure 1: Cyclic Innovation Model; *Based on: Berkhout G., Duin P. van der, Hartmann D., Orit R. (2007) The cyclic nature of innovation; connecting hard sciences with soft values. Amsterdam: JAI Press (6).*

CIM shows that innovations can have many starting points; not just technology. Because it brings together four quadrants/types of stakeholders that co-exist in many healthcare systems. The upper part of the model represents “hard science”, divided in fundamental research and applied technologies. The dynamics of technology developments is cyclic and driven by both scientific insights and new product-service specifications. The lower part of the model represents “soft science”, divided in (psycho)social and behavioral science and market and marketing technologies. Innovation processes can start at any of these quadrants. CIM also allows us a better understanding of innovation processes; where and how things can go wrong. The model shows technological and social innovation are both necessary for innovations that impact users. Also, it shows that business model innovation and scientific innovation too are necessary to ensure innovation has impact and measure that impact meaningfully. Cutting the model in half (vertically or horizontally) we see what often goes wrong in innovation processes in practice. A gap between technology push and market pull, between a build product and users that do not know why to use it or how to use it well. Or a gap between theory and practice, between knowledge and too little valorization.

Finally, CIM makes clear which parties are required to develop and implement innovations. By its design, CIM shows a stakeholder analysis framework. In each quadrant, we can analyze which actors are or should be involved. Also, we can see if one or more quadrants are too dominant and whether new or other actors are required to balance partnerships or accelerate the innovation process. Then it becomes all about “who do we need for success” (instead of “who wants to join”). This way, innovation is about creating entrepreneurial partnerships (12). This way, the CIM offers a refreshing theoretical approach to healthcare innovations. To successfully translate the CIM to an approach that facilitates innovation in the healthcare sector of the NSR, it is important to get ahead of generic barriers and facilitators in healthcare innovation processes.

2.3 Key barriers and facilitators for innovation in healthcare

In 2006, the Harvard Business Review Journal closely examined healthcare systems, and identified the main factors that are important for healthcare innovations (11). These factors are crucial to a point that their presence or a lack thereof can either drive or smother innovative processes in the healthcare sector. These factors will be discussed in this paragraph.

The first make or break factor are the players in the field. In the healthcare sector, there are many players at the table, who each have their own agenda. In order for an innovation to thrive, it must match these agendas, or be so disruptive (highly innovative) by nature that the agendas of others will be adjusted to it. The players are also often the ones who hold at least part of the funding, such as healthcare insurers. Related to the players is the level of evidence that is required by professionals in the healthcare sector. In this domain, professionals are used to be convinced by evidence provided by experimental studies such as randomized controlled trials. This traditional train of thought can prove a serious barrier for innovation processes to take place. It is therefore worthwhile to consider the mindsets and convictions of professionals as stakeholders in an innovation process. Conclusively, a stakeholder analysis that maps out the relevant stakeholders and their interests is essential for healthcare innovation.

The second factor is the funding process, during which revenue must be generated, capital must be acquired, and many different parties are involved. Moreover, there are two processes of funding that need to be arranged for when it comes to healthcare innovation. First, initial funding is needed for

bolstering the innovation process. Second, it needs to be determined who will eventually and continuously pay for the innovation once it is available. Particularly in healthcare, this is usually not the customer (patient), which complicates the development, as well as the implementation, of healthcare innovations.

The third factor is policy, described as 'The regulations that pervade the industry, because incompetent or fraudulent suppliers can do irreversible human damage.' The main problem with policy is that healthcare is regulated by law, which is sturdy and hard to change by nature. Therefore, the hands of many stakeholders in the innovation model can be tied, and regulations may prevent the innovation from development to another level. Especially in healthcare, it is essential to examine where the innovative product or service will match in the current healthcare system, including the match with current (patient) safety procedures, as changes in healthcare policy are slow and unpredictable, which will kill the innovation.

The fourth factor is technology, from which most advantageous innovations with regard to treatment improvements and healthcare delivery can be expected. The main important aspect of technology seems to be timing: an infrastructure should be in place in order to support the innovation, which needs to be developed thoroughly and not hastily. However, there is always the risk of other innovations catching up with your idea, and therefore, an innovation should also try to develop as fast as possible. This is an everlasting battlefield with regard to development and timing, and the timing of the innovation should be discussed in an early stage, as well as an exploration of the presumed competition. For most innovation processes in the healthcare domain, the second phase is known to be the problem. In the first phase, funding is acquired from grants or governments. However, after this phase, an idea or product needs to be further developed and implemented, and it is difficult to obtain funding in this second phase. That is why this phase is often referred to as 'the valley of death' when it comes to innovation processes. It is key to start looking for investors for phase two while still solidly operating in phase one.

The fifth factor are the customers, a group who is rapidly changing in terms of empowerment, increased level of education and healthcare literacy, and decreasing levels of trust and reliance upon doctors and other professionals. The availability of the internet, amongst other things, has greatly contributed to this development. This may make the market for a healthcare innovation unpredictable. However, it may also provide opportunities, e.g., customers may be engaged in the product from day one, as proposed by the cyclic innovation model.

The sixth factor is accountability, described as 'The demand from vigilant consumers and cost-pressured payers that innovative healthcare products be not only safe and effective but also cost-effective relative to competing products.' Increasingly more stakeholders demand measures of effectiveness, such as health technology assessments or other effectiveness evaluations to prove an innovation is worth investing in. Moreover, particularly in healthcare, patient safety should be guaranteed. However, such requests are directly in conflict with the process of cyclic innovation, including customer engagement in the developmental process, and startup, try-out and scale-up of the innovation. In other words, accountability is a grey area with regard to innovations, and it is important to keep in mind that accountability is highly related to perceptions. Once the idea is suggested that an innovation is unsafe or not evaluated properly, or unproven and not evaluated, policymakers, the customers and healthcare regulators may be skeptical about the innovation, and the chance of success diminishes rapidly.

These are the six forces that are important for healthcare innovations, which all need to be addressed and managed intelligently. If not, they are likely to create obstacles for the prosperity of an innovation with regard to the technological aspects, the business model, or the customer-aspects. For the NSR, these factors are important to consider in order to obtain a new, successful perspective on healthcare innovation (11). Moreover, most innovation processes in the healthcare domain are currently initiated by entrepreneurs outside the healthcare sector. There needs to be a balance between innovation from within the sector and from without the sector.

2.4 Ecosystems for innovations

Clearly, the above has made clear that innovations do not just surface and offer successful solutions to existing problems. And clearly, those entrepreneurial partnerships do not just arise. For most innovations and partnerships to originate, grow, and mature, a supportive environment is necessary. An environment where people and organizations find and get to know each other, can experiment together. This is what is called 'an ecosystem' (6,15).

An ecosystem is an environment in which one or multiple stakeholders join forces, take risks, and hope to gain from innovative ideas and hard-working entrepreneurs (16). Depending on the type of innovation and the type of sector, different requirements can be made from stakeholders and resources within an ecosystem. Although these differences may be extensive, there is one common characteristic that is shared between most ecosystems for current innovations, and that is that these ecosystems are generally artificial by nature. That is, these ecosystems are generally more supportive towards entrepreneurship compared to regular business settings.

Increasingly more innovative processes occur outside the traditional in-company ecosystem, and within new types of well-designed ecosystems. These are often organized as or referred to as incubators, accelerators, startup labs or business boot camps. The goal of such systems or programs is to create an optimal environment for the developmental growth of innovative ideas and the translation of these ideas into practice or products that can be valorized.

Within incubator- or accelerator-like programs, new ideas from different origins are generally nurtured in an actual physical environment, where entrepreneurs discuss their ideas, develop a plan for production, practice, and valorization, and explore the market of potential consumers and investors. The number of startup generating programs has increased tremendously over the years.

Estimates are that there are currently circa 300 of these programs in the US alone (17). Although some of these startups are rooted in areas with an idea-generating environment, such as Silicon Valley (US), the trend of supporting entrepreneurs in a professional way has spread across the globe. Especially over the last six years, startup programs in Europe have gained the attention of public and private investors, and currently billions of Euro's and dollars are being invested in promising ideas. To illustrate, Forbes has started publishing an annual list of the 50 hottest startups of the year, and trophies are being awarded to programs with the highest success rate in survival or in investments collected.

Startup programs are available for a variety of sectors nowadays. The most prevalent one is the technology sector. But more and more, we also see programs targeting opportunities for innovative ideas for sectors like healthcare, energy, and web communications. Across the sectors, we see a variety of program types, ranging for the discovery of new ideas and startups, to launching startups and new

ventures through their first phase of business modelling and storytelling, to incubator and accelerator programs that support startups in their growth. The different programs target one area of expertise, for which they offer a tailored ecosystem. For instance, single boot camp days are hosted for wannabe-entrepreneurs with a vague to relatively clear idea for innovation in their area. Once an idea is more matured, persons can enter a program in which office space, meetings with investors and potential customers, and mentorship are offered, and dedication in terms of time and money are required. Usually these programs last for several months, after which potential entrepreneurs are asked to decide whether they are going to take the leap, or whether they need to get back to the drawing board.

Entering an innovation program for startups, though it comes with certain boundaries and requirements, is not a fixed deal per se. That is, especially during the more intense program, the original idea can be developed, transformed, or even exchanged for a better idea. And even then, there is no guarantee for success. In fact, many papers and articles have been dedicated to the fact that many promising startups eventually fail to gain sustainable funding or income, or find that their product or service is not robust enough to survive in the real world. Also, we see different payment models for different program types. For instance, a 1-day discovery program demand pay for service. But some incubator programs have a pay-for-performance model, where startups pay only when the have reached a performance indicator related to financial investment.

To learn from past successes and failures in the past, chapter 4 will discuss a few interesting examples of innovation in healthcare. Both from the perspective of successful startups in the NSR as well as from startup programs in the NSR.

Related to this, it should be mentioned that there is an immense increase in the number of start-up facilitators, incubators and academies. These are all focused generally on phase 1 innovations. However, as mentioned previously, the tricky part is phase 2, where, if no investors are found, innovations end up in the so-called valley of death. Therefore, so-called accelerator programs aimed at phase 2 are tremendously important for sustainable innovation.

2.5 Regional ecosystems

The above-mentioned programs can be local, national or even international. But, more and more innovation processes take place in regional networks, often referred to as regional ecosystem. These ecosystems are (open) innovation networks which are increasingly flexible and agile to adapt to new technological developments and market developments.

In a region stakeholders join forces around a specific goal and/or sector for better and more meaningful/impactful innovations. These stakeholders are large and small companies, research organizations, universities and regional governments. Together, they create an open collaboration network for innovation in which they interact, collaborate and share skills and resources to create value. These networks can be an offline and online platform. Social partners play a vital role in the regional stakeholder landscape. They often offer living lab or test bed facilities to co-create and embed innovation in real-life. So, aligned to the CIM model, regional partners for business model innovation, social innovation and scientific innovation are equally important as technological innovation partners (6,12).

The regional context defines which partners have easy access to the ecosystems and shared values. Also, the regional context defines which parties are present and what are the regional challenges. We see regional ecosystems choose a smart specialization strategy fitted to these contextual elements. The stakeholders together set up programs and activities to realize the ambitions of their strategy. Having a clear and focused core contributes to the success of the regional ecosystem. This will not be easy however, since regions are often home to large institutes each with their own norms, values and culture.

In today's regional innovation ecosystems, we see an increased focus on the emerging of new ventures like startups, scale-ups, spin offs, joint ventures. Figure 2 displays an example of such a regional ecosystem with a focus on startups in healthcare. Within the context of general national & regional innovation policy and the specific national & regional healthcare system different stakeholders will interact.

New ventures are stimulated, to stimulate the regional economy. Depending on their development stage, the new ventures can highly benefit from a well-organized regional ecosystem. It allows them access to and collaboration with several existing organizations, such as universities, funding organizations, research organizations, service provider organizations (like legal, financial services etc.) and large corporations (16). To optimally support new ventures and the regional economy, regions create ecosystem-driven support programs like incubators, accelerators, co-working spaces etc.

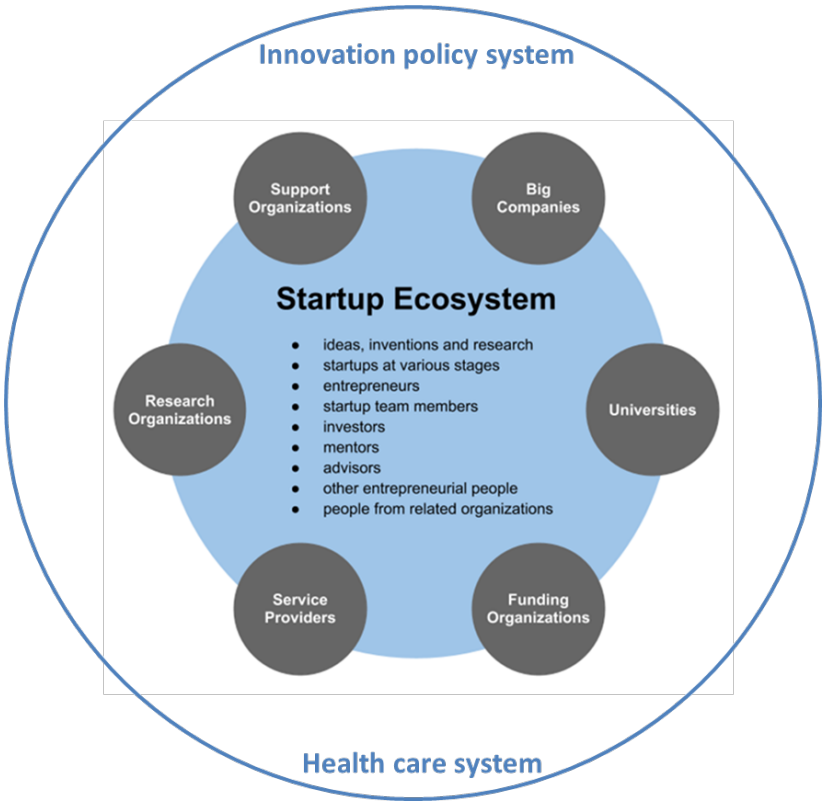


Figure 2. Regional ecosystems (16).

Many reports, books and websites currently discuss what makes a startup ecosystem successful. We already mentioned the Harvard Business Review paper (11). But if you go online, there are many examples to be found of conditional frameworks. Without being complete, we analyzed some of the different frameworks to distinguish essential building blocks or conditions for regional ecosystems to

thrive (18-21). This online search taught us that most frameworks consider similar conditions are essential building blocks to stimulate innovations and the regional economy. The following list of general building blocks describes what these conditions are (21):

1. Entrepreneurs and leaders with entrepreneurial culture: a region needs actors that have and create agendas to innovate or disrupt the present. Regional parties should identify these entrepreneurs and support them.
2. Mentors that are experienced entrepreneurs in corporate or startup companies: to give advice and provide support to new entrepreneurs from people that already have a lot of experience. Mentors can have background in different sectors, like finance, technical, healthcare and science.
3. A regulatory environment supporting new ventures: policy and law should support innovation processes as well as locational advantages for establishing businesses. In healthcare policy and law should also support the establishment of public private partnerships.
4. A collaborative business culture with strong regional networks: end users or consumers should also be part of the regional networks. In healthcare, consumers are changing the demand they place on the system. Also, consumers should be part of the co-creation process of innovation development.
5. Inspirational successes and role models that are visible in the region: regions should show and tell their success stories. These are inspirational to new entrepreneurs. Also, the cases that are successful can serve as examples for new startups.
6. Risk tolerance and not a culture that blames failure: the ecosystem should create a culture that does not blame entrepreneurs who financially fail with their innovation. Often, the rules and risk margins for safety and quality in healthcare are and should be more flexible. Especially in healthcare even the suggestion of unsafe innovations introduces high skepticism (11).
7. Availability of and access to funding/capital (also risk investments): along with funding and capital come rules for return on investment. There are several financial instruments for this. In the healthcare sector the interest in shared value creation is growing, this implies that not only economic value should be returned, but also societal value. Example of these are social or health impact bonds.
8. Talent and technical skills: to develop technology thoroughly and not hastily (11). Talent and skills are required and should be stimulated. To develop and implement an innovation, also social skills and sciences are required, so that the innovation is used and leads to the desired results. Finally, entrepreneurial talent is important. The educational organizations in a region can bring together and further develop these talents and skills in students and link / introduce these students to startup programs.

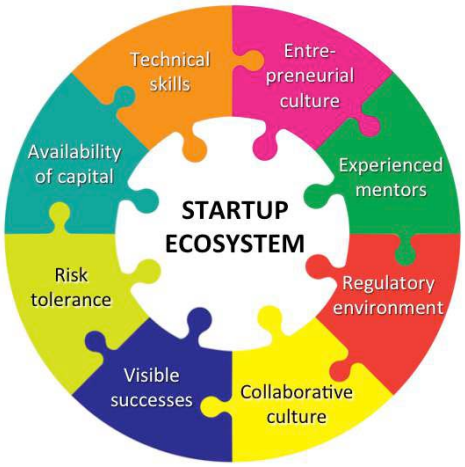


Figure 3 graphically summarizes these general building blocks (21).

Figure 3: General building blocks for innovation ecosystems.

These building blocks can be used as a conditional or guiding framework for setting up a successful regional innovation ecosystem in general as well as specific start up innovation programs. In the next chapter, we will introduce the 3 regions in this SHINE project, elaborate on their stakeholders and specialization strategy as well as on their conditional framework. For the latter, we will more closely look at these building blocks.

3 Opportunities in the North Sea Region

In the SHINE project, we focus on regional health economy ecosystems in West Flanders, South Holland and Scotland. These regions want to learn how they can stimulate new health ventures (startups, spin offs, scale-ups, etc.). To make a fit between what they can learn from where they are now, we first analyzed the current ecosystems in the three regions. Hereto we developed a format that can be found in Annex 1. All regional project partners completed the format for their region. These inputs are also in Annex 1. In this chapter, we will analyze and compare their inputs.

3.1 Health systems and innovation policy

Systems drivers in the three regions are the same. That is, the healthcare systems in the three regions all face the challenge of an ageing population. Also, they experience changes in demand from a population that wants/needs to self-manage more and stay at home longer. And all three want to use the driving force of technology for the benefit of the populations' health, the healthcare sector and the healthcare economy.

The innovation policies in the three regions differ though. This is because of both national and regional policies. Flanders mostly defines its own innovation policy and national policy is not leading. Many regional networks are in place, especially within stakeholder groups, but increasingly in between stakeholder groups. The province West- Flanders stimulates public-private partnerships and cross-sector collaboration in four focus areas. South Holland and Scotland have both strong leading national and regional policies. In South Holland, the national top sector policies have defined Lifesciences & Health a national top sector and stimulates public private partnerships to further knowledge and innovation. Regional policy is set out by the Medical Delta initiative, a life sciences & health network of almost all relevant stakeholders in the regions. For South Holland, the challenge is to create local success and a clear local structure for value adding collaboration. Scotland too has a strong national agenda set up by the NHS. Scotland itself has prioritized communication for its own region. Many different networks and initiatives already exist, and many support facilities are in place. This makes Scotland also a dynamic health innovation region.

3.2 Regional specialization strategy, issues and future challenges

The three regions all have their own specialization strategy for the health economy.

3.2.1 West Flanders

West Flanders has developed a smart specialization strategy for the healthcare economy. This is based on both a typology of local SMEs and the needs of the healthcare sector. It has led to the identification of four major focus areas where West Flanders is particularly well placed to strengthen and to generate new economic activity: build and care, food & health, smart textiles and assistive technology and communication technology. The POM West Flanders strategy focuses on activation, sustainability and scaling up of complex partnerships within these four focus areas.

With this specialization strategy, West Flanders wants to trigger additional economic activities to meet the growing demand for healthcare. The province stimulates system innovation and cross-border

collaboration. Relevant to SHINE, they aim for co-creation between companies, healthcare and research institutions, who currently know each - other insufficiently to achieve successful coalitions. For its regional specialization strategy to be successful, all actors of the quadruple helix model must collaborate more in a structured and systematic way to integrate efficiently and as quickly as possible technological applications in healthcare so that a lasting quality care can be offered in the future.

However, in practice it proves to be difficult to build a more positive entrepreneurial culture (22). Except for two lead production plants, the majority of businesses in West Flanders are small and medium-sized enterprises (SMEs) and they have the tendency to remain small and don't always have experience in working together. The province notices that the flow of new technological innovations is not disseminated well enough and therefore that the implementation of new technology often takes too much time. In addition, there is clearly a trend in healthcare to shift from cure to care at home, which also takes time and resources.

public-private collaborations and liberalization and cooperation between the healthcare sector and the profit sector proves to be difficult in West Flanders. The province struggles to bring together health suppliers, patients, private businesses, government institutions and university colleges. Also, severe regulations currently discourage to commercialize innovative ideas.

Because of different mindsets, there is a lot of work to be done to bridge the gap between healthcare institutions and the profit sector. West Flanders has listed the challenges that need to be tackled for the future development of the regional ecosystem.

- Overall, entrepreneurship and the entrepreneurial culture should be stimulated more, also among healthcare institutions.
- Collaboration between SME's and healthcare institutions needs to be encouraged.
- Entrepreneurial success should have a positive perception. Also, entrepreneurs who fail should nog be haunted by a negative label.
- Another action is to make the administrative process for start–up companies less complex, so that startups will not be discouraged in West Flanders.

3.2.2 South Holland – 071 region

South Holland set up a specific regional partnership for life sciences and health: "Medical Delta". Medical Delta is a network of life sciences, health and technology partners that facilitates innovative cross-disciplinary collaborations in the life sciences and health sector. It was initiated by the scientific community (TU Delft, Leiden University and Erasmus MC). So far, for more than 100 million euro of public-private partnerships has taken place in the region with the help of Medical Delta and in collaboration with over 120 private companies. One of the biggest achievements of the Medical Delta is the foundation of the Holland Particle Therapy Centre (HollandPTC) in Delft, where the three universities of Delft, Leiden and Rotterdam collaborate in innovative research. Also, Rotterdam is one of the six co-locations of EIT Health, the large European consortium to improve the competitiveness of the European healthcare industry, the quality of life of Europe's citizens and the sustainability of the European healthcare system.

Medical Delta primary focus is to organize and stimulate innovative healthcare research and infrastructure and to educate students. Support instruments can be sourcing of funds for projects (from EU funds), project management and coordination, providing research facilities and equipment, and

setting up new connections and collaborations. Medical Delta provides local stakeholders a platform through which they can easily launch collaborations. One of the instruments to encourage and accelerate innovation is by setting up 'Living Labs'. The Medical Delta focus is on six themes: eHealth & Self-management, Imaging & Image Guided Medicine, Interventions & Care, Molecular & Cellular Technologies and Vitality.

Within South Holland, many local ecosystems exist that are linked to the Medical Delta. For SHINE, we took a closer look at the Leiden region, the so-called "071-region", which has a long tradition in Life Sciences & Health. Already existing is the Leiden Bio Science Park, a successful business cluster in life sciences and health with a strong focus on red biotechnology and biomedical therapeutics.

For SHINE, we focus on the 071-region strategy to develop the Center for Vitality (CfV). This CfV was established in 2014 by the local economic board (Economy071). Local science partners are Leiden University Medical Center, Dutch applied research organization TNO, University of Applied Sciences Leiden. Via the local economic board six municipalities are involved, both the local government and end users (inhabitants, employers etc.). Also, Innovation Quarter and HUBspot are partners. The latter being a local startup facility.

The ambition of CfV is (i) to increase the local economic activity in health, lifestyle & vitality and (ii) to increase the health & vitality of the area. To reach this ambition, CfV want to create an ecosystem that joins providers of lifestyle, prevention and healthcare to innovations and (startup) businesses from within and outside the traditional medical sector. The most pressing issue for the CfV is that its ecosystem still lacks the involvement of private companies and struggles with the interests of the parties already involved. Also, CfV lacks a strong content-driven lead and incentives for investing in vitality, lifestyle and health (prevention).

For future innovations in this ecosystem, the region faces two challenges. The biggest challenge is to create a clear set of valuable interactions and collaborations among the variety of stakeholders involved in health, lifestyle and vitality. Interactions that lead to products and services that benefit health and lifestyle of the end users as well as the local and regional healthcare economy. The second challenge aligns to this. It is to develop a business model for health, lifestyle and vitality and the healthcare economy. The Dutch health system is based on a payment structure for providing care and supporting sickness. It does not invest or support health. Prevention and health support also works in the opposite way of care. The benefits are in the long run and often lack hard evidence. Whereas care and medication have short term effects and controlled scientific evidence.

3.2.3 Scotland – Highlands

The devolved nation of Scotland is part of the UK. Within Scotland, there are 14 territorial Health Boards (HB) and 5 Special HBs, including e.g., the Scottish Ambulance Service and National Services Scotland. NHS Highlands is a territorial HBs in Scotland.

Scotland as a nation has a significant commitment to a specialization strategy based on the digital economy and the delivery of services through digital platforms. There have been several actions and programs established in the past 3 years aimed at progressing this strategic approach. The specialization strategy aims to integrate health and social care and wellness through the seamless use of digital technologies across the whole of the population and the land – where remoteness and rurality provide

substantial challenges to the effective provision of health and social care. Scottish Ministers' aspiration is for Scotland to be a leading digital nation by 2020. *Scotland's Digital Future: A Strategy for Scotland*,[69] published in 2011, outlines the key elements that are required to ensure Scotland is well positioned to take full advantage of the digital age.

In the Highlands, communication although physically difficult because of the challenges of obtaining

mobile signals in the mountains, is relatively easy amongst the stakeholders developing health innovations in the region. The relatively small number of individuals and organizations, many of whom are based in and around Inverness (the capital), means that many of these individuals are in regular communication and meet at many of the same events, and are members of the same committees.

Resources are shared in the Highlands. There is some sharing of labs and similar facilities for innovation and health purposes – between the Universities, and with the NHS and with businesses. One of the key facilities in Inverness is the Centre for Health Science, which is situated on the main hospital campus, and there is substantial joint working and integration of use of facilities and joint hosting of events. It is recognized that to achieve progress in innovation needs stakeholders and partners to work effectively and efficiently in terms of the use of resources, so many activities follow this path. There is some sharing of data, although it is recognized that it is difficult for the NHS to provide access to clinical data with pursuing the full governance route. Further, there is a move towards branding across institutions or at least a focus on 'selling' access to the joint resources available in the region, but this is not yet fully developed. Joint patents are sought only when there are evidenced contributions from two or more partners in the development of new inventions/products.

To launch new products, the NHS is main launching customer. Nonetheless, there continue to be barriers, especially in relation to procurement, to be overcome. NSS, or National Services Scotland, while supported by Scottish Government policy to ensure it is easier to support the entry of products, especially from SMEs into the NHS system, has yet to ensure that this is truly integrated. Large suppliers still tend to dominate NHS procurement.

The issues in Scotland relate to the confusion and crowded nature of the innovation and health sector. There is substantial commitment towards innovation in the health sector. Yet, many centers of research, development and innovation have been established within the last 4 – 5 years. As a result, the current ecosystem is fragmented and needs a bottom up approach where innovation tackles issues in delivering health and care education and services. Also, current culture impedes innovation. Innovation is still thought off as something that others do. There is early recognition on the benefits of collaboration, but a lack of programs and initiatives that (financially) support collaboration in healthcare.

The challenges for future innovation in Scotland are threefold. One, of course, will be the withdrawal of the UK from the EU of which the effects are yet unsure but anxiously awaited. Next, is to overcome the current culture of the NHS – which for many employees is firmly fixed in the public service mentality and for the general population which see the NHS as 'free'. This attitude is not sustainable for the NHS, and is restrictive as it does not allow for NHS commercialization and development of its own ideas and products. Thirdly, is to overcome the approach of SMEs which generally develop a product and then seek input from the NHS. This often results in failure because having missed discussion with the NHS, a product can be not fit for requirement. Instead, joint development of products is a much more efficient and effective way.

3.3 Current conditions for the regional health ecosystems

Based on the conditional framework introduced in chapter 3, we asked the three regions to rate how each of the building blocks are now shaped for the health ecosystems. This rating gives an overview of the current situation and challenges in the three regions and is displayed in the figure below.

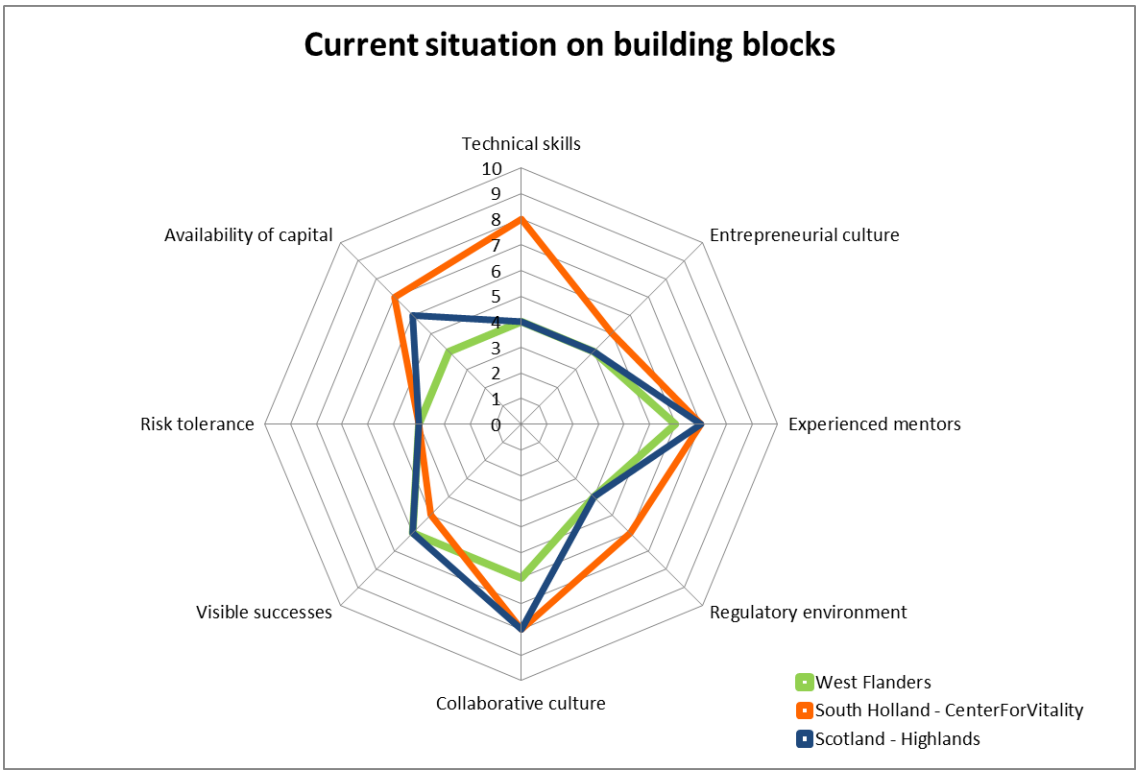


Figure 5: Current building blocks per region.

Now we know how the regional health ecosystems are shaped and what their challenges are. To support further innovation in these regional ecosystems will not only take learning from literature, as was described in chapter 2. We also want to learn from real life cases of innovations in the SHINE regional health ecosystems. Therefore, we analyzed some new ventures as well as programs supporting new ventures. The next chapter describes these cases.

4 Leading Examples

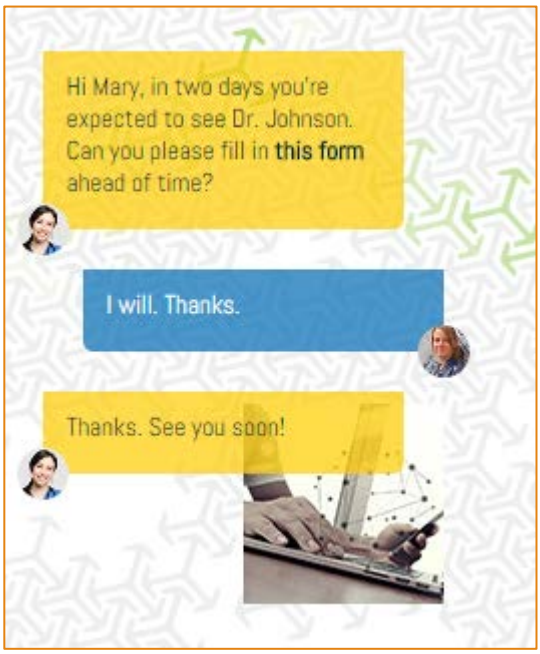
In this chapter, 14 exemplary cases are presented to illustrate successes and challenges when it comes to real-life innovation in the healthcare economy. To assemble the case information, we analyses documents and online information. Additionally, whenever possible, we interviewed primary stakeholders over the phone. We describe seven actual startups/spin-offs from the Netherlands, Belgium and Scotland as well as seven programs or ecosystems to support new ventures (startups especially). From these 14 cases in total, lessons learned about the building blocks for innovation in healthcare were deducted and analyzed in Chapter 5. For each region, one (randomly selected) case is presented here, and we have added an example of a startup program as well. In Annex 2, the leading examples are continued.

4.1 Case: PEX Life (Netherlands)

4.1.1 Purpose and developmental history

The purpose of this innovation is to improve and personalize digital communication in healthcare settings. Further information about PEX Life can be found http://www.pexlife.com/nl/.

PEX Life is improving and personalizing digital communication between healthcare providers and patients. The company uses a unique technological platform and design for creating chat boxes and online platforms that allow patients to interact with a digital assistant. With this digital communication, powerful and personal interventions are possible. This can be used, for instance, in case of practical matters, such as instructions on where to park when visiting the hospital, reminders for appointments, or rescheduling of check-ups. The technology can also be used for health coaching and in medical information, for example in situations where triage is needed or around guidance within a specific health domain. At this moment projects are created around Diabetes care, MiGuide.



PEX Life is a spin-off of CX Company that created the technology and applies it to different sectors worldwide, including customer services for large companies, such as banks and insurance companies. The idea for PEX Life started within CX Company in 2013 with a few enthusiasts who saw the possibility for a new market, Healthcare. Essentially the idea for PEX Life was to employ existing innovative technology from CX Company and use it in a healthcare setting, thereby tailoring the product to the specific needs of the healthcare sector. In 2014, a managing director was assigned and the company started off as a 'daughter' of CX Company. The set-up as a spin-off company allows for great advantages for PEX Life, including years of experience with the technology, from development to sales to implementation. Of course, the product needed to be altered about, e.g., privacy regulations, but the spin-off construction allowed for flexibility to investigate the requirements while simultaneously exploring the market.

4.1.2 Structure and facilities

PEX Life is a spin-off from CX Company, which is in three offices in the Netherlands, and one in Germany and one in the UK. There are several activities on each location in the Netherlands: Research and Development, content teams, project management, and marketing. In Germany and the UK, the offices are mainly focusing on sales. PEX Life is blending in with the usual activities at CX Company, and uses their space and supplies. Currently, six people are working for PEX Life. Another 3-5 are currently working on specific projects, but may also work for CX Company, depending on the amount of work. That is part of the brilliance of a spin-off: if you need more people you can get them assigned to you, and if you do not need them, they can go back to other projects at CX Company. Within CX Company, several teams are dedicated to different topics, including development teams (for technology), content teams (for text-writing), project teams, business development and sales. The managing director oversees all activities and is held responsible for them. Now, 5 projects have been completed.

4.1.3 Financial history

PEX Life was funded by CX Company. The current construction is that 70% of the shares belong to CX Company, and 30% belongs to the managing director of PEX Life, who invested in the company by working without compensation for the first period of the startup. At the start, PEX Life had access to cash flow to startup, and immediately was asked to conduct several projects through the existing network of CX Company, which propelled the (financial) growth.

The main benefit of becoming a spin-off company is that many of the costs for research and development, making demo's and developing pilots for instance, are easily made with the CX Company competence. Also, if you need more manpower in the spin-off, you can borrow personnel from the main company, without losing any productivity or ending up with high costs. The flexibility in terms of personnel, funding and cost distribution is one of the main advantages of this type of business construction. The spin-off construction was also valuable because the product from PEX Life is always tailored to the customer. This includes thorough phases of monitoring, auditing and contemplating with the customer and developers. Conclusively, it takes a long time before a product is sufficiently modified and delivered to a hospital. As a company, you need to be able to survive these valleys of deaths, where you're doing all the work but are not being paid yet. PEX Life being a spin-off company had the financial support to back their existence during this time. Also, the spin-off construction allows PEX Life to take big orders from clients, without having to worry about personnel shortages. Furthermore, as a spin-off, PEX Life can work with very experienced workers from CX Company, which saves a lot of time when starting new projects.

The only downside to this type of construction is that you can only have so much progress and growth in your company as the number of people working for you allows. And among entrepreneurs, the drive and ambition always exceeds the current speed of development. To accelerate, PEX Life is currently looking for a new partner. The requirements for this partner are that they should have a solid network, access to reliable medical content, and that their ambition is complementary to the ambition of PEX Life. It is not

necessary for PEX Life that this partner will also invest financially in the company, but PEX Life is also looking for new ways to become fully financially independent.

4.1.4 Key factors for success

- Spin-off from an existing company allows for flexibility, and stability in finances and personnel, regardless of any fluctuations in product demand.
- Particularly in healthcare, you need partners with a network who are willing to cooperate with you and to communicate your message. Otherwise, if you are a company outside of the healthcare sector, you will not get into the market easily.
- It is important to become a familiar face to the stakeholders in healthcare: expand your network, set up presentations, attend conferences and so on. Become the 'go-to' person for your type of innovation.
- Have faith, and patience. Starting up is frustrating, it is difficult to penetrate the market with your product and it takes a long time before a company gets in a stable flow of supply and demand.
- Make sure you define what area of healthcare you are targeting: find your niche and make sure you are the best in the field in that area.

4.1.5 Barriers for success

One of the biggest barriers is the way the money is distributed in the Dutch healthcare sector. Further, on a more fundamental level, it can be concluded that the current routing of the money in healthcare does not promote innovations which provide efficiency. That is, if you make patient processes more efficient, patients will need less consultation, for instance, and the hospital receives less income from the insurance companies. Healthcare providers are generally not inclined to improve these processes, because it will cost them dearly. Therefore, you need to be smart about how you sell your product, and you need to adapt it. PEX Life simplified their product, i.e., they were not trying to improve complex medical procedures, but focused on digital communication for practical matters, such as parking or rescheduling appointments. And that proved valuable. For example, hospitals understand that if you improve patient communication, it will save the hospital staff a lot of time answering simple practical emails of phone calls. From that perspective, hospitals can save money by improving their digital communication, and then you've created a demand for your product.

Another barrier for starting up is the fact that the structures of the healthcare sector and of individual healthcare facilities are highly complex. To illustrate, the ownership of patient communication and the website of a hospital is shared within the organization. Even more complex is the fact that numerous divisions and research groups are responsible for a small part of content on a place on the website. In that way, everyone is somehow involved in the communication process to the outside world through the digital channels, and making a change there is obviously a massive task.

Furthermore, in healthcare there is lots of talk and presentations about digital innovations; many conferences and papers are dedicated to this topic. But little of this knowledge and conversation is translated to concrete action. At best, there are a few pilot studies where people try out different types of digital innovation, but it is not clear how much money and manpower is invested in these changes. At

least it is not enough, pilot studies do not have the level of impact you need to fabricate sustainable change in fossilized procedures and systems within a hospital, and within a country. This essentially means that the care environment for PEX Life's products needed to be prepared to fit the product into their perspective and daily routines.

Then there are a few very basic problems that PEX Life encountered as a new entrepreneur in healthcare. PEX life had to learn to understand the healthcare market and learn to speak the same language as healthcare professionals. To overcome these barriers, PEX Life invested in their own level of skill and knowledge, and demonstrated their intentions and the potential benefit for the customer repeatedly. Simultaneously, PEX Life was expanding and building their network, and made sure to become a familiar face at conferences and meetings. That was an important key to success and market access.

Finally, there is increasing awareness in healthcare that the old systems may need an update and that there are other, smarter, ways of working and communicating. The fact that CX Company already has a good reputation also helps to increase the level of curiosity: hospital staff are interested to see what they can learn from us, and from other sectors. Traditionally, the healthcare sector never looked to other sectors to manage and improve itself. But now, that is changing, and it provides startups with good opportunities to get into the sector and sell their product.

4.1.6 Regional influences

PEX Life is part of several regional networks, including HealthValley, which is a large network of healthcare entrepreneurs. HealthValley hosts several events and conferences, and provides networking opportunities. However, regional factors were not important for PEX Life, as they could use the existing network and reputation of CX Company. Therefore, they did not need additional funding or support from the region.

4.1.7 Future

The current goals of PEX Life is to grow and increase the number of projects and products supplied to hospitals and care facilities. They are also trying out various new ideas in the market, and testing 'user cases' to see if there are improvements to be made. PEX Life is also involved in several health programs, including a program for pregnant women in Ghana and a diabetes platform for general practitioners and the patients. Eventually, PEX Life is aiming to become the leading company for digital communication in healthcare, particularly for the communication from hospital to patient.

4.2 Case: Mime Technologies (Scotland)

4.2.1 Purpose and developmental history

The purpose of this innovation is to offer software solutions that support care, from monitoring at home to pre-hospital care provided by first aid responders. More information about MIME Technologies is available at http://mimetechnologies.com/.

MIME stands for Managing Information in Medical Emergencies. The company designs software solutions to support the first person on-scene in a remote or so-called pre-hospital setting. The software uses a combination of on-scene help screens displaying (first-aid) instructions. Additional information can be gathered through wireless vital signs monitoring. These products can be used by, for instance, community first responders. In Scotland, there are 16.000 people who volunteer within their community, and who respond to emergencies before the ambulance arrives. They can use the products from MIME Technologies to improve first aid procedures and potentially decrease the chance of adverse health outcomes. MIME Technologies is currently penetrating various markets, including first/humanitarian aid, first responder schemes, emergency services and hospice/care homes.

in the MIME project commenced in 2010 at the University of Aberdeen, funded by the Research Councils UK 'dot.rural' Digital Economy Hub. The spin-out company MIME Technologies was incorporated in June 2015. The founder of MIME Technologies developed a software algorithm after his PhD research, which focused on casualty monitoring in remote and rural search and rescue. Among others, opportunities for wireless data transfer in remote areas were explored, which can be applied in mountain rescues and search and rescues in remote areas. The aim of the PhD project was to evaluate the potential of such technology, including sensors, and develop a solid idea of what this type of technology might look like. The university supported this idea and its development beyond the PhD project. To explore the potential of this type of technology, the founder started with mapping the types of problems and real-life situations that might occur, and figured out how these can be put in layman's terms. The software code was the only product developed at that time. The team started developing the software code and explore options for data gathering, to test the software. With additional funding in 2015, it was decided to build an app. By August 2015, the app was prototyped. Since then, the app or software has essentially not changed, except for exploring new market applications and tweaking the software for clients.

Current users of MIME Technologies purchase a software license, with that they can download the app on their phone or tablet. The company also offers sensors for heart rate and blood oxygen levels, these are mainly designed for home monitoring and can be applied in, for instance, hospice/care facilities. In several aspects, MIME Technologies is an advanced technological company with regard to product development and content. Business-wise however, MIME Technologies is currently

maturing fast: it has moved out of the university setting three months ago and is developing a sales model and a business case.

4.2.2 Structure and facilities

The company is based in Inverness, Scotland. The company uses university space for storage, and the founder works mostly from home or during business travels. The company has several executives, including a CEO, a director of customer development, a university director, and a clinical advisor. Since the company spun out of the university, a lot has changed. The company was officially incorporated in June 2015. At the time, it was basically a dormant company with two shareholders: the founder, and the professor who was working with the department. The company went live in September 2016, when the company got a license for the IP. It was decided not to take the university professor with them into the company, mostly because his duties at the university conflicted with the time that needed to be dedicated to MIME Technologies. The founder, together with a colleague, gave up his job and took a risk to invest in this company.

4.2.3 Financial history

The university had a Digital Economy hub that funded the research for MIME Technologies' software development in the first place. The hub was funded by the Research Councils UK Digital Economy Program. This was a very academic process, and completely different from economic sectors in every aspect. Before the company spun out of the university in 2016, MIME Technologies was supported by the Royal Society of Edinburgh, which provided a year of funding and support for the business idea in the form of an Enterprise Fellowship. The founder participated in monthly trainings, within a competitive business accelerator program. The program offers unlimited access to mentors and trainers. In the training, a variety of topics were covered, including investments, contracts, sales training, team strategies, accounting.

Also, the company received funding through a loan, provided by the University of Aberdeen. Additionally, the regional development agency Highlands and Islands Enterprise provided funding, and the company received a Scottish Edge award of 10.000 pounds as well. Overall, MIME Technologies gathered circa 105.000 pounds to spend, which is currently used as seed funding. The company also received a seal of excellence from the Horizon 2020 program, but not funding. A current problem with regard to finances is that the team is spending a lot of time on writing grant applications. They would prefer to spend that time in sales and business development. With the current financial structure, the company needs to attract match funding from investors, which is a huge challenge. Private investors with a suitable network and business expertise would be welcome to join MIME Technologies, to support the growth of the company.

The main aim is to get up to speed with their sales program, to sustain the company and create stable cash flow. Also, successful sales are a way to validate the product and see if there is a market for it. A few sales opportunities are opening now. Also, the company is involved in consultancy, and sells vital monitoring products for home-bound patients. Lead development for sales is the main priority right now. If the sales are successful, this might also attract new investors. To control the product and retain the brand, MIME Technologies is currently not looking for resellers to market the product. Also, resellers are looking for the wrong kind of profit margins, in their experience. The company is looking at a sales price of 1500-2000 pounds per system, including software and sensors.

"When you come from an academic background, you have no experience whatsoever, it's a very steep learning curve."

4.2.4 Key factors for success

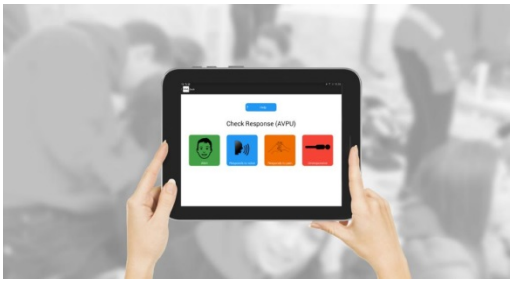
- The enterprise fellowship of one year was essential; having the time to start up and develop your ideas. Also, the business accelerator program was very useful: pressure-testing your ideas with other companies and having a canvas for business development is very educative.
- There are always things that could have been done quicker. For instance, there are regulations on when and how to register certain things, that are accompanied by strict deadlines. Some stuff you can only learn as you go, and only as fast as you can. Be prepared to learn about topics that aren't directly related to your product. For instance, the team at MIME Technology had to be trained in cyber security.
- The university did everything for MIME Technologies at first: they offered a shelf company and they renamed it for them. Though such constructions, you can avoid a lot of the paperwork and legal complications.
- Don't underestimate the value of making money through your customers, and make sure you have a good solid network that is going to deliver cash to you. And do lots of marketing as well.
- Investors will invest in you if you have a second-grade product but a first-rate team, and not the other way around.
- It is no use if organizations or people just provide funding, investors should have the knowledge to propel you forward.
- It's important to find people who share your passion, they might not have the answer but they are going to find the answer for you.
- Coming from an academic background, it is a very steep learning curve to become an entrepreneur. Make sure you are prepared for this.

4.2.5 Barriers for success

- Just the spin-out process was a barrier. The company started within the university, and the university was a collaborator. At the start, you get a lot of documents to read and you need to negotiate the best deal for yourself and for the company. This is a difficult process, particularly if you are dependent of an institution such as a university.

- A major disadvantage of the spin-out construction is that the university becomes an important shareholder of the company (about 20%), so you can never be fully independent. This happens a lot in Scotland and the UK. In the perspective of the founders of MIME Technologies, this is not preferable. Having a university as a shareholder is almost sure to complicate and delay the growth of a company. For instance, MIME Technologies is currently involved in a two-month-debate with the university about the IP license and the terms of royalties for the university. Because the university is on the company board, it is difficult to negotiate. There is a clear conflict of interest. Another downside is that universities use spin-out constructions for their own benefits: universities with spin-outs get higher ratings, and the companies are considered as impact delivered. This can easily lead up to circa half a million pounds in additional funding for the university.

4.2.6 Regional influences



The company indirectly received some funding (circa 90.000 pounds) from a local innovation center (Digital Health Institute). It was easy to qualify for this support; the center was very supportive and helped to identify a few bits and pieces. The difficult picture in Scotland is that there are lots of different people who give lots of different support, and it's hard to find the people and organizations who will help entrepreneurs with the exact piece of the puzzle that they need. And there's lots of activity and cross-over partnerships in the region, that makes it difficult to find what you need. Furthermore, a good deal of people and organizations in the region do not understand the pressure of money and time that entrepreneurs experience. The pace is very different, and that makes it hard to cooperate. It is no use if organizations or people just provide funding, investors should have the knowledge to propel you forward. But overall, it was helpful that this was a unique company in the region. Had the founders started in, e.g., Glasgow, it would have been more difficult to create USPs.

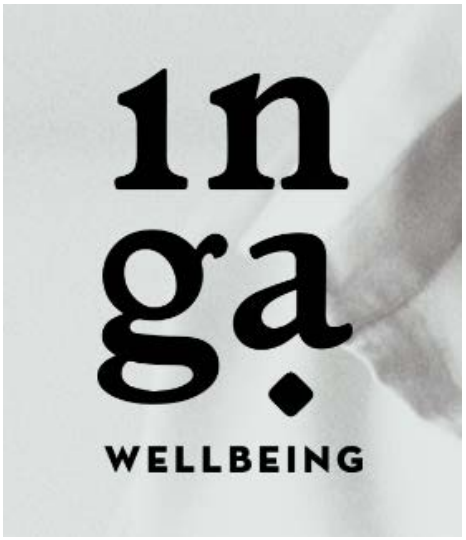
4.2.7 Future

Right now, MIME Technologies is still looking to survive. After that, it has the ambition to grow. The company is dedicated to a very particular field, and the founder is confident that investments will be achieved in the next years. The company was set up with an exit strategy. The goal is to dedicate a lot of work and energy towards the company for 5-6 years, and then sell it to a large company. The team is convinced that there are lots of people who can benefit from MIME Technologies' product, and they want the company to sustain itself financially.

4.3 Case 3: Inga Wellbeing (Belgium)

4.3.1 Purpose and developmental history

The purpose of this innovation was to design and produce hospital clothing that is not only practical, but also comfortable and attractive. Several designs are available through the website http://ingawellbeing.com/.



The idea for this innovation came into being about 3.5 years ago, when two of the founders exchanged their experiences with relatives in the hospital, and the large impact that patient clothing had on them. The traditional hospital gowns are not well-fit for the purpose, and patients spent a lot of time handling these uncomfortable clothes, dressing and undressing. For example, patients are often hooked up to all kinds of machinery, for which the clothing should have openings, while still making it easy to dress and undress. Also, visitors feel like there is an elephant in the room: patient clothing changes the relationship and the dynamics between people. Specifically, the current hospital gowns increase the experienced level of illness, as patients are uncomfortable and feel vulnerable and unattractive in these clothes; they do not look like, or feel like, a normal person. Further, people aren't always sure what to wear or what to bring, and hospitals do feel that it helps the patient to wear their own clothes or something like it.

To offer a solution to these problems, the two founders joined forces with a fashion designer, Fiona Mc Greal, who created a collection of fashionable yet practical patient clothing for hospital settings. After the initial design, the team met with a manufacturer who incubated the prototypes. The team then worked in several hospitals to learn what functionalities the clothes needed. They also investigated how the patient population could be reached. Since then, clothing was designed and tested for multiple patients and various hospitals. For instance, the team itself tested their own gowns by sleeping in it, wearing it to meetings, tying strings to doors to simulate IV's and try to dress and undress. The team further worked with an institute that simulated a lot of medical interventions, to make sure that in practice this design was going to work, from a medical professionals' point of view. Compared to the regular gowns, the materials are made of natural fibers because that helps the body's temperature and reduces the body odor. Also, openings for all kinds of medical conditions are incorporated into the design, and are combined with a fashionable look.

Currently, a team of three is running the company, with a strong personal motivation to improve patient wellbeing. The first large production of patient clothing was delivered to the company in November 2016. There are several types of products for men and women, including tops, pants, dresses and nightwear. Price range is circa 50-90 Euros for most products. All products are being produced with care for the environment and the manufacturers.

4.3.2 Structure and facilities

Three members are currently running the business from their homes, one in the United Kingdom and two in Belgium. They are all equal shareholders. The clothing is primarily sold online through the website, where patients can buy items for themselves or someone can buy an item for a patient. The clothing is also sold through various retailers (circa 6) in Belgium, for instance in hospital shops, and specialist online retailers. The reason for starting in Belgium was that, at the start, all the founders lived temporarily in Belgium. However, because they are all originally from the UK, the company is officially registered in the UK. Tasks are currently divided between the team members: the team is currently doing the marketing, communication, logistics and everything else. They are looking to connect with people who can support them in these branches of the business. Also, the company is currently looking to expand their market, by exploring delivering directly to hospitals in bulk.

4.3.3 Financial history

The company started from personal savings from the team members. The founders chose to do so, because they felt that they had to get to a certain stage of credibility before applying for funding. Then, they received a price of 10.000 Euros from receiving an Award (PRoF Award), and some financial support from the Wallonia municipality. Also, the team received an anonymous foundation of a 1000 Euros through a foundation. This helped the startup of INGA Wellbeing and confirmed the idea that this type of innovation is desirable and necessary. Now, the team is looking for new sources of investment. They are speaking with different seed investors and social impact funds who share the team's drive and motivation. The company is also looking for communicators and marketers who will inform patients that they have options when it comes to patient clothing.

4.3.4 Key factors for success

- The team members are convinced that part of their success can be attributed to their own investment in their learning curves as new entrepreneurs. They actively started networking and attending business schools to resolve gaps in skills and knowledge. The team also worked with two business developers who mentored them, which was a big support.
- Although presently not the case, the team also mentioned that while working in Belgium together, just being in the same space, improved their efficiency and communication.
- It is important to ask for advice, and particularly to ask people who know everything that there is to know: hospital staff, business developers, patients and so on. Ask anyone anything. This made a huge difference in the course of INGA Wellbeing.
- Internal motivation, having a real passion and believing that you can make a difference, is crucial to success. You must have a real drive.

4.3.5 Barriers for success

INGA Wellbeing also experienced some challenges in the startup process. First, it is challenging to obtain funding to go from the first stage of starting-up, to scaling up: arranging for infrastructure, getting contracts and a foot in the door with large hospitals, and marketing your product. In addition, subsidy-chasing takes up a lot of time and energy, it is difficult to know what types of funding your quality for as a company.

Also, with scaling up come new challenges, for instance, to deliver to hospitals, the clothes must be fit for industrial cleaning, which needs to be incorporated in the design of the product and choice of materials. Also challenging is the fact that this product is slightly more expensive than the product that is currently being used in hospitals, this makes it harder to proof the case to a hospital board. One way of overcoming this, is by finding a cost-neutral way for hospitals, in which patients can lease the clothes and the hospital can get a refund on the clothes they buy. Another barrier for scaling up, is that more financial resources must be available to place the orders at the factories, and, the fact that for small orders, the company is charged by the minute for fabrication. This leads to much higher prices if you order in small quantities. Therefore, it is important to find existing companies or persons in the industry to support the scale-up.

Finally, an important challenge comes with the market access. The company is speaking to several hospitals to supply their clothing. In this process, there is a lot of infrastructure to get through, including full hospital board approval, and this takes up a lot of time. The company and its products must adhere to new regulations to fit the bill. Overall, there is a general problem that healthcare in general is quite rigid, and there are a lot of limitations placed on innovations in healthcare. For instance, it is hard to find ways to test innovations in daily practice.

4.3.6 Regional influences

INGA Wellbeing had one main obstacle to overcome: they were in Belgium, whilst two of the co-founders were British, the third having spent most of her life in Belgium. To provide the benefits of VAT exemption for chronically ill patients provided by the UK Treasury, INGA Wellbeing was registered as a limited company in the UK. This was particularly problematic about subsidies, i.e., the company did not qualify for most Belgian subsidies because they were registered elsewhere. Also, the Belgian structure for subsidy and funding was confusing: they divide the money between the regions (Flanders, Wallonia or Brussels) and companies must apply for these subsidies locally, there are few national subsidies. In the end, the company did get some subsidy from Wallonia, and is looking forward to delivering there and return the investment to the community.

Important determinants of success in the region was that the hospitals were willing to work with the team, they offered immediate cooperation and commitment, and there was a lot of collaboration. Also, within the region there is an organization called the Innovatie Centrum (Innovation Center), and they helped the company by introducing them into the market, by connecting them to several clients and hospitals. Also, the fact that regulations were less of a burden in the UK helped to keep the startup simpler. If the company would have started in Belgium, it would have been more complicated. That is, Belgium has specific requirements, including a minimal financial requirement that you must have in the bank, and a 3-year plan for your finances. There are also greater legal costs involved in starting up in Belgium. For a very lean company as INGA Wellbeing, this would not have been effective.

4.3.7 Future

The current goals of INGA Wellbeing are to increase their access to the market, to find a way to secure a place in the market for patients and carers, and to find a way for hospitals to use our clothes as a standard option for patients.

The next big step is to make possible the integration of smart technology into the clothes. The company has been working with SmartPro, a European consortium that is looking to integrate smart technology into clothes and fabrics in the care sector So in the future, sensors may become integrated into the clothing, and lead to less invasive technology for these patients.

4.4 Case: YES!Delft- Dutch ecosystem

YES!Delft is an incubator for technological innovations and entrepreneurship in the Netherlands. It is located in Delft, near the campus of a technical university. The aim of YESDelft! is to stimulate entrepreneurship among students and scientists, by providing counselling, support, and intensive programs for startups. The incubator was founded in 2005, and has counselled over 180 companies since then. Currently, circa 70 companies are active on-sight, working and learning at YES!Delft in an Incubation Program. YES!Delft focusses on complex technological developments that take circa 2-5 years of development before market entry. Its target areas are Cleantech, Medtech, ICT and Industrial Solutions. Each of the categories contains about 20 startups. Most of these companies are just starting off, or are still in the process of exploring the market value of their idea, and identifying their target group. A minority has already started successfully and are now in what is called an 'acceleration phase', in which new investment rounds are organized and potential for company growth is explored. The incubator is funded by the technical university TU Delft, the municipality of Delft and research Institute TNO. Also, occasional subsidies from European funds are made available to the incubator.

4.4.1 Activities and programs

YES!Delft organizes network events, discovery days (one day crash course in entrepreneurship), is most famous for offering two programs; LaunchLab and the Incubation Program. Both the LaunchLab and Incubation Programs consist of coaching, mentorship, networking and finding investors. However, the programs focus on different stages in entrepreneurship. LaunchLab is a three-month program in which entrepreneurs can define their idea, and explore whether their idea is marketable, and who their target audience is. The main target audience of the LaunchLab (pre-incubation program) are entrepreneurs with new ideas that need to be validated. It is also an attractive program for young entrepreneurs and recently graduated students, because the program sharpens the thinking of the participants, not only with regard to their innovative idea, but also with regard to entrepreneurial skills. Essentially, it is a validation program. During LaunchLab teams validate their technology by talking to as many customers as possible. Ideally teams have found product/market fit after completion of the program. To participate in LaunchLab, YES!Delft asks a contribution of 1250 Euros per team of entrepreneurs.

The Incubation Program is a five-year full-time program for those who are past that stage, those are ready to start building their company. During the first six months of the program, entrepreneurs develop the basics, work on the company strategy, draft a milestone planning, perform risk analysis and are trained in entrepreneurial skills. At six months in, there is a so-called 'grow or go' moment. Companies who stay, start by renting office space at the YES!Delft incubator. In YES!Delft's Incubation Program, companies can stay on-sight for several years to mature in a supportive and engaging environment. Most companies stay in the YES!Delft environment for about five years. It is not uncommon for entrepreneurs to start in LaunchLab and then enter the Incubation Program. For the Incubation Program, YES!Delft handles a success fee. The incubator does not take equity, but asks for a maximum of 25.000 Euros in revenue, if the company is successful in generating investments. This contribution is re-invested into the YES!Delft programs. Further, when in a program, entrepreneurs can lend money up to circa 15.000 Euros to startup, which is supplied by TU Delft and a Dutch Bank. The conditions of the loan are very reasonable, and allow for options if the innovation turns out to be a failure.

YES!Delft is famous both in the Netherlands and abroad, and was classified in 2015 as one of the top ten business incubators in Europe (23). As a result, a lot of want-to-be entrepreneurs are applying for a spot in YES!Delft's programs, and YES!Delft uses a thorough selection procedure to select potential entrepreneurs for their programs. For instance, only 10-20 companies are allowed into the Incubation Program annually. To qualify for LaunchLab or the Incubation Program, entrepreneurs must align with YES!Delfts' focus: their idea must have a potentially large impact on the market as well as on the development of technology. Further, the selection committee looks at whether the idea is an actual solution to an existing problem, and not just an 'interesting extra'. Finally, in 2008, YES!Delft for Students was designed, an initiative which aims to encourage students to think about the market value of their ideas and discoveries, and entrepreneurship (24).

4.4.2 International network and opportunities

One of the key ingredients of YES!Delfts programs is that it promises participants that they will meet over 100 potential investors and clients while in the program. This is a tremendous accelerator for product development and growth of a company. A large part of the network of YES!Delft is internationally oriented. Especially with regard to technological innovations, this provides unique opportunities. Some startups at YES!Delft immediately scale-up and expand to, for instance, Silicon Valley in the US, or technological markets in Asia (25).

YES!Delft is also active in its communication to the startup community internationally. For instance, representatives of YES!Delft undertake business trips to expand the incubator's network, and create opportunities for a 'soft-landing' of Dutch companies in other countries. This is important because internationally market access can be particularly difficult if a company is located elsewhere. In some cases, companies originating from YES!Delft are extremely successful, receive a lot of funding and grow rapidly. Entrepreneurs starting at YES!Delft generally remain connected for life, or at least for a long period of time. They stay within the network of the incubator, and occasionally share their lessons learned with new companies or contribute to new programs or initiatives. This success helps to build the reputation of YES!Delft, and makes sure that the incubator has a solid future.

This case-study is partly based on an interview conducted by Hamza Boutaybi, and the content was verified by YES!Delft (25).

4.5 Case: Accelerator West-Flanders: Imec

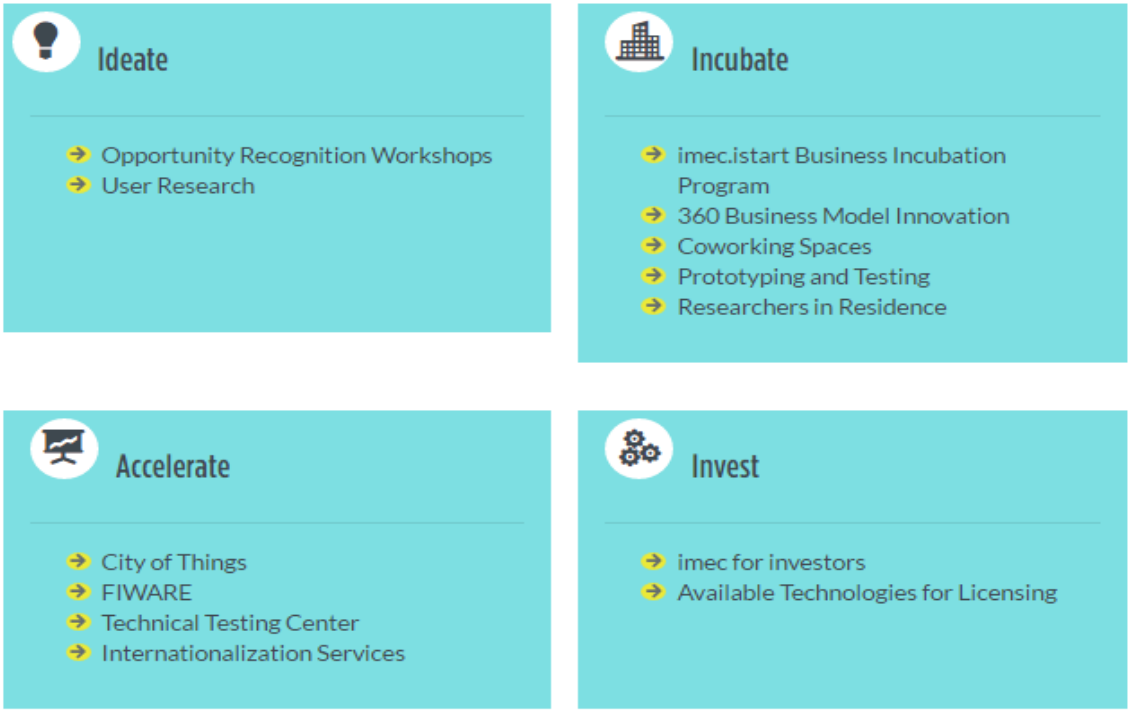
Imec is a cross-border research and innovation hub that specializes in nanoelectronics and digital technologies (27). The combination of advanced microchip technology, and software and ICT expertise, is quite unique compared to other facilities in Europe. Imec is active in a variety of application domains, including healthcare, smart cities and mobility, logistics and manufacturing, and energy.

imec
embracing a better life

Imec functions as a partner for companies, startups and universities. Within imec, circa 3500 persons from 70 nationalities are cooperating. The imec headquarters are located in Belgium (Leuven). The hub also has research & development departments in various Flemish universities the Netherlands, Taiwan, USA, China, and holds offices in India and Japan. In 2015, imec's revenue (P&L) totaled 415 million euro. Early 2016, research institute iMinds (1000 researchers) and imec (2500 researchers) merged to combine their technological and research expertise in a variety of fields. It is also expected that this merger puts Flanders on the map as an innovative and highly technological region. Within the health domain, the hub is mainly dedicated towards digital health: specifically, the development of advanced health and clinical decision-support systems, and the removal of technological and societal barriers for system adoption.

4.5.1 Activities and programs

Aside from research facilities, imec offers different types of programs for entrepreneurs (see below). Programs are offered in four categories: Ideate, Incubate, Accelerate and invest. Within each category, a specific audience is targeted. Also, the type of activity matches with the developmental stages of a new company. To illustrate, the 'Ideate' category is low-key. Within the 'Ideate' activities, three-day recognition workshops are organized to explore the potential of new projects. The main audience for this type of activity consists of (PhD) researchers: those who might want to expand their horizon outside of the university, and who might want to turn their ideas into business. Alongside this workshop, coaching is available for half a day. Imec also offers user research in this category, to explore valorization of a new project or product.



The 'Incubate' category holds various programs for startups. The two main events are the Business Incubation Program and the 360 Business Model innovation. The incubation program is internationally known and recommended. It is designed with a focus on technological innovations, particularly ICT. The program is quite comparable to other successful incubation programs mentioned in this handbook. It constitutes of business development in an intense, supportive environment, where coaching an co-working is offered and stimulated. Within the program, several components are important, of which the most crucial are: mentorship, a collaborative culture, and access to a network:

- Pre-seed funding (convertible loan up to 50.000 Euro)
- Expert coaching
- Workshops and mentoring
- Support and council from experienced entrepreneurs
- Network access
- Working facilities (e.g., office space)
- Support in acquiring follow-up funding after startup

Entrepreneurs can apply for the program three times a year, when a call is issued. There is also a 'light' version of the program, targeting researchers who already have proof of concept of their idea, and are looking for a less capital and less intensive support. In exchange for their support, the program takes a considerable amount of shares in the new company, and entrepreneurs pay interest over the amount lent to them.

Furthermore, within the business model module, entrepreneurs are stimulated to develop a clear vision on four important aspects of their innovation:

- value proposition: the added value for a specific market segment or customer
- functional architecture: the technical components, the processes, tasks and roles
- Value network: the various stakeholders, their respective roles and the (inter)relationships between them
- Financial model: the pricing model and the return of value across the value network

Coaching is an important part of the business model program. Like most incubator programs, the hub also offers office space so that startups can work together (Co-working space). Additionally, within the Researchers in residence option, academic researchers are connected to companies who need specific expertise. This helps to lower the costs of employment for new companies, while gaining access to high-level expertise. The hub also offers support in developing prototypes and testing them.

In the 'Accelerator' category are events and activities that help companies to grow and mature. For instance, the 'City of Things' allows for real-life testing of innovations in a large-scale living lab, and the FIWARE component holds four programs dedicated specifically to the acceleration of innovations related to the Future Internet. Also, international services are offered to companies looking to expand abroad. The living lab is one of the key programs offered by imec today.

Finally, the 'Investors' category presents results of startups and technological companies to investors, and connects entrepreneurs with relevant funders.

This information and text used for this case-study is derived from the iMinds website (27).

5 Essentials of innovation

From the analysis of the leading examples, there are multiple conditions in the regional context are important for startup companies and innovations in healthcare. Also, there is no single, one size fits all solution to propelling innovations in regional healthcare systems. Healthcare innovations and regional ecosystems are both complex fields. Yet, there are general lessons to learn and ways to go forward.

By following a step-wise approach, this report showed how regional ecosystems can improve. First, by taking a closer look at what are general building blocks and essential conditions for a regional economy to thrive. Next, the report took a closer look at the situation in each region, its specialization strategy and the challenges the regional parties meet in realizing that strategy. This regional description of the regions shows where the differences and similarities are amongst regions. Our third step was to dive deeper in some of the new ventures the emerged from the regions in recent years. Also, we took a closer look at some of the available regional programs to stimulate the new ventures. Finally, we connect the dots between these steps by analyzing how regional should general stimulate new ventures and where the SHINE regions face challenges.

5.1 Building blocks revisited

Likewise, to chapter 3, we rated the importance of the building blocks of the conditional framework. We did so based on the case analysis. Figure 8 displays this.

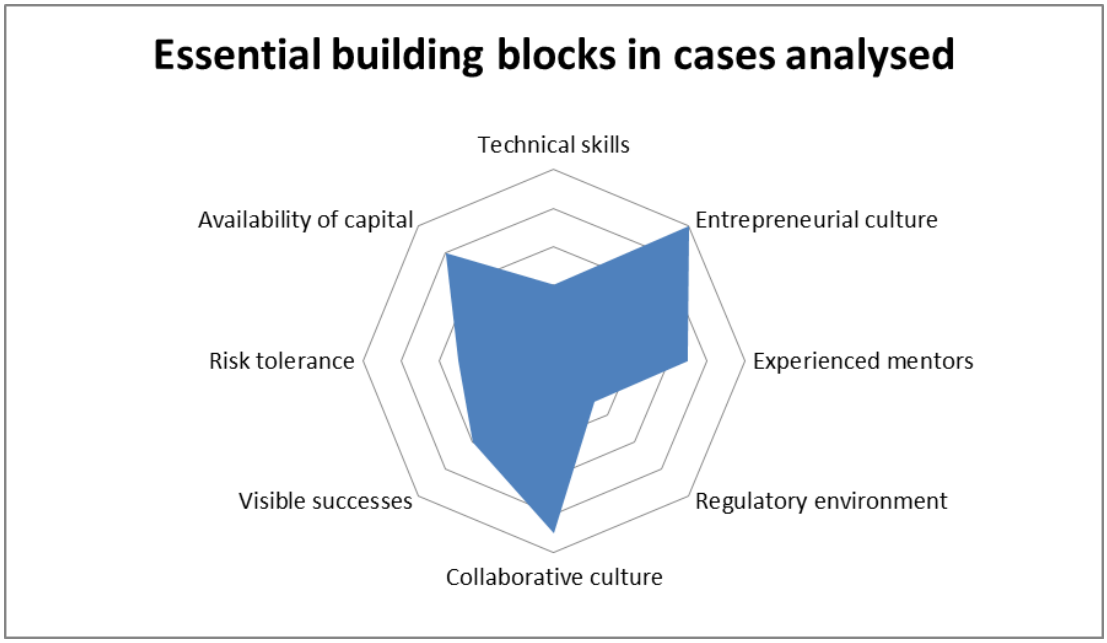


Figure 8, building blocks for healthcare innovation.

From figure 8, an entrepreneurial culture, opportunities for collaboration, experienced mentorship and availability of capital are the most crucial elements for innovation to succeed. Other factors, such as technical skills, presence of regulations in the environment and visible success, are also relevant with regard to product development and demonstration, but are less crucial in the sense that they cannot predict and influence the potential success of an innovative idea in healthcare. These factors can be thought of more as important conditions that may delay or speed up the innovation process, rather than determine its survival or downfall.

We compared the case analysis to the current situation in the three SHINE regions. This allows us to identify in which areas each region must develop the building blocks. The figure below shows this comparison.

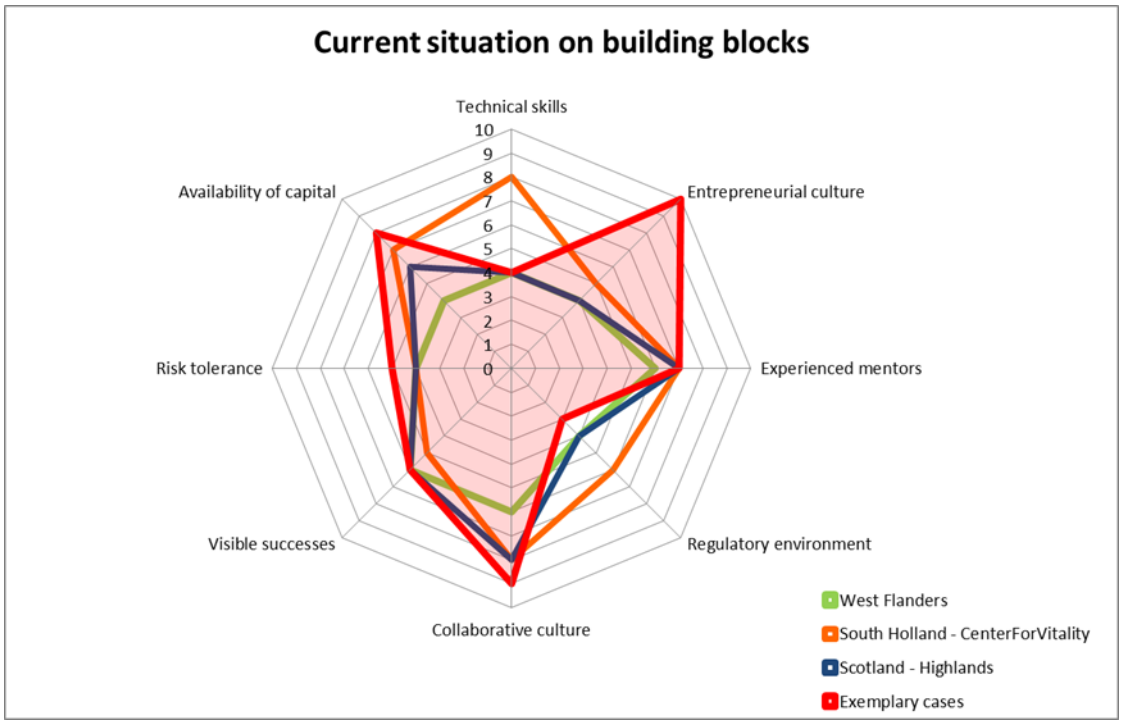


Figure 9: Comparison of region and cases.

5.2 Developing regional programs

So far in this report, we have studied how currently healthcare innovations take place. We used both literature and case analyses. Within SHINE, we want to apply these insights to the three North Sea Regions. Therefore, based on the findings in this report, the three SHINE regions have set up a regional program to (further) support the different stakeholders involved in their regional healthcare economy. The overall goal of these programs is to stimulate the valorization of products and services that stimulate health & healthy living.

5.2.1 POM – West Flanders

In chapter 3 the challenges for West Flanders were discussed. To summarize, the region needs to further stimulate the entrepreneurship and entrepreneurial culture, also among healthcare institutions. Additionally, collaboration between SMEs and healthcare institutions needs to be encouraged and entrepreneurial success should have a positive perception. Finally, the region needs to make the administrative process for start–up companies less complex.

With their regional program for the healthcare economy, POM mainly wants to stimulate more the entrepreneurship and entrepreneurial culture among and within healthcare institutions. Through training of skills, POM wants to encourage successful collaboration between healthcare institutions / professionals and SMEs. POM has set up a skill training program for healthcare entrepreneurs that is based on the 8

building blocks or conditions for regional ecosystems to thrive. The program started February 2017 and is evaluated within the SHINE project.

5.2.2 Innovation Quarter – South Holland

As chapter 3 described, South Holland faces two challenges for future innovations in the Leiden / 071 area and in the Center for Vitality. The biggest challenge was to create a clear set of valuable interactions and collaborations among the variety of stakeholders involved in health, lifestyle and vitality. The second challenge was to develop business models for health, lifestyle and vitality and the healthcare economy.

For their regional program, Center for Vitality came up with a building block approach. They offer tailored support to startups that have a business case related to vitality and lifestyle/health and that want to invest in the 071 region. The program is tailored in the sense that the Center for Vitality has an onboarding session with a startup / (new) entrepreneur and following selects the type of support befitting the needs of the startup/entrepreneur to validate the business model and or content of the product/service concept.

Where the general program attracts a broad selection of startups, the Center for Vitality offers a specialty track set up a specialty track for a selected group of startups. The focus of this track is "Vitality, Lifestyle as Medicine" and was set up together with Innovation Quarter and TNO. It connects the regional state of the art knowledge and technology base to a startup and their ideas and prototypes. The aim of the specialty track is to validate the theoretical concepts and content and improve ideas and prototypes. In the track, the regional experts on lifestyle as medicine in metabolic syndrome and lifestyle related diseases provide expert coaching and workshops. To also offer extensive business model validation to the teams in the track, the Center connected the track to HUBspot, the new local startup accelerator in Leiden. HUBspot already had plans to set up a Startup Academy to accelerate teams with a clear idea for a startup/spin off, preferably also with a prototype. The Academy will provide coaching and skills training on entrepreneurship, business modelling, networking, capital building. The specialty track (and HUBspot Academy) started in March 2017 and is evaluated within the SHINE project.

5.2.3 NHS – Scotland / Highlands

The NHS program is scheduled for October 2017 and is evaluated within the SHINE project. NHS Highland Early Stage Accelerator Programme (ESAP) is a two day training course in Inverness, specifically designed for those with early stage business ideas and prior to the uptake of a full business accelerator initiative. The programme has two core aims 1. To provide examples of exemplar approaches to creating a start-up and 2. To deliver an overview of managing the start-up process. ESAP is a hands on programme that will be delivered by those who have been through the real-life experience of company formation and early stage growth. On the 2nd and 3rd of October programme participants have also the chance to liaise with experts in the industry and (where relevant) be introduced to NHS procurement representatives. The course focuses on the importance of value proposition and company offering, understanding your customers from the outset, designing and testing product prototypes, making sales, working with the NHS and aspects of successful marketing. ESAP will also provide a high level overview of exemplar business models that work and provide participants with information on maintaining company IP.

5.3 The future

The aim of this report is to support innovation in the healthcare economies of the NSR regions. We mapped obstacles, opportunities and examples of innovation in healthcare in the report. Furthermore, we explored several generic models for innovation, extracted building blocks and key elements for innovation processes in the health domain, provided a regional analysis of Scotland, West-Flanders and South-Holland to map opportunities for innovation in their health domain. Moreover, we discussed exemplary cases of innovation in the healthcare domain in these regions, and we provide recommendations for stimulating innovation in each of these region. It is our hope that this report inspires readers that want to play a role in bringing disruptive innovations to the healthcare domain in the NSR Region.

What's next in the SHINE project you might wonder. The three SHINE regions have now set up programs to stimulate innovations in their regional healthcare economy. In the next phase of SHINE, we will study how participants experience these programs in each region. And what the result of the programs is. Are participants developing their product, the business and/or their skills to do so? And do participants value the programs? During 2017, we will monitor the programs and in the first half of 2018 we will reflect on the results.

6 Annex 1: Format - three step approach to analyzing the regional health ecosystem

Information is gathered in three steps. The first steps focus on the context of the ecosystem, i.e. both the healthcare system and innovation policy system. The second step focuses on the elements of the regional health economy ecosystems. The third step focuses on the barriers and drivers for current performance and future development.

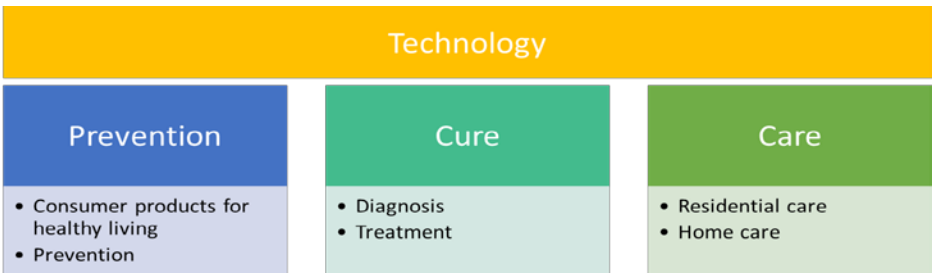
6.1 Step 1: National and regional context of the health economy ecosystem

1. Healthcare system
    a. Briefly describe the general structure and organization of the healthcare system in your country/region (choose region, when the region differs from the country). Also describe the business model/funding of healthcare
    b. List in a table the basic socio economic indicators related to health in your country and region (share in the total economy, healthcare expenditures per capita, demographics)

2. Innovation policy system
    a. Briefly describe the national innovation policy for health (national programs, role of knowledge institutions in innovation policy) and the relevant support instruments of the national government (financing, facilitating, launching customer, regulatory support etc.)
    b. Briefly describe the regional innovation policy for health (regional programs) and the relevant support instruments (financing, facilitating, launching customer, regulatory support etc.)

6.2 Step 2: the regional health economy ecosystem

3. Healthcare covers prevention, cure & care and in each section technology & innovation plays its role (see the schema below). What is the specialization strategy of your region, why and what is the ambition/goal of this regional health ecosystem?
4.



5. What is the structure of the ecosystem - list the stakeholders involved in the following table

	Number	Size (employees)	Turnover	Specify role(s) in / contribution to ecosystem	Investment in regional health ecosystems
Service providers					
Research organizations					
Universities					
Funding organizations					
Support organizations					
Big Companies					

6. Describe how the stakeholders in the ecosystem currently collaborate
    a. Who do stakeholders communicate (online/offline platform)?
    b. Who shares which facilities (labs, patents, data, etc.)?
    c. Who shares which services (office space, events, branding, patents etc.)?
    d. Which stakeholders serve as launching customers?
    e. Other…?
7. Describe which instruments are currently available in or to the regional health economy ecosystem
    a. Public financing instruments (tax instruments, subsidies, capital funding)
    b. Private financing and investors (business angels, venture capitalists, etc.)
    c. Which innovation programs already exist (e.g. tech transfer program, accelerator or incubation program, mentors etc.), who uses them and with what result?
8. Status
    a. What are outputs and results are your striving for?
    b. What is the current performance?

9. Drivers & barriers (see the figure below for possible drivers/barriers)
    a. What are current drivers of success for the ecosystem?
    b. What are the current barriers to success?

Figure 6: Elements of a vibrant startup ecosystem

10. What are the main challenges you face to accomplish the ambitions?
    a. In the types of stakeholder groups involved
    b. In stakeholder collaboration
    c. In available instruments (financial, innovation programs)

6.3 Step 3. Issues

6.3.1 Region West-Flanders

Health system

Belgium is a federal state with a parliamentary democracy. There are three levels of Government: the Federal Government, the Federal States and local authorities (provinces and municipalities). The Federal and Regional level are responsible for healthcare policies. The Federal authorities are responsible for regulating and funding its compulsory national health insurance. Furthermore, they manage the determination of recognition criteria, the financing of hospital budgets and intensive care departments, the legislation on various professional qualifications, and the registration of pharmaceutical products and their price level (= focus on “cure”). The Regional authorities are responsible for health promotion and prevention, 'mother and child'-care, different aspects of out-patient services, coordination and collaboration in primary healthcare and palliative care, the implementation of accreditation standards and the provision of additional recognition criteria, and finally the financing of hospital investments (= focus on “care”).

The Belgian health system is based on the principle of social security characterized by horizontal (between healthy and sick people) and vertical (largely based on the labor incomes) solidarity, without risk selection.

The financing is largely based on proportional social security contributions that are proportionate with taxable income and, to a lesser extent, on progressive direct taxation and on a growing alternative financing associated with the consumption of goods and services.

Almost the entire population can enjoy a wide range of reimbursed healthcare as the health insurance is compulsory. The compulsory health insurance scheme is managed by the National Institute for Health and Disability Insurance (INAMI/RIZIV). The latter assigns a prospective budget to the health insurance to finance the healthcare costs of their members. All persons who are entitled to health insurance need to register with a health insurance or register with one of the six health insurance organizations, or at a regional office of the Auxiliary Fund for public health and disability insurance. The organization of health services is characterized by the principles of therapeutic freedom for physicians, freedom of choice for patients and a fee based on a fee per service (fee-for-service).

In Belgium patients carry some of their healthcare costs themselves (75.2% of expenditure is financed by the government and 24.8% is borne by the individuals themselves), this is realized through a system of co-payments and various supplements. The main feature of the payment mechanism is the pay per performance. There are two payment mechanisms:

1. a direct payment (especially for outpatient care), the patient pays the full cost of care first themselves to the care and then a portion of these costs get reimbursed by health insurance;
2. the third-party payer system (especially for outpatient drugs and hospital stays) where the health insurance pays the lender directly and the patient only if any co-payments, supplements and non-reimbursed services must be paid. The third-party payer system may, in specific cases also be used for ambulatory care, to improve financial access for socio-economically disadvantaged citizens.

The reimbursement of healthcare depends on the type of services granted, income and social status of the member (preference scheme or not) as well as the cumulative amount of co-payments already paid. For the socio-economic disadvantaged groups were taken several steps to ensure access to quality healthcare (OMNIO statute, settlement of the maximum invoice, etc.).

Some demographic and economic indicators on healthcare. On 1 January 2016, Belgium counted 11,3M inhabitants. In 2014, average life expectancy in Belgium at birth was 81.07 years. In 2012, the total public health spending in Belgium amounted 10.9% of GDP. The expenses per capita amounted up to € 3,747 in 2013 (OECD, 2013). The province of West Flanders has 1.2M inhabitants of which 28.6% is 60 years and older. The population aged over 60 is twice the population under 20 years. The number of people employed in healthcare in West-Flanders amounts to around 54k FTE. In West Flanders, there are 18 general hospitals and 6 psychiatric hospitals operational and 281 residential care centers. Additionally, 193 regional companies deliver products and services to the regional healthcare actors.

Innovation policy system

Innovation policy in Belgium is the responsibility of the regions and this competence was extended by the sixth state reform. West Flanders as a province of Flanders only has limited possibilities to foster innovation.

The Flemish innovation policy focuses on:

1. Knowledge acquisition and innovation to strengthen the competitiveness and the anchoring of the Flemish companies
2. Support R&D projects initiated by companies to reduce the risk for the businesses and bring together large companies, R&D knowledge-intensive companies and SMEs
3. Development of a programmatic approach for smart specialization and cluster pacts to enhance effectiveness and valorization of innovation
4. Development of the strategic Research Centers (SRC's) to bridge the gap between basic and applied research and improve the impact of these SRC's in terms of valorization and the creation of spin-offs

Investments in innovation are both private and governmental. About 43 Belgian companies offer venture capital or participate with private equity in startups (www.bva.be). This is not exclusive for the healthcare economy sector. Flanders government has the following instruments to invest:

a. Flemish Participation Company PMV ("Participatiemaatschappij Vlaanderen"): focuses on the specific financing needs caused by market failure. They provide funds through
   - SOFI funds: a tool for very early-stage funding (incubation).
   - TINA fund: for companies with an innovative project (ca. 200 million euros available)
b. Limburg Investment Company LRM ("Limburg Reconversie Maatschappij"): focuses on supporting the implementation of the "Strategic Action Plan for Limburg Squared"
c. Participation Fund Flanders ("Participatiefonds Vlaanderen"): provides subordinated loans to increase the success rate of businesses, sometimes in co-financing with other partners. It is the daughter of the Flemish investment company PMV. Participation Fund Flanders offers two services:
   - The SME-financing: a subordinated loan of up to 350k euros for startups and existing businesses
   - Start Loan +: a subordinated loan for unemployed people who wish to start a business (max. 100k euros)

In 2012, Flanders spent 5.204 billion or 2.42% of GDP on R&D. of the total workforce, 1,39% was employed in R&D in 2012. Compared to Europe, Flanders has a lower number of students graduating in mathematics, science and technology; only 17.8%. Of the Flemish companies 56 % spent resources on innovation in 2012. The share of innovative companies in Flanders is higher than the European average (62% in Flanders, 53% for EU28; (2010). Nevertheless, bridging the valley of death between the development of new ideas and effective market deployment remains a concern.

Flanders wants to support integrated partnerships among stakeholders with the focus on realizing demand-driven and customized care where the patient comes first. To realize this, businesses and the government need to co-invest in a sustainable innovation system. This requires new business models to balance between social and economic valorization. Flanders therefore stimulates entrepreneurship and open innovation in the healthcare sector, for example through networking among service users, businesses, healthcare providers and research institutions. Also, for the assistive technology products

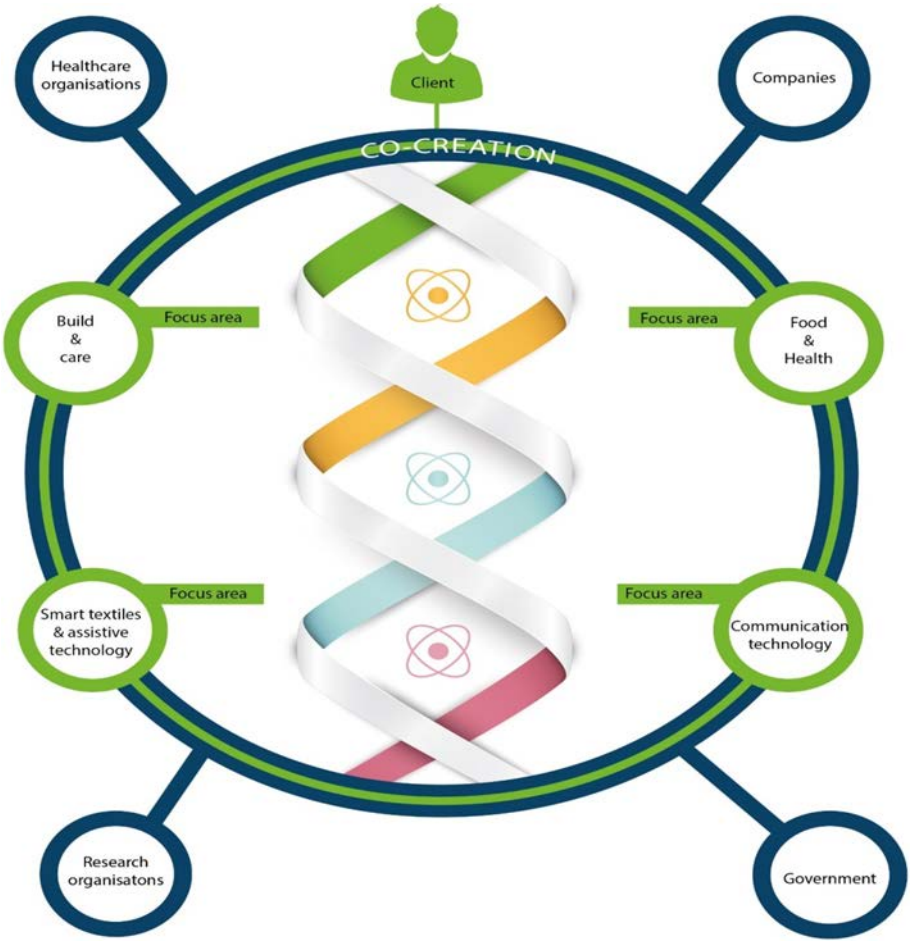
sector, the aim is to provide an environment with few regulations where co-creation between the care, knowledge and entrepreneurs can get space through experiments.

The strategic plan of the province of West Flanders includes, among other economic incentives, the setup of "The Factories of the Future" to develop an integrated partnership with all stakeholders within an industrial cluster. Given the importance of the healthcare sector in West Flanders, the cluster of the healthcare economy was also included in this trajectory, to fasten the implementation of innovative concepts.

To stimulate spin off creation, also in the healthcare economy, West-Flanders has created Spin West to support its economic start up policy. Spin West helps new and experienced entrepreneurs, knowledge and creative sectors in the design, accelerating or spin out of their business.

Regional specialization strategy

West Flanders has developed a smart specialization strategy for the healthcare economy. This is based on both a typology of local SMEs and the needs of the healthcare sector. It has led to the identification of four major focus areas where West Flanders is particularly well placed to strengthen and to generate new economic activity: build and care, food & health, smart textiles and assistive technology and communication technology. The POM West Flanders strategy focuses on activation, sustainability and scaling up of complex partnerships within these four focus areas.



With this specialization strategy, West Flanders wants to trigger additional economic activities to meet the growing demand for healthcare. The province stimulates system innovation and cross border collaboration. This policy focuses on:

- Stimulating co-creation between companies, healthcare and research institutions, who currently know each - other insufficiently to achieve successful coalitions
- Foster open innovation to enhance the complementarity of actors and attain sustainable results
- Appeal for Flemish and European project funding to leverage and accelerate the implementation of new concepts which also arise business opportunities on international level.

Current collaboration among stakeholders in the regional ecosystem

Collaboration takes place on different levels. First, at European level, the province of West- Flanders is part of the Reference site network from the European Innovation Partnership on Active and Healthy Ageing. This network highlights the actions from regional or national stakeholders that jointly implement a comprehensive, innovation-based approach to active and healthy ageing, and can give evidence and concrete illustrations of the impact of such approaches “on the ground".

Secondly, regional collaboration takes place in a structure called “Healthcare Economy West-Flanders”. This formalizes and encourages cooperation between the stakeholders in the care economy. It has a Steering Committee, an Advisory group and Knowledge Cluster. This Healthcare Economy Cluster of West-

Flanders collaborates with Flanders Care. Their mission is to demonstrate innovation and improve the provision of quality care and to promote corporate responsibility in the care economy.

Finally, bilateral collaboration takes place, also formalized in signed agreements. Yet, up till now, cooperation between companies and healthcare stakeholders is mainly based on the classic customer-supplier relationship. Universities and research institutions join forces with healthcare actors or companies based on concrete cases, often on a project basis. And only recently have member associations for private companies such as Voka and Unizo started to consider the healthcare sector as a major economic player.

In the region innovation programs exist. They are quite diverse but the most frequent services offered are:

- learning researchers to detect market opportunities
- providing training, workshops and coaching
- offering co-working spaces or housing
- support by expertise - and experience expert coaching
- giving access to networks and relevant platforms
- providing of accommodation for testing and prototype development
- supporting feasibility studies and internationalization

Issues

Demand in the region is changing. First, the region is aging and young people are leaving. Because of this combination, the demand for care is growing while the number of care providers is decreasing. It will not be possible for the government to fund the increasing demand for care and as a result the quality of care will no longer be at the same level. Moreover, the supply of residential care centers will also be insufficient. Next, demand for care is changing. The customer/patient wants to have in control his care and this brings us to a demand-driven model. However, the needs of the patient /client are not always known by the companies. And the flow of new technological innovations is not disseminated well and therefore too little applied. Overall, a shift from cure to care is needed, yet this is going too slow and insufficient.

The budgetary constraints reinforce the need for new collaboration systems in the healthcare sector. However, liberalization and cooperation between this sector and the profit sector is difficult. Also, severe regulations discourage to commercialize innovative ideas. Most businesses in the West Flanders region are SME and not big companies. The threshold to the constantly growing healthcare actors is often large. Moreover, there is a lack of willingness to be entrepreneurial (22). SMEs prefer to remain small and moreover, they have little experience in working together.

Future challenges

All actors of the Quadruple Helix model must collaborate more in a structured and systematic way to integrate efficiently and as quickly as possible technological applications in healthcare so that a lasting quality care can be offered in the future.

Building a healthcare cluster offers opportunities for all stakeholders;

- for both care organizations (non-profit) and SMEs (profit), this could lead to innovation opportunities. External focus, openness, communication and developing trust relationships are hereby essential elements to achieve a sustainable partnership.
- In this cluster policy, the knowledge institutions that are willing to take a proactive role perform a crucial link
- The government must create the conditions to allow system innovations to take place, to maximize the impact of the innovations.
- Focusing on a preventive healthcare will be an important issue for the future. The companies are not yet familiar to provide solutions for this "new market" in a profitable business model.

Clearly, there is still a lot of work to create a regional environment in which organizations / businesses and citizens embrace innovation and entrepreneurship. The recent attention and support by the government for entrepreneurship is positive but it is necessary to continue to build a more positive entrepreneurial culture (22).

6.3.2 Region South Holland

The Dutch healthcare system is among the best in the world. For many years, it has been ranked high in the Euro Health Consumer Index, and in first place in 2012. The systems have also been given much acclaim for its solidarity. There is a uniform level of healthcare provision for all, irrespective of income. Table 1 displays key indicators of healthcare in the Netherlands.

	OECD	Netherland	South-Holland	Leiden region	Year
Health expenditures					
per capita (in euros)	3093	4418			2015
as % of GDP	9,0%	10,80%			2015
Demography					
Population (x1000)		16979	3622	418	2016
Population growth (in promille)		4,6	6,2	7	2015
Population by age					
- Younger than 20 years (%)		22,5	22,8	22,4	2015
- 20 to 65 years (%)		59,3	60,0	59,8	2015
- 65 years and older (%)		18,2	17,3	17,8	2015
Quality of life					
Life expectancy at birth (in years)	80,6	81,8			2014

Table 1: Key indicators of healthcare in the Netherlands (source: OECD, CBS, Volksgezondheidenzorg.info)

The Dutch healthcare system can be divided into curative care (hospitals and primary care) and long term care (home care and residential care). Curative care is defined by the "Dutch Healthcare Act" (in Dutch: ZorgverzekeringsWet (ZVW)). In the current ZVW there is a universally obligatory health insurance

scheme in which private health insurers provide a basic health insurance package for all persons. Curative care via the ZVW is financed for approximately 50% through premiums that insured persons pay to a health insurance company of their choice, and for the remainder predominantly by income-dependent employer contributions to the Health Insurance Fund. People are free to insure themselves supplementary to the basic package. Long-term care is defined by the Dutch Healthcare Act (ZVW), the new Long Term Care Act (WLZ) and the Social Support Act (WMO). The WMO makes municipalities responsible for the governance and provision of preventative care and home support (see also below). Nursing care is placed under the ZVW. Long-term residential care and complex home care are covered under the WLZ.

In practice, the Dutch health system is decentralized and characterized by two gatekeepers. The first is the primary care practice, as gateway to curative and specialized (hospital) care, except for trauma / acute conditions which do not require referral and are directly treated in emergency departments. The second is the municipality, as gateway to domestic help, assistance and personal (long-term) care. The municipality also leads public health and informal care.

The healthcare system has been reformed over the last ten years into a regulated market system, including privatization of hospitals and health insurance. The payment model between insurance companies and health providers is volume based. This has led to a higher quality of healthcare and lower waiting lists, but also the costs for healthcare have increased rapidly. Recently, due to budget cuts of the government in response to the economic crisis, the growth rate of total expenditures on healthcare has slowed down. The expectation is that the trend of rising healthcare costs will continue due to the ageing Dutch population and increase in chronic diseases.

The current debate in the Netherlands is on how to lower the costs for healthcare as in the long run the current healthcare system is unsustainable. The limits of the system concern especially the public financing of the healthcare system. This is a major driver for investments in healthcare innovations, especially for medical instruments and pharmaceutical industries.

Healthcare innovation in the Netherlands are driven by the changing demand for care on the one hand and the driving force of technological innovation on the other. Demand changes are related to the increasing number of frail elderly and people with chronic and complex health problems who receive care from multiple providers. Also, we see more obesity and mental health problems (OECD 2014a), integrating minorities and continued employment (e.g. postponing early retirement and promoting greater mobility in the labor market) (OECD, 2014b).

The current challenges radically change the perspective on health, care and prevention and the overarching healthcare system in the Netherlands. The definition of health put forth by Incubatorer and colleagues in 2011 has found acclaim in the Netherlands (Incubatorer et al, 2011). This definition steps away from the 1948 World Health Organization (WHO) definition; ‘a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’. As populations age, chronic diseases become more prevalent and persons live longer in disability. Incubatorer et al. thus suggested that especially the WHO’s focus on ‘complete’ health is no longer relevant. Instead they proposed defining health as the ‘ability to adapt and self-manage’ (Incubatorer et al, 2011). The role of human capacity is highlighted and coping is recognized as more relevant than complete recovery. The new definition considers health not as an end but also as a means, for example for participation (in work, society, etc.). It also broadens the horizon of healthcare, where medicine or disease was usually the point

of entry. Lifestyle and health management are getting increasing attention. And in the slipstream, more and more innovations and businesses from outside the traditional medical sector are entering the system. An example it the increase in “consumer e/mHealth” for self-diagnosis, monitoring and managing health.

Innovation policy system

National

The national innovation policy system of the Netherlands focuses on nine top sectors since 2011, after the Dutch government announced the ‘Top Sector Approach’ to strengthen the international competitiveness of the Dutch economy and cope with emerging social challenges. One of the nine top sectors is Life Sciences and Health. The aim of the top sector approach is to stimulate innovation and valorization of knowledge, to resolve the innovation paradox in the Netherlands. The Netherlands has an excellent position in fundamental knowledge, but successful implementation of innovations and private R&D investments stays behind in the Netherlands.

The top sector Life Sciences and Health has three strategic objectives. First, to maintain health and functioning. Second, to maximize effects and minimize burden of disease or disability. Third, to enable people to self-manage health and adapt to disease at home / outside institutions. To achieve these objectives, collaborative innovation contracts for prevention, cure and care are formed between private sector companies, universities and research organizations, and government in so-called Top consortia for Knowledge and Innovations are developed (TKI’s).

The co-ordination of the innovation activities in the top sector approach is based on public-private partnerships between businesses, government and knowledge institutes. Also, the financing of private R&D activities shifted from direct stimulation based on subsidies to an indirect stimulation based of fiscal instruments. Fiscal instruments consist of tax reduction for wages of R&D researchers (WBSO), R&D investments in materials (RDA) and a general profit margin of innovative products (Innovation Box).

Besides innovation policy instruments, there are also public facilities to stimulate entrepreneurship and growth of SMEs. The Netherlands Enterprise Agency (RVO.nl) is part of the Ministry of Economic Affairs and encourages entrepreneurs in sustainable, agrarian, innovative and international business. It helps with grants, finding business partners, know-how and compliance with laws and regulations. RVO can for example provide seed capital, better terms for loans etc.

SMEs are traditionally strongly financed by the banking sector. Since the economic crisis, banks are withdrawing from the market for risk-financing of SMEs due to new regulations. Innovative companies, startups and growing SMEs need new ways to find growth capital. Venture capital (private) and regional development agencies (public) are becoming more important for the financing of innovative companies. Venture capital funds like LSP, Gilde Healthcare, Thuja Capital and Gimv specifically focus on companies in the life sciences and health sector.

Regional

For three years, the region of South Holland has a regional development agency: InnovationQuarter (IQ). Other, more industrial regions in the Netherlands already have a long tradition with regional development agencies. The main instrument to stimulate economic activity of IQ is its revolving investment fund of 58 million euro to finance new and growing companies. Also, IQ helps to develop the regional ecosystem by assisting and attracting foreign direct investments and by organizing network collaborations (e.g.,

incubators, pilots and field labs) and events. On the regional level, other public financing instruments are also available in South Holland. The MIT arrangement of the province of South Holland is a region-specific measure to stimulate innovation activities for SMEs, for example by providing knowledge vouchers and financing of small innovation projects.

In the regional, several stakeholders also have instruments to valorize their own knowledge and products using technology transfer programs and incubation programs. TU Delft (TU Delft Valorization Centre), University of Leiden (LURIS) and Erasmus University Rotterdam (Erasmus Medical Center TTO) have technology transfer offices to connect scientific knowledge with society and markets. Also, some private high tech companies and research institutes have a knowledge exchange program. This TekDelta is a joint initiative of Dutch R&D organizations and the startup community. Participants are TNO, ECN, Philips, KPN, NXP, YES!Delft, Rockstart, TU Delft, TU/e, Kennispark Twente, HealthValley, StartupAmsterdam, and LabForRent. TekDelta aims to connect tech startups with high tech organizations. Its mission is to help startups solve technological challenges by mobilizing the knowledge and facilities of the Dutch R&D ecosystem. Examples of regional incubators (i.e. physical locations where startups and entrepreneurs are located, supported and facilitated by universities) are Yes! Delft, ECE Business Campus, Erasmus MC Incubator, ESA BIC Noordwijk and Biopartner Leiden.

Regional specialization strategy

South Holland set up a specific regional partnership for life sciences and health: “Medical Delta”. Medical Delta is a network of life sciences, health and technology partners that facilitates innovative cross-disciplinary collaborations in the life sciences and health sector. It was initiated by the scientific community (TU Delft, Leiden University and Erasmus MC). So far, for more than 100 million euro of public-private partnerships has taken place in the region with the help of Medical Delta and in collaboration with over 120 private companies. One of the biggest achievements of the Medical Delta is the foundation of the Holland Particle Therapy Centre (HollandPTC) in Delft, where the three universities of Delft, Leiden and Rotterdam collaborate in innovative research. Also, Rotterdam is one of the six co-locations of EIT Health, the large European consortium to improve the competitiveness of the European healthcare industry, the quality of life of Europe’s citizens and the sustainability of the European healthcare system.

Medical Delta primary focus is to organize and stimulate innovative healthcare research and infrastructure and to educate students. Support instruments can be sourcing of funds for projects (from EU funds), project management and coordination, providing research facilities and equipment, and setting up new connections and collaborations. Medical Delta provides local stakeholders a platform through which they can easily launch collaborations. One of the instruments to encourage and accelerate innovation by setting up ‘Living Labs’. The Medical Delta focus is on six themes: eHealth & Self-management, Imaging & Image Guided Medicine, Interventions & Care, Molecular & Cellular Technologies and Vitality.

Within South Holland, many local ecosystems exist that are linked to the Medical Delta. For SHINE, we took a closer look at the Leiden region, which has a long tradition in Life Sciences & Health. Already existing is the Leiden Bio Science Park, a successful business cluster in life sciences and health with a strong focus on red biotechnology and biomedical therapeutics, with more than 170 companies and 17 thousand jobs (90 out of 130). Successful companies originating from the campus are for example Galapagos and Janssen Biologics.

For SHINE, we studied the newer Center for Vitality (CfV). This CfV was developed in 2014 by the local economic board (Economie071). Local science partners are Leiden University Medical Center, Dutch applied research organization TNO, University of Applied Sciences Leiden. Via the local economic board six municipalities are involved, both the local government and end users (inhabitants, employers etc.). Also, Innovation Quarter and HUBspot are partners. The latter being a local startup facility.

The ambition of CfV is (i) to increase the local economic activity in vitality and (ii) to increase the vitality of the area. The focus on vitality fits in the changing perspective on health, care and prevention in the Netherlands. CfV wants to join health providers, innovations and businesses from within and outside the traditional medical sector. CfV focuses on vitality and active ageing as well as the vitality of workers, students and the whole population. CfV wants to be a living lab for research projects on vitality, match local supply and demand of vitality products and services, and validate research projects.

The CfV just formally started. Hogeschool Leiden leads the project since the beginning of 2016 and funded and equipped the center up to the end of 2018. Activities for the current period are:

- Built a network of HR directors of corporate companies in the Leiden region that can make use of vitality products and services to improve the vitality of employees.
- Launch of an interactive website for supply and demand of vitality products and services
- Create a local economic system with 'health coins' to experiment with business models for vitality products.
- Arrange the physical location of the Centre within HUBspot, the Centre for Entrepreneurship in Leiden, so it can make use of startup support facilities of HUBspot.

Current collaboration among stakeholders in the regional ecosystem

The status of the Center for Vitality is embryonic. Network meetings have taken place to explore possible ways to collaborate in the centre. The introductory meetings with potential stakeholders of the Centre have led about 35 companies who are interested in collaborating within the Centre to develop and validate new products and services, mostly small companies. Also, large companies are interested in the Centre as potential user and co-creator of new products. A network of HR directors of corporates in the region is looking for opportunities to improve the vitality of their employees. Also, two large health insurance companies are involved.

Current organization of the center is funded and equipped for three years by Hogeschool Leiden. It enables Hogeschool Leiden to test and validate research and to introduce students to entrepreneurship in the vitality sector. Also, the municipalities of Leiderdorp and Voorschoten are in the Board of the Centre and have committed themselves to 2 local pilot projects to improve the vitality of citizens.

Also, the Center for Vitality collaborates with HUBspot, so it can make use of shared startup facilities and services of HUBspot to help young companies to develop a business case for their ideas for new products and services.

Issues

The concept of Vitality in CfV was heavily inspired by the work of professor Rudi Westendorp. Up to 2015, professor Westendorp played a leading and orchestrating role in the vitality research community in South Holland. With others, he initiated the Center for Vitality. However, in 2015 he left to Denmark to join the

Centre for Healthy Ageing (CEHA) in Copenhagen. With his departure, the region lost a linking pin, initiator, and leader for collaborative research in the field of vitality. On the other hand, it also gave opportunity to link to other running research programs. This change in local leadership brought about a delay of one year. Hogeschool Leiden took over the project lead of the Centre.

Present issues are the lack of involved of private companies and the different interests of the parties already involved. Also, the focus is rather broad without a strong lead. Vitality is of course strongly linked to prevention and wellbeing. The incentives for payments/investments for related products and services is still rather low. Especially in specific target groups with low social economic status and/or specific cultural backgrounds. But also for health insurers and employers.

Future challenges

The biggest challenge for future research in vitality in the region is collaboration. Vitality research needs collaborating partners. Compared to other health research disciplines, it also needs collaboration with more diverse partners. Many people are involved with different backgrounds and with less experience in research collaborations, e.g. volunteers, care professionals, insurance companies. Scientists and technical professionals in vitality have relatively less experience also in working in public private partnerships and to organize techtransfers from the science community to the market. The alliance and collaboration strategy to create interactions and collaborations between all these partners is the major future challenge. Collaboration in general is often already a challenge for people.

The second challenge is to develop a business model for vitality with a clear focus on target groups and businesses involved. The Dutch health system is based on a payment structure for providing care and not health. However, stimulating vitality and promoting and sustaining health works the opposite way. Lifestyle and vitality products and services are often not reimbursed. The benefits are in the long run and so far, mostly lack hard (scientific) evidence.

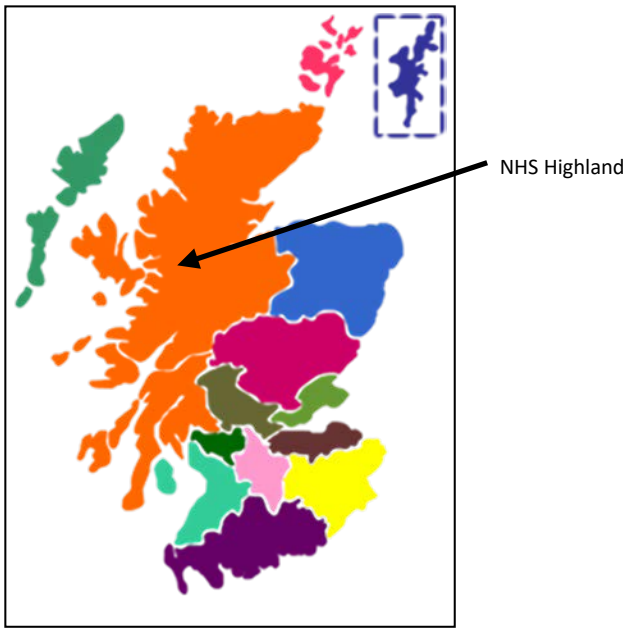
6.3.3 Region Scotland / Highlands

Health system

In the UK and in the devolved nation of Scotland, healthcare is largely provided through the National Health Service (NHS). In the UK, there are 294 NHS Trusts/Boards/Special Trusts or Boards and other NHS organizations. The NHS provides free healthcare to the population through a publicly funded system via central Government funding. For 2015/16, the overall NHS budget was around £116.4 billion.

The UK also has a small private sector in healthcare providing a lesser set of treatments than those obtainable from the NHS. Private healthcare is sometimes funded by employers through medical insurance as part of a benefits package to employees though it is mostly the larger companies that do. Insurers also market policies directly to the public. Most private care is for specialist referrals with most people retaining their NHS GP as point of first contact. The private sector now does some subcontracting work for the NHS. Private healthcare used by about 8% of the UK population, but remains a relatively small proportion of patients using non-NHS services.

In Scotland specifically, there are 14 territorial Health Boards (HB) and 5 Special HBs, including e.g., the Scottish Ambulance Service and National Services Scotland. Each HB receives an annual allocation of funding from the Government and allocates spending against this budget locally. In Scotland, the cost of the NHS territorial HBs and two of the special HBs together require funding of nearly £11 billion annually. Each HB is accountable to the Scottish Ministers.



The Health Boards of the NHS in Scotland

NHS Highland, similarly to other territorial HBs in Scotland, is organized and managed by a Board of Executive and Non-Executive Directors and is accountable to the Scottish Government through the Cabinet Secretary for Health and Wellbeing. The Chair and each of the Non-Executive Directors are appointed by the Cabinet Secretary. Executive Directors are the Chief Executive, Medical Director, Director of Public Health, Chief Operating Officer, Director of Human Resources, Director of Nursing and Director of Finance.

Operationally, NHS Highland delivers the following services: accident and emergency; acute hospital care; acute mental health; adult social work teams; equipment to support people at home; care at home; care homes; 22 community hospitals; community mental health teams; community nurses; day care services; dental services; district general hospital; handyperson services to support people at home; learning disability services; midwifery services; nutrition and dietetics; occupational therapy; pharmacy; physiotherapy; podiatry; primary care services (106 GP practices, 86 dental practices accepting NHS patients and other primary care services); respite services; 3 rural general hospitals; self-directed support; speech and language therapy; tele-care.

Some socio-economic indicators. In 2014, the UK had 63.7 inhabitants in 2014 and spent 9,1% of GDP on healthcare. In 2015, Scotland had 5.3M inhabitants, 234K of which lived in the Highlands. In the Highlands, 27.9% of the population was aged >60 years. Of the total workforce in the Highlands, 18% is employed in healthcare (this is 13% in the UK).

Innovation policy system

Three documents are important for the innovation policy in health.

- Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS (IHW) (December 2012): a key statement of intent to build on the potential for the NHS to innovate
- HEALTH AND WEALTH IN SCOTLAND: A STATEMENT OF INTENT FOR INNOVATION IN HEALTH (2012): the main document for innovation in Scotland.
- Scottish Life Sciences Strategy 2011: Creating Wealth, Promoting Health: stated aims to double the economic contribution of Life Sciences to the Scottish economy by 2020

Following the publication of the policy documents In Scotland, investment has been made into several Innovation Centers, including ones for Digital Health and Care (DHI), Stratified Medicine Scotland which is largely biomedical research (SMS), Centre for Censor and Imaging Systems, Industrial Biotechnology (IbioIC) and DataLab which supports data science innovation. There are other centers in Scotland that also contribute towards research and innovation for health out with the Universities. These include the Farr Institute which is a UK-wide research collaboration involving 21 academic institutions and health partners in England, Scotland and Wales.

The Scottish Government has supported the Scottish Collaborative Innovation Partnership Process (SCIPP) since September 2014. It has taken an explicit collaborative approach nationally to developing innovative ideas to reduce reliance on hospital care in line with the 2020 Vision. SCIPP focuses on the health and care system from the perspective of the individual receiving care and support in 'how it works for you'. Building on the collaborative process and ideas generated nationally, local partnerships and organizations across Scotland are now being offered the opportunity to undertake a SCIPP local as part of a strategic approach to improving health, care and support locally.

The Innovation Partnership Board, formed in December 2012, represents a unique attempt to make progress on health and innovation on a joint basis, with board members from across the NHS, life sciences industries, Scottish Enterprise, the research community and the Scottish Government. The IPB meet quarterly and provide strategic leadership to health and innovation in Scotland.

Since 2013, each NHS Board has an Innovation Champion. Innovation Champions serve as internal and external contact points on innovation and as drivers around the innovation agenda. Scottish Government works with the Innovation Champions through quarterly meetings and ongoing engagement.

The Health Innovation Assessment Portal (HIAP) managed by NHS National Procurement, is the first step in a national process that is being developed to provide health innovators with feedback, signposting and onward direction from NHS Scotland, including the Scottish Health Technologies Group, and Scottish Government. Innovations submitted via the portal are assessed by a panel of relevant experts, including NHS clinicians where appropriate.

To support innovation, the following schemes, programs and initiatives are available not only to the Highlands, but also to Scotland more widely. *R&D Tax Credits:* allows companies to deduct up to 225% of qualifying expenditure on R&D activities when calculating their profit for tax purposes. *Patent Box Regime:* at 10%, the rate available on profits attributable to patents is currently less than half the standard rate of UK corporation tax in the UK. *Care and Well Being Fund:* Loans and other investment of between £500,000 and £2.4 million are available for social enterprises that are innovating within the community care space for people with cancer and other long-term illness in the UK.

Highlands and Islands Enterprise - R&D Funding Scheme: the agency responsible for delivering economic and community development throughout the Highlands and Islands region of Scotland. It supports independent and collaborative research, development and innovation projects undertaken by private sector enterprises and research institutions within the Highlands and Islands area of Scotland.

Synthetic Biology Startup Fund: £10 million of funding to provide kick-starting finance to technology startup companies that evolve (or 'spin-out') from publicly-funded research.

Small Business Research Initiative (SBRI) Funding Competitions: to enable businesses in the UK to develop technologies to meet the needs of public sector bodies and government departments. The program offers competitive R&D contracts. Successful companies receive a direct contract, which covers the cost of proving technical feasibility of up to £100,000 and within a six-month period. The most promising technologies will receive further contracts to demonstrate product capability within a two-year period.

Business Growth Fund: Government sponsored equity investment fund targeted at high-growth UK companies with a turnover between £5 million and £100 million.

Scottish Enterprise R&D Grant: R&D Grant funding supports businesses developing new products, processes and services to improve company competitiveness and to benefit the Scottish economy.

Scottish Enterprise High-Growth Spinout Programme: **t**o support projects at the pre-production, conceptual development stage, to contribute to advancing the commercialization of innovative scientific knowledge for the benefit of the Scottish economy.

Innovation Voucher Scheme (Scotland): a scheme that aims to build relationships between SMEs and Higher Education Institutes in Scotland by supporting collaborative projects that will lead to new products and processes that will benefit the business, the institution and the Scottish economy.

The award for an individual project is for between £1,000 and £5,000.

ScotGrad: matches skilled graduates with ambitious growing Scottish businesses to undertake innovative projects which the companies would otherwise not be able to progress.

SMART: SCOTLAND: to help small and medium-sized businesses to improve their competitiveness by developing new, highly innovative and commercially viable products and processes to the benefit of the Scottish economy. The program provides grants on a discretionary basis for technical and commercial feasibility studies, and research and development projects.

Regional specialization strategy

Scotland has a significant commitment to a specialization strategy based on the digital economy and the delivery of services through digital platforms. There have been several actions and programs established in the past 3 years aimed at progressing this strategic approach. The specialization strategy covers all

three components of the schema provided (above) and aims to integrate health and social care and wellness through the seamless use of digital technologies across the whole of the population and the land – where remoteness and rurality provide substantial challenges to the effective provision of health and social care.

Under the Vanguard Initiative, Scotland is taking steps to actively address common challenges and opportunities faced by society across Europe. Scotland is a recognized leader in the fields of telehealth, telecare and eHealth. For example, we are key partners in the European Innovation Partnership on Active and Healthy Ageing a major initiative of the European Commission which is part of the Innovation Union Strategy and has at its heart the goal to improve healthy life-years for European citizens by two years by 2020. Scotland is one of only three regions in Europe to have been awarded two three-star ratings for its work in this area, and is playing a lead role in promoting the spread and adoption of ICT-enabled integrated care, helping to reduce unnecessary hospitalization of, for example, older people with chronic conditions.

Scottish Ministers' aspiration is for Scotland to be a leading digital nation by 2020. *Scotland's Digital Future: A Strategy for Scotland*,[69] published in 2011, outlines the key elements that are required to ensure Scotland is well positioned to take full advantage of the digital age.

Support to develop Scotland's digital economy is being delivered through the Digital Scotland Business Excellence Partnership. The Partnership brings together key partners from the public and private sectors, with separate business and skills programs hosted respectively by Scottish Enterprise and Skills Development Scotland. The combined £13.6 million available under these programs is supporting and enabling businesses across Scotland to take advantage of the huge opportunities offered by digital technologies and approaches. It is also helping to support skills development by implementing the ICT and digital technologies Skills Investment Plan published in March 2014 and designed to ensure that the workforce is equipped with the necessary skills to embrace the opportunities of the digital age.

Scotland's Digital Future - Delivery of Public Services jointly introduced in 2012 by Scottish Ministers and COSLA, is a key enabler of our public service reform program. The strategy sets out our overarching vision that Scotland is a country in which digital technology provides a foundation for innovative, integrated public services that cross organizational boundaries and deliver responsively to those who need them.

The first major partnership project is the Scottish Wide Area Network (SWAN) which aims to enable infrastructure and service sharing that will produce cost efficiencies built upon aggregating demand. The SWAN Vanguard Project (the first project under the Program) was designed to deliver a single public services communications network in Scotland which is open to all public service organizations. The four SWAN Vanguard Partners are: NHS Scotland; Pathfinder North (Highland Council, Argyle & Bute Council, Moray Council, Orkney island Council and the Western Isles); Pathfinder South (Dumfries and Galloway Council and the Scottish Borders Council); and Education Scotland.

The new infrastructure went live and was made Ready-for-Service at the end of July 2014. Education Scotland and NHS Scotland now have services running over SWAN and over 1,500 sites are now connected. Education Scotland transitioned entirely to SWAN by the end of January 2015 and the NHS sites are working towards a full transition in mid-2015. Pathfinder South started its transition in

November 2014 and is planned to be complete by the end of May 2015. Pathfinder North will have its transition completed in 2016 to make use of the new infrastructure being delivered as part of the Superfast Broadband roll-out. Using this new infrastructure, SWAN can reach approximately 700 of the 750 sites and will provide a £7 million saving over the lifetime of the contract.

Current collaboration among stakeholders in the regional ecosystem[1]

In the Highlands, communication although physically difficult because of the challenges of obtaining mobile signals in the mountains, is relatively easy amongst the stakeholders developing health innovations in the region. The relatively small number of individuals and organizations, many of whom are based in and around Inverness (the capital), means that many of these individuals are in regular communication and meet at many of the same events, and are members of the same committees.

Resources are shared in the Highlands. There is some sharing of labs and similar facilities for innovation and health purposes – between the Universities, and with the NHS and with businesses. One of the key facilities in Inverness is the Centre for Health Science, which is situated on the main hospital campus, and there is substantial joint working and integration of use of facilities and joint hosting of events. It is recognized that to achieve progress in innovation needs stakeholders and partners to work effectively and efficiently in terms of the use of resources, so many activities follow this path. There is some sharing of data, although it is recognized that it is difficult for the NHS to provide access to clinical data with pursuing the full governance route. Further, there is a move towards branding across institutions or at least a focus on 'selling' access to the joint resources available in the region, but this is not yet fully developed. Joint patents are sought only when there are evidenced contributions from two or more partners in the development of new inventions/products.

To launch new products, the NHS is main launching customer. Nonetheless, there continue to be barriers, especially in relation to procurement, to be overcome. NSS, or National Services Scotland, while supported by Scottish Government policy to ensure it is easier to support the entry of products, especially from SMEs into the NHS system, has yet to ensure that this is truly integrated. Large suppliers still tend to dominate NHS procurement.

Issues

There is substantial commitment towards innovation in the health sector. Stakeholders in government, business, development, health and academia recognize that much potential exists for Scotland to turn ideas into products that can contribute towards better health for the population as well as economic growth for the sector across the country. Scotland is at the early stages of government initiatives on Pre-Commercial Procurement where businesses are funded to develop solutions to public sector needs. Also, there are several successful healthcare startups (however not through a regional ecosystem) throughout Scotland that have also international success. Companies such as LifeScan, Optos and Touch Bionics are examples of Scottish inventiveness.

[1] This section has been completed focusing on the Highlands specifically, as it thus provides a snapshot of one of the regions in Scotland which may have the potential to be significantly further developed. Other regions in Scotland, such as the cities of Glasgow and Edinburgh are likely to have a better developed collaborative ecosystem focused on the two large historical Universities in each of these cities.

However, one of the problems or challenges is the confusion and crowded nature of the innovation and health sector. Many centers of research, development and innovation are being established within the last 4 – 5 years. Along with a refocusing of the support mechanisms available in Scotland and in the UK more widely. As government and business budgets change from year to year these mechanisms tend to expand or contract. Currently, the ecosystem is fragmented and needs a bottom up approach where innovation tackles issues in delivering health and care education and services.

Also, culture impedes innovation. Current thinking is that innovation is something that others do. There is early recognition on the benefits of a collaborative approach to education, research and technology innovation. But Scotland and the UK do not have programs and initiatives that financially in support stakeholder collaboration or in available instruments. Specifically, there is no real evidenced integration of the stages of the innovation management system. Current initiatives want collaborative innovation but tend to fund academic partners only. And when stakeholders want to collaborate, yet this is being stifled by access to funding and the lack of a turn-key solution that covers every stage in the innovation pathway. Also, where many initiatives and resources for entrepreneurship are in place in Scotland, healthcare still tends to be dominated by academic spin-outs and multi-national companies.

Future challenges

One of the challenges for innovation and health in Scotland will be the withdrawal of the UK from the EU. It is unsure how that affects the access to EU funding programs Scotland currently has. The may also have some influence on how SMEs can gain entry and grow into new EU based markets, although there may be opportunities arising outside the EU.

Also, the NHS in Scotland, as more widely in the UK, must develop different business models if it is to survive beyond the next 20 years. A challenge here is the culture of the NHS – which for many employees is firmly fixed in the public service mentality and for the general population which see the NHS as ‘free’. This attitude is not sustainable for the NHS, and is restrictive as it does not allow for NHS commercialization and development of its own ideas and products.

One other problem is the approach of SMEs which generally develop a product and then seek input from the NHS. This often results in failure because having missed discussion with the NHS, a product can be not fit for requirement. Instead, joint development of products is a much more efficient and effective way.

7 Annex 2: Leading examples continued

7.1 Case “Voor ik het vergeet-app” (Belgium)

7.1.1 Purpose and developmental history

The purpose of this innovation is to develop an application that would support conversations between professional caregivers and residents with dementia, particularly conversations about the residents’ future needs and wishes for (palliative) care. The application is called “Voor ik het vergeet” (“Before I forget”), and is available for IPad, tablet and smartphones (Android and Apple), and is supported by the website http://www.voorikhetvergeet.be.

The app was developed in-house by residential care facility Woonzorgcentrum De Ruyschaert, located in Marke, Kortrijk, Belgium. The main acute driver for the development of this app was that the Belgian government issued legislation that enforced registration of so-called indicators of quality of care. One of these indicators was that all the residential care facilities in Belgium were required to register was the amount of conversations with their residents about future (palliative) care and end of living. Soon, the care facility discovered that the outcome of this type of conversations was not always reliable in residents with dementia. Therefore, the staff of the facility decided to explore ways of making conversational topics more graphic, by using photos and pictures to talk to residents. These conversations were particularly dedicated to daily preferences and wishes for future (palliative) care, including quality of life and end of living decisions.

The initial concept of the app was based on an existing app that showed photos. The staff used this app with their own selection of photos, to test the concept with the residents. After this turned out to be a success, a new app was designed particularly for having future-care conversations with residents with dementia. Eventually the app became part of a larger method for conversation. It is important to provide the healthcare-workers in training to learn how to use the app in conversations, to obtain the desired results.

The method includes several steps. First, receiving an informed consent from the resident or the family is necessary because the conversations are recorded on videotape. One of the healthcare-workers will sit with the resident in an informal setting.

They will use an IPad to flip through a digital photobook, with all kinds of pictures showing different topics, and the resident can express their preference. Some questions are very low key and accessible, such as “what’s your favorite dish” or “would you rather sit alone in your room or would you like to join a group”. Other topics are heavier, such as “if necessary, would you prefer to be resuscitated or not?”

The resident’s family is involved in the process of analyzing these conversations, so that the staff gets an impression of the results, both from the patient and the family. Particularly in the case of dementia, it is said to be helpful for the staff to hear from the family how they interpret or recognize a certain sound,

word or movement from the patient to indicate his/her preferences. An unanticipated side-effect of the method is that families can be pleasantly surprised when seeing the participation level of the resident, for instance when their mother unexpectedly is still able to communicate through her response to the photos demonstrated in the app. At last, the residents' general physician is also involved in the process. Within the developed method, the staff is properly trained for this type of conversation.

Since October 2016, two product packages are available on the market:

Light version	Full version
Installation at max. 3 devices	All the features of the light version plus:
Access to all existing themes and photos	Adding/ changing themes
Output in the form of patient reports	Adding/changing photos
75 Euros annually	**95 Euros annually**

The app and its method were evaluated in 2015 by two Master students from a Belgian University, whose research concluded that the method was indeed effective in improving communication between patients and caregivers. Previously, it was generally assumed in healthcare that residents with dementia cannot express their needs fully or properly anymore. With this innovation, it was proven that these residents can still answer difficult questions and give their opinion on matters important to them. Essentially, this app gives the residents with dementia their voice back. Currently, the method is being used by circa 30 care institutions in Belgium.

7.1.2 Structure and facilities

In the early stage, the app was designed within the care facility, in cooperation with students Bachelor of applied computer science, major in application development, process choice Apps & Gamification VIVES in the further process of the development an external IT-company was involved what is necessary for technical adjustments or updates to the app. The administration that comes with the application, the method and the training for caregivers, is provided from the facility as well.

7.1.3 Financial history

Initially, multiple routes for potential financing of the app were explored, including universities, several funding agencies and investment projects. However, no financial support was obtained from any of these sources. This was reported as a tiring and demotivating experience, and it caused the initiators at the care facility to doubt if the idea was feasible and if it was worth all the trouble. At last, a financial injection was provided by the Belgian "Koning Boudewijn Foundation (Koning Boudewijn Stichting). The foundation issued a call for innovative solutions for conversations with persons with dementia about future (palliative) care and end of living, for which the care facility filed a proposal in 2012. This proposal was granted. This money was used to finance the initial development of the app. In face of a lack of external resources to finance the further project, the care facility then decided to sponsor the professional version of the app out of their own pockets. Since October 2016 the app is available in two versions, for which a yearly monetary contribution is required. The consumer price is not primarily intended for the benefit of profit. Although the care facility itself hopes of recouping the amount of money invested

7.1.4 Key factors for success

From the care facility's perspective: the moment that the odds turned into favor of the app, was when two organizations joined the initiative: both an expertise center for dementia and the Belgian federation for palliative care became involved. These organizations have large networks and a lot of expertise, through which content and 'body' was added to the app. The organizations gave advice about crucial elements of the app, e.g., how was the app made, how and where can appropriate photos be found and selected, how can the app be distributed in the field, and so on. Additionally, they provided relevant counseling on how to deal with privacy issues and legislation.

Another important factor for success was the fact that the care facility immediately at the start of the project already started to involve other care centers and colleagues to determine whether there was a need and a market for the app. This not only confirmed the sense of necessity of the app, but also had a positive impact on the level of motivation and determination of the team developing the app. This helped them believe in their idea even when initial funding was not provided.

Overall, cooperation with others, both experts and potential customers, was essential for the development and success of the app. Further, the care facility staff mentioned it is important to follow your instincts, and to always keep your target group in the front of your mind: what do they need, and how are you going to provide that. Feedback from potential customers and users, as well as testers, was crucial to move forward. And when it comes to the context of the developmental process: they said it is important to think outside the box, to look beyond problems that present themselves immediately, and look for chances to create value. Other factors that are important were: determination, don't be a quitter, and celebrate the successes that occur in between, even the small ones. What also mattered was the fact that this product was unique: there was no competition with other products on the market. And it was important to the developmental process that the facility started with an idea as a solution to their needs, which created instant support for the app. If someone outside the facility or outside of care had developed such an app, it might not be easily adopted in care facilities.

Finally, it was acknowledged that if eventual funding would not have come through, it would have been hard to carry the project forward, both on a financial level and a motivational level. Receiving funding confirms that gut feeling that you're on the right track and that your innovation matters.

7.1.5 Barriers for success

Several barriers for success were mentioned as well. About the developmental process, it was difficult for the care facility to figure out the specifics of building applications and how the technology works. Content-wise it was easy to develop the product, but the technological and legal side was not part of the core business of the facility. This took up a lot of time and energy, combined with the process of looking for funding. In fact, privacy regulations were a major issue for this innovation. However, it did not delay the innovation because the pressure was very high: the privacy issues had to be fixed before the app was allowed into the market. One potential customer was lost because of privacy concerns during the test-phase, which were fixed shortly after.

About marketing, there may be two potential problems for the scale-up of this product. Firstly, although the app and method itself are easily used and accessible, it is important that care facilities make a thorough selection in which employees shall use the product. That is, not all employees may possess the

proper skill level for this type of conversation. If care facilities do not select the proper employees or if they do not train their employees in communication skills, this could reduce the level of success of using the product in their facilities. Secondly, it is important that the people using the app have a basic skill level with regard to the use of the technology, e.g., experience with a tablet or IPad. Also, facilities must invest in buying IPad or tablets, which can be a barrier for purchasing the product.

7.1.6 Regional influences

In the immediate environment of the care facility, there weren't a lot of facilities available. Although funding was eventually provided by a national foundation, locally no subsidies or financial support were available. It was said to be particularly troublesome that there are a lot of subsidies available, but they are generally granted to large projects and universities. In other words, it is difficult for small innovations to get a piece of the cake when it comes to the more traditional sources of financing.

An important, crucial regional factor for the distribution and marketing within the care sector and the region was the fact that the facility started a partnership with both het Expertise centrum Dementie and the Federatie Palliatieve Zorg Vlaanderen. Both organizations had several networks available to them, which were soon connected to the innovation and developmental process. Because of these networks, the facility now has many parties that are interested in using the app in their own facilities.

7.1.7 Future

The team behind the app is now aiming to expand the reach of the app, and to ensure that more care facilities adopt the app and the method that comes with it, to improve their care to patients with dementia. Potentially, other sectors could also benefit from this app, for instance, the app could have unknown applications for use in care for patients with brain damage.

7.2 Case: NightBalance (Netherlands)

7.2.1 Purpose and development history

The purpose of this innovation is to offer positional treatment for positional obstructive sleep apnea patients, by means of an electronic wearable device. More information about NightBalance is available at http://www.nightbalance.com.

Currently, approximately 2-3% of the population across Western-Europe is suffering from obstructive sleep apnea. This condition may result in various health problems, including irritability, cognitive failure and fatigue. Furthermore, obstructive sleep apnea is associated with an increased risk of heart failure. The start-up company NightBalance developed a small wearable device to treat positional sleep apnea and relieve patients from traditional treatment devices that often cause discomfort during sleep. The device developed by NightBalance constitutes of a small electronic sensor that is worn around the chest during the night. The device monitors the sleeping position of the patient, and sends a vibrational stimulus whenever a person is lying on their back. Without waking the person, the signal stimulates the person to roll over to their side. As a result, positional sleep apnea can be treated effectively without invasive or uncomfortable side-effects.

NightBalance was founded in 2009. The company was inspired by the development of a prototype for treating positional sleep apnea, which was created during the university study of the NightBalance founder. To explore the potential of the prototype in effectively treating positional sleep apnea, the founder in question joined, together with a co-founder, the Incubator Program at YES!Delft in 2009 and from that point onwards, the business plan for NightBalance was developed. In 2016, NightBalance moved to a new office location in The Hague, to facilitate the need for company expansion and a new, more mature, environment to sustain the company's acceleration. On page 45, additional information about YES!Delft is included.

7.2.2 Structure and facilities

NightBalance was founded by two persons, and is currently managed by a Management Team consisting of a CEO, a CTO, a CFO and a COO. NightBalance employs fifteen persons in a variety of functions, including sales, software and product development, office management, quality assessment, and customer services. NightBalance' s company structure is hierarchical, it's way of working is non-hierarchical. NightBalance is currently exploring opportunities to hire experts in all fields needed for its expansion, with a focus on market access, marketing and sales.

7.2.3 Financial history

Soon after NightBalance was founded, the company was awarded on several occasions for their innovative product. These awards and the financial bonuses associated with them provided NightBalance with sufficient start-up capital. This was particularly essential to NightBalance' s success because, being

listed as a medical company, considerable start-up capital is required to develop prototypes and run the required technical tests and clinical trials.

Since 2010, NightBalance has gathered capital from investors through three investment rounds. For each investment round, it was considered which type of investor would fit the profile and needs of NightBalance at the time. During the first round, investors were focusing on the market potential of NightBalance' s product, and on the strength of the medical evidence regarding the product's effectiveness in treating positional sleep apnea. In the second round of investments, NightBalance had to convince investors of their market potential, and of the cohesiveness of their team. This round of investments is more formal, and puts considerable pressure on the entrepreneurs. In the final and third round, NightBalance collected approximately 12.5 million Euros to expand the company and aim for market access in the US.

Now, NightBalance is successfully present in various markets in the Netherlands and abroad. Market penetration remains a permanent challenge for the company, because of established (financial) structures within the healthcare domain. To distribute their product, NightBalance works with local distributors across countries, who sell the product directly to patients. A requirement for purchase of the product is a prescription by a (specialist) physician. Now, patients are required to pay for the product themselves, and receive no compensation by health insurers.

Without a doubt, health insurance companies have a crucial role in the growth and market penetration of medical start-ups, such as NightBalance. For instance, if health insurers decide to reimburse patients for using NightBalance' s product, their market share will be likely to grow exponentially. However, in European countries, the vetting of products for standard care by governments and insurance companies is often a long-term, challenging and political process. That is, the market for medical innovations is highly subjective to national and international laws, regulations and political decisions. This is one of the current challenges of NightBalance, but one with good hopes for the future.

7.2.4 Key factors for success: recommendations by NightBalance

- Make sure you meet with other entrepreneurs, discuss ideas and cultivate your business strategy.
- Become part of a start-up ecosystem. Join a program, an incubator, or a launch lab, that will get you in touch with successful entrepreneurs.
- Understand what becoming a company, an employer and an entrepreneur entails. Simultaneously, start developing skills and gathering knowledge regarding accounting and human resource management.
- Investigate what you want and what you need, and ask all the questions that come to mind.

- Figure out if there is a market for your product, and identify your target group. You might have a great idea for a product or service, but to become successful, the public must have a need for your product, and most importantly, they must be willing to pay for it.
- It is essential to select the proper investors for your company during the various phases of company growth. Furthermore, if you have a high-potential product, you may find that many investors are offering their services. However, you need to determine which investors share your company's core values, if they have the proper network and the right background for your company.
- It is crucial to have a back-up plan and financial savings in place in case of fluctuating orders, or if you need to wait for orders to come in or payments to be made.
- Especially if you are offering a product, it is necessary to invest in your relationships with distributors and suppliers from the start, because you will experience fluctuations in supply and demand at first.
- For medical start-ups, financial support for several years is necessary, because it takes more time to create cash flow and sustain a medical company compared to other types of start-ups due to the regulatory aspect of the business.

7.2.5 Barriers for success

- As NightBalance is categorized as a medical company (offering treatment), two things were key during the start-up phase. The first was to develop a working prototype, and the second was to obtain clinical evidence about the functionality and effectiveness of the product. From that perspective, scientific publications about the products' effectiveness are critically important. Because of the need to conduct scientific studies with the product, the company's acceleration is limited.
- Aside from NightBalance' s product, two other treatments for positional sleep apnea are present in the market. Moreover, these products are well-established in the market: they are registered as effective treatments and paid for by insurers. This is a barrier for market penetration and growth of customer demand for NightBalance' s product.

Compared to the US, it is considerably more difficult as a start-up company to get in touch with potential investors. That is, the thresholds for investors are much higher in Europe, and the investments themselves are significantly lower compared to the US.

7.2.6 Regional influences

Cooperation with the YES!Delft institute was crucial during the start-up phase of NightBalance. Also, the local facilities in the region surrounding YES!Delft (Randstad) supported NightBalance during their start-up process. In the region, there are several relevant companies present, as well as technical universities, innovation centers, medical industrial partners, and academic hospitals.

7.2.7 Future

The current goals of NightBalance are to expand the company both in Europe and the US, and to make sure the company is viable for the next years. In the long run, the company aims to be recognized as a

standard option for treating positional sleep apnea, including financial compensation for patients by healthcare providers or insurers.

7.3 Case: Zorgkeuzelab (Netherlands)

7.3.1 Purpose and developmental history

The purpose of this innovation is enable patients to have an equal share in the decision-making process, together with their specialist, nurse or physician. Further information about ZorgKeuzeLab can be found http://www.ZorgKeuzeLab.nl.

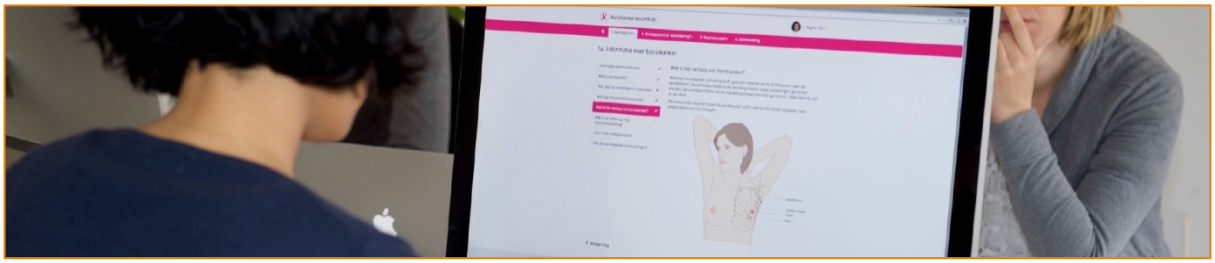
ZorgKeuzeLab started when one of the founders, an industrial designer, developed a decision aid for patients in an academic hospital. The decision aid was to assist in the choice for the most appropriate treatment option. Very soon, an ambition grew to create more than a decision-aid for patients, rather to improve the entire decision-making process. Nowadays, ZorgKeuzeLab maps the complete process of decision-making within hospitals, and the stakeholders involved, such as clinicians and nurses. This process is called a patient journey. The overall aim of ZorgKeuzeLab is to enable and empower patients to actively participate in their patient journey, to provide transparent and objective information about the treatment options available to them, and to ensure that patients, together with professionals, make an informed choice that matches with their personal preferences.

ZorgKeuzeLab
samen beter kiezen

What ZorgKeuzeLab offers in terms of product, is a digital decision-aid and implementation support for hospitals. The aid is slightly comparable to an online form; every step of the patient journey is displayed on a map, together with relevant information at that point in the journey. The aid is designed in such a way that the professional and the patient cooperate and make informed choices together. ZorgKeuzeLab' s product is innovative because it not only ensures equal patient participation in decision-making, it also provides tools to healthcare professionals to understand what matters to the patient about treatment options and potential comorbidities or side-effects. Another important advantage of the method is that the outcome of the decision-making process is much more likely to be patient-oriented, and that quality of care is enhanced because of it.

"ZorgKeuzeLab wants to empower both patients and clinicians to collaborate in a shared decision making process. To make this happen, a shift in culture and approach is needed among clinicians. We are supporting clinicians and hospitals who want to make this shift happen!"

The feasibility of founding ZorgKeuzeLab was first explored in 2013, when the two founders joined a launch program (LaunchLab) for new start-ups in YES!Delft, a well-known incubator in the Netherlands. For more information about YES!Delft, see page 51. Within this program, the founders worked alongside ten other start-up companies, developed their product, built their network and were pushed to find connections and meet potential customers. The incubator program also supported ZorgKeuzeLab in terms of healthy competition and access to coaching from business developers. Over time, a strategic business plan was developed, which constituted of a clear-cut plan on where to go and who to meet, to build ZorgKeuzeLab' s brand and to create a successful company. Estimates were that it would take two years before ZorgKeuzeLab could successfully penetrate the market. However, soon after the founding of ZorgKeuzeLab, they received their first assignment through one of the professors in their professional network. Due to intensive networking and endorsements from healthcare professionals, several other ideas for decision-making aids were soon turned into plans. Simultaneously, ZorgKeuzeLab gained the attention of important stakeholders, and started to grow.



Decision aids from ZorgKeuzeLab are designed on several levels of specificity. They develop aids for certain conditions in general, up to the level of decision-making during disease progression or stagnation. Every project starts with a pilot phase of usually six to twelve months, during which the decision-making process is mapped, needs assessment and usability testing are conducted among patients and clinicians, content is developed and the product is designed. Then, the decision-making aid is implemented at selected hospitals and evaluated. This research phase takes circa six to twelve months. After the research phase the decision-making aid is implemented on a larger scale, i.e., in more hospitals. Decision aids are designed in cooperation with the leading medical expert or specialist in the field of a condition. This expert is asked to form a council of five to ten specialists and an expert panel of fifteen to thirty specialists. Collaboration with the specialist council is a guarantee for developing a decision aid with medically correct and up-to-date information. The specialists in the specialist council are generally also involved in the updating of national guidelines on treatments and conditions. Their involvement guarantees that the decision-aids are always up to date and ensures support on a major level in health care. This is a very solid way of getting the product into the hospital, and making sure that it is adopted by the staff. During development, a patient panel is created as well, to conduct needs assessments and usability tests. Finally, patient federations are also included in the developmental process of new decision aids, whenever possible. ZorgKeuzeLab makes long-term arrangements with all the partners they work with. That is also part of their promise: to provide a product that is medically up to date, of the highest quality, and effective. On a weekly basis, the team at ZorgKeuzeLab evaluates all the new feedback and results, and decides which actions should be taken.

> *"The conversation between patient and doctor is key.*
> *Everything we do supports that conversation."*

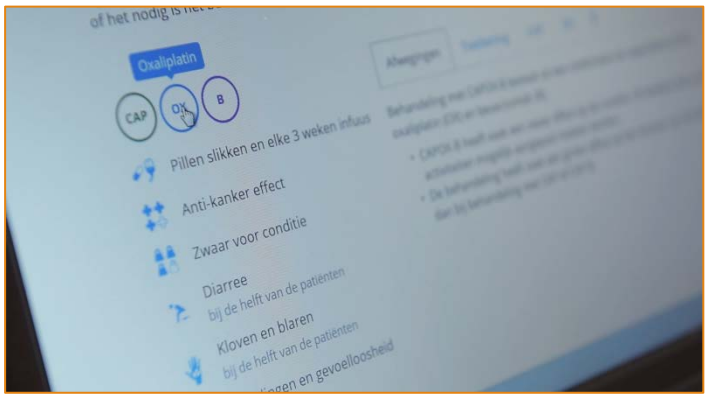
Currently, patient federations, healthcare insurers and specialist unions are demonstrating interest in the products of ZorgKeuzeLab. ZorgKeuzeLab is also receiving information requests from hospitals and care facilities outside of their network. About competition, there are other companies who offer slightly comparable products. However, these products are generally aimed at improving the efficiency of doctor-patient communication, instead of changing the overall decision-making process. Also, ZorgKeuzeLab is unique in the sense that it offers a complete product from development to implementation, including education of professionals, kick-off sessions, training in actual daily practice settings, as well as full monitoring and evaluation procedures. Important stakeholders in care facilities and hospitals are also involved in the evaluation and reports of effectiveness. Finally, with their medical partners, ZorgKeuzeLab conducts scientific research to evaluate the effectiveness of their products. Current results show that the decision-making aids from ZorgKeuzeLab increase patient satisfaction and are helpful tools for a satisfactory patient journey.

7.3.2 Structure and facilities

While in the LaunchLab program in 2013, ZorgKeuzeLab was invited to join a group of young companies and share a building in Delft with several in-house offices. Currently, ZorgKeuzeLab is located there and has expanded their office space within the building. Four people are permanently employed at ZorgKeuzeLab, of which two are the founders and one is an industrial design engineer. They are working with 6 medical partners and 10 PhD researchers, who are conducting the scientific studies. These PhD researchers are on the pay-roll of the specific project they are investigating. Additionally, freelancers are hired based on project-demands. These include text-writers, medical illustrators, legal counselors, technological experts (including ICT), and the occasional project leader at a new site. Currently, 14 decision-aids have been developed and countless pilot studies are well on track. Most of the decision-aids focus on long-term illnesses and diseases with high-impact, because that's where change is the most apparent and the benefits of using a new method are the greatest. Now, ZorgKeuzeLab is present in 23 hospitals, and the number of teams involved within the hospitals is well beyond expectations. About eight scientific studies are currently being conducted.

7.3.3 Financial history

Initially, ZorgKeuzeLab was funded through the private savings of the founders. The company did not receive any other type of funding or investment. The founders did explore options for financial support or collaboration with financial partners/innovation centers. They decided against this because external funding was not needed at the time, and, as a new company, the founders wanted to protect their neutral market position. They did receive a small amount of money through subsidies, and the projects are now financially covered by the stakeholders. In general, when ZorgKeuzeLab is introduced to start a new project, the project's financial aspects have already been arranged. In other cases, ZorgKeuzeLab helps the medical partner to apply for funding for the development and the research phase. Hospitals and insurers fund the structural implementation phase of a project.



A small part of expenses is covered through subsidies and charitable funds. Also, medical specialists may contribute through research grants. In the future, ZorgKeuzeLab considers expanding abroad or into different branches. Therefore, they are open-minded about collaboration with external investors, if these parties share ZorgKeuzeLab' s core values and ambition.

7.3.4 Key factors for success: do's and don'ts according to ZorgKeuzeLab

- Currently, several key professors, physicians and specialists are supporters of ZorgKeuzeLab, taking up a key position as endorsers. Essentially, these are ZorgKeuzeLab' s ambassadors. This ensures and helps to build ZorgKeuzeLab' s market position.
- Clinicians in healthcare perceive ZorgKeuzeLab as a joint initiative of their peers in collaboration with technical engineers, instead of a mere commercial initiative. That helps to create a trust-worthy relationship between ZorgKeuzeLab and healthcare stakeholders.
- Hospitals with an open, pragmatic and patient-oriented culture are easier to start with as a new company. These hospitals may have more experience with patient engagement during consultation, and make this a priority component when defining quality of care. In hospitals that are primarily focusing on budgets and organizational procedures, it has proven more difficult to implement the decision-aids, and professionals may be more reluctant to change their ways.
- Currently, the Dutch government is actively stimulating initiatives for patient empowerment, which is a big support to ZorgKeuzeLab' s business case.
- In the process of sales, it is always important to emphasize what professionals may gain from using your product. You need to have a clear-cut vision of how your product can work in daily practice settings, so that you can convince professionals with your vision, and not only with your product. Also, make sure you design your product in such a way that it is easy and even fun to use.
- Working together with professionals that hold key positions in health care, including clinicians and patient federations, is crucial for successful entry in the market. Identify key persons in your field of interest, and see if they will support you. That immediately helps to get a sense of the potential of your idea, or the lack thereof.
- Do not underestimate the time you need to gain access to the market. It is very important to have a financial buffer that helps you bridge the gap between getting an assignment, developing a product, and being paid for it. This can easily take a few years.
- Connect with other entrepreneurs and join programs for young companies, such as incubators and launch labs, because they will propel you forward and help you decide which direction to take.
- ZorgKeuzeLab had a session of financial coaching with an expert in healthcare. This was important as it gave them insight in how finances are distributed in healthcare, and what potential opportunities and barriers for market entry could be.

- You must be strict to yourself and make choices: you can win or lose a lot of time with good or bad partnerships, things that give you energy or that cost you energy. Trust your instincts in this, does it feel right? Is there a connection? Set your priorities straight.
- In the end, make sure you choose your own path and do what feels right to you. Listen well, stay alert and don't be afraid to change your course when new ideas come to mind over time.

7.3.5 Barriers for success

If you start a company in the Netherlands, you are required to pay the director of the company at least 44.000 Euros in salary each year. As ZorgKeuzeLab had two founding directors, they had to be able to pay themselves 88.000 Euros a year as soon as they founded the company. As an entrepreneur, you would prefer to give yourself less wages and invest more money into the company. Another barrier for a successful scale-up of ZorgKeuzeLab could be that the implementation process of a decision-aid is highly tailored to the local situation in the hospitals. Also, there will always be professionals who do not feel the need to improve their consultation, or those who are afraid that a new method of decision-making will be time-consuming. This is a barrier for successful implementation as well. It is therefore extremely important to create a critical mass of supporters of patient-oriented consultation in hospital settings, who provide both the carrot and the stick, to move forward.

7.3.6 Regional influences

As mentioned previously, being in the LaunchLab at YES!Delft was a key to a successful start-up. Further, ZorgKeuzeLab received sessions of coaching from professionals. As a matter of fact, one of these coaches is still involved as an Advisory board member in the company. These regional networks were invaluable to a start-up company like ZorgKeuzeLab. Other important regional aspects for ZorgKeuzeLab include support from the network of Medical Delta, and an application at the European subsidy program Horizon 2020. Even though the application was not granted (the chances of success are very slim), the effort by ZorgKeuzeLab demonstrated their determinacy to the other parties involved, including hospitals. This created new business opportunities for ZorgKeuzeLab.

7.3.7 Future

The current goal of ZorgKeuzeLab is to expand their business, both by implementing the already-developed decision-aids in new hospitals and care facilities, and by developing new types of decision-aids for other types of conditions. Also, keeping the quality standards high for the existing and completed projects remains an important point of focus for ZorgKeuzeLab.

7.4 Case: Sense Health (Netherlands)

7.4.1 Purpose and developmental history

The main purpose of this innovation is to connect smart technology and sensor data to patients' daily life. Further information about Sense Health can be found http://www.sense-health.com/.

Sense Health started as a spin-off company in 2008 with a main focus on context awareness technology; using sensor data to recognize human behaviors. Sense was a spin-off from a research and development company in IT, Almende, which is dedicated to self-organizing networks in companies and among people. The application of this type of technology in the field of behavioral psychology allows for pro-active interventions for humans, in contrast with passive interventions or advice that dependents on the actual input of people into the technology. Consider using sensor data on your smartphone to provide advice on exercise and sleep (pro-active), as compared to completing a daily questionnaire about your health and then receiving advice (passive). The original technology on which the idea for Sense Health was based, has been tested and developed over the years in various experiments. During this process, making a step towards the healthcare sector was the obvious choice, as there is a lot to gain when it comes to improving, and assisting in, patients' behavior. As such, Sense Health was officially founded 2014 as a joined venture with Parnassia Group, which is the largest mental health institute in the Netherlands.

From the perspective of the entrepreneurs behind Sense Health, Parnassia was a strategic partner. Sense Health had been involved in mental health projects before, and they needed a partner that could support the company with expertise, a professional network, and financial support. Parnassia provided all of these ingredients, including a network of several professors and experts. Moreover, Parnassia has a 13% market share in mental health sector in the Netherlands, which allows for Sense Health to develop technology for a significant part of the patient population.

Sense Health is therefore currently mainly focused on the mental health sector. On the side, they are also involved in cardiac diseases, chronic illnesses and diabetes. The most prominent clients of Sense Health are the mental health sector and companies who want to use Sense's technology to improve the health of their employees. In line with that, Sense currently has two main products on the market, both mobile applications. One is 'Goalie', which is applied to the mental health sector. It helps patients deal with anxiety and stress, and pro-actively stimulates patients to make necessary changes in their lives, for instance, it offers methods to develop a daily structure, and continuously monitors the patients' behavior. This technology is extremely advanced in the sense that it does not only provide advice and coaching to the patient on the exact moment that they need it, but is also provides caretakers and treating physicians with important information about the

patients' wellbeing and progress. An additional benefit of the technology is that professionals can cut back on their paperwork.

The second application is 'Brightr", which is based on the same technology as Goalie, but aims to provide advice to improve the health of employees, for instance by monitoring sleep and exercise. An interesting fact about Sense Health is that the technology was initially not developed for the healthcare sector. It was merely that the founders saw the inefficiency and inaccuracy in health care organizations, and instantly knew their technology could make a difference in this field. Essentially, this type of innovative technology may be key to improve health care processes and logistics.

7.4.2 Structure and facilities

Sense Health is located in Rotterdam and has two shareholders: Parnassia and Almende. The leading man for the spin-off has left Almende after Sense Health was founded, and became the director of the company. Sense Health also has a board of directors and an advisory board. The company has a non-hierarchical structure. There are generally three teams: two production teams for Goalie and for Brightr, and an overall technological support and development team, which serves as the mainframe for both products. A few people are dedicated towards sales, marketing and business development. Sense Health employs 20 persons in Rotterdam. It also has a small auxiliary branch in Bandung, Indonesia, as this is a hotspot for decent technology developers. Bandung has an excellent university of technology, and it is difficult to find personnel with the right level of skills in the Netherlands. All personnel are hired by Sense Health themselves, and they are committed to their teams in Rotterdam and Bandung. Because of this type of construction, many of the employees work and meet online.

7.4.3 Financial history

Sense Health was founded by the partners (Parnassia, Almende) and through what is called 'credit for innovation'. This is a source of financial support that was offered in the Netherlands, but it is a long and difficult selection process to receive it. Applying and qualifying for it took Sense Health about 12-14 months. They decided for this type of financial support because they needed funds for a period of 2-3 years to bridge the gap between product development and successful pay-up by customers. Other choices that are popular among startups, such as investment rounds and crowdfunding, were not very attractive for Sense Health as they did not fit in the traditional start-up scale-up pattern. They were too mature for seed capital, and yet not mature enough to attract investors that support scale-up. Various investors were in fact interested, but wanted to become a shareholder in the company as well, which wasn't considered an ideal option from Sense Health's standpoint.

7.4.4 Key factors for success; advice from Sense Health

- As a spin-off, Sense Health was fortunate to start with a few ongoing assignments for customers, and had already been through learning experiences and support with HR management and accounting while in-house at Almende.
- For new entrepreneurs, it is recommended to evaluate whether your idea is innovative, if it has the right potential, and if it is meaningful.
- Support from healthcare partners who believe in your innovation is critical. It is very important to attract people who are willing to commit to your ideas for a longer period, and who are prepared to learn and work together.
- When developing a technological innovation, a good deal of time needs to calculate to develop, mature and validate your product.
- When it comes to healthcare technology, Sense Health expects that there are three ways for future innovation: (1) in-depth technological innovations, such as labs on a chip and home testing; (2) new methods for self-organization and logistics in healthcare; and (3) technology that allows for more accurate interpretation and prediction of events. It is important to decide in which category your innovation would fit best, to decide upon the best strategy to found your company.
- It is essential to understand the needs of the person or patient that will use your product (end-user), and how treating professionals such as physicians relate to this picture.
- It is very useful to connect with large companies and attend networking events. Make sure you also visit events that are not specifically targeting startups, because you need to meet patients, users, and healthcare providers.
- If you have the chance, make a startup journey or trip abroad, for instance to the US or Berlin, both innovation hotspots. This helps to expand your network and sheds a new light on your product and ideas.

7.4.5 Barriers for success

- A well-known and challenging barrier for Sense Health is that many people in the healthcare sector are interested in innovations and technological advancements, but very few people are cooperating when it comes to implementation of such technology and changing behaviors.
- At the beginning, as an entrepreneur you meet a lot of people, and it is difficult to get a clear picture of which persons can help your business forward, this takes up a lot of time.
- As with other innovations in healthcare, proof is often required before the product is fully developed and implemented, this is an important barrier for company growth.
- To this day there is no ideal match between innovative technological products and the existing financial structures in healthcare. The quite rigid culture in healthcare, the heaviness of legislation and the lack of flexible market mechanisms and financial stimuli for innovation, prove difficult to overcome. Conclusively, from a legal perspective, there are still many barriers to overcome for new companies to thrive in the healthcare sector.

7.4.6 Regional influences

Within the region of Rotterdam, it is easy to connect to others. The area is an innovation hotspot, with numerous events and networking opportunities. On the other hand, the region is quite small, so it is quite easy to get an idea of who is who and where you need to go for certain types of expertise or support. The presence of a university of technology in the area also helps to grow businesses in terms of excellent graduate students who can be employed. This region and its internationally-oriented character are also attractive for workers from abroad, which is a tremendous help if you are looking to employ personnel with a certain skillset. Within the region, parties like InnovationQuarter also help to propel innovations forward and keep things going, by hosting activities and providing consultation.

7.4.7 Future

The fact that the Dutch government is increasingly interested in the potential of eHealth holds an important promise for the future of Sense Health, it might give the entire sector a big push. Also, the fact that the Netherlands is very advanced in the field of mental health, is promising for the future. Sense Health keeps exploring new opportunities for their technological applications, such as home monitoring and the use of robotics in home care. In the nearby future, Sense Health is looking to grow and mature, and to become financially independent. In the longer term, Sense Health aims for their technology to become a catalyst for new ways of (self-) organization in the healthcare sector.

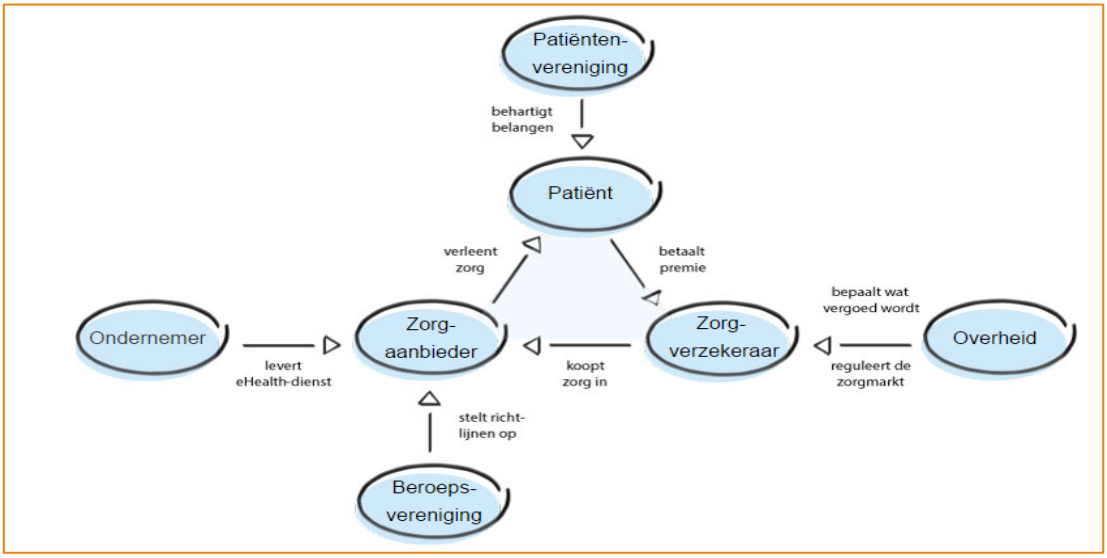
7.5 Case: Paths for innovation in healthcare – Dutch initiative

In the Netherlands, the website 'Paths for innovation in healthcare' is designed to support entrepreneurs in the field of eHealth with basic knowledge. The website offers two tools and tailored advice on how to apply and implement eHealth innovations into the daily practice of healthcare systems (26). It was designed as a result of the project 'Entrepreneurship and success in eHealth', which was conducted by the Lectorate ICT-innovations in healthcare in cooperation with 27 eHealth entrepreneurs, healthcare stakeholders and innovation experts. The project was sponsored by a grant from the foundation 'Stichting Innovatie Alliantie'.

7.5.1 Tools and advice

- Map of stakeholders

The website provides a map of important stakeholders in healthcare that need to be considered to develop and implement an eHealth innovation. These stakeholders are, for instance, patients, patient federations, healthcare providers, and insurance companies. For each of the stakeholders, information is available on their role in the healthcare system, on their interests and motivations, and on their convictions, including an estimate of the themes that these stakeholders will support or try to obstruct.



- **Four paths towards innovation**

Four paths for innovation in healthcare are described on the website. A consumer-based path, a provider-based path, an insurance-based path and a governmental path. The routes are rated based on their complexity to achieve successful innovation and market penetration. The paths based on consumers and providers are rated as relatively easy (one star), the insurance-path is more complex (two stars) and the governmental path is deemed the most challenging (three stars).

To offer tailored advice, a system was developed. Each of the paths consists of a number of six questions that help to create a clear idea of where an innovation would fit, who the proposed client is, and what could be potential implementation problems.

For instance, take the consumer-path. This path is designed for innovations that are offered directly to patients, without the interference of healthcare insurers or medical specialists. Questions that are asked to the entrepreneur include:

- Is your innovation fit to be sold directly to patients?
- Given a few examples of consumer-eHealth-products, does your idea for innovation share some of the characteristics of these products?
- Given a few important criteria for patients to adopt such an innovation, does your idea comply to these criteria?
- Given information about financial structures in healthcare and the necessary amount of startup capital for this path of innovation, is your idea feasible?
- Given information about the most relevant stakeholders in this innovation path, have you been able to connect with them and discuss your ideas?
- Given information about the most important pitfalls in this innovation path, do you have a strategy to avoid them?

All questions can be scored with ‘certainly’, ‘possibly’, and ‘no’. At the end of the short questionnaire, a score is calculated. When the questionnaire is taken for each of the four paths, the entrepreneur is advised on which innovation path is the most suitable for his innovation (highest score). Also, personal advice about the routes can be downloaded and the information about the innovation path is displayed on the map of stakeholders, giving tailored advice to the entrepreneurs about which steps should be taken next, and who should be involved. Finally, the website offers additional advice on changes in healthcare policies and relevant legislation for future entrepreneurs.

7.6 Case: Early-stage startup incubator program West-Flanders: Start it@KBC

In West-Flanders, a large startup program has been located since 2013: Start it @KBC (28). Start it @KBC is a cooperation between KBC Groep NV, Flanders DC VZW, Accenture NV, the University of Antwerp, Cronos NV, Vikingco NV, en iMinds VZW. Start it @KBC has six location across Belgium, and offers several services to (young) entrepreneurs with innovative ideas, with a focus on ideas that are scalable.

Topic-wise any idea can quality for Start its programs. Currently they support over 100 startups in more than 30 categories, including HR, gaming, food, wearables, sport, engineering and virtual reality. To support startups, Start it has access to a large network of circa 30 partners, including other startup accelerators and large businesses in the innovation and technology sector. Most of these partners are actively involved in activities to boost startups and help them grow and mature, by sharing their expertise. Also, Start it has access to circa 50 mentors from a variety of backgrounds, and is continuously looking to expand their pool of mentors for future startups. Information about the success rates of the program was not published yet.

7.6.1 Programs and services

In general, entrepreneurs can get acquainted with Start it by submitting their ideas for a Pitch day. Three Pitch days are hosted every year, which are juried by a variety of experts. Not all entrepreneurs who apply are eventually invited, a selection of fruitful ideas is made before each Pitch day. During Pitch day, entrepreneurs get 8 minutes on stage to demonstrate their idea and convince the jury of its potential; 3 minutes for pitching and 5 for questions and answering. Feedback on the entrepreneurs' ideas is provided instantly, and at the end of the day the entrepreneurs are informed if they are allowed into a startup incubation program. This program is kicked off by a welcome meeting between the selected entrepreneurs, Start it experts and mentors that are being assigned to the entrepreneurs during the following program.

During the program, the startups can stay on-site and rent-free. The program offers coaching, housing and mentorship during the first phase of starting up: developing a business plan and product valorization are important elements in the program. Regarding financial support: Start it assists the entrepreneurs in their search for financial support and investment rounds, but does not invest financially or take shares in startup companies.

For startups that are maturing, Start it offers 'Academy': series of activities, info sessions and lectures for startups to stay on top of their game. Topics included are: pitching, sales, marketing, expert legal advice, crowdfunding, digital storytelling, and accountancy.

Aside from the main startup program, there are a few more low-key events organized regularly such as a coffee-meet, new years' drinks, and lunch sessions. The organization is very active on social media, which makes it easily accessible and lowers the threshold for entrepreneurs that are just starting to define their ideas for innovation.

This information and text used for this case-study is derived from the website of Start it @KBC (28).

7.7 Cases entrepreneurship in Scotland: Highlands and Islands enterprise

The Highlands and Islands Enterprise (HIE) was founded in 1965 (29). To this day, it presents itself as 'an ambitious organization with a unique remit that integrates economic and community development'. The organization is active across Scotland. The Scottish government has appointed HIE as the go-to 'economic and community development agency for the north and west of Scotland'. The purpose of HIE in such is to 'generate sustainable economic growth across the Highlands and Islands'. The HIE's vision for Scotland is that it is a highly successful and competitive region, that attracts people who want to live, work, study and invest in Scotland. The HIE works according to a multi-year strategy, that is closely attached to Scotland's economic strategy (29). For the period of 2016-2019, the priorities of the HIE are to:

- Support businesses and social enterprises in their growth aspirations
- Strengthening communities and fragile areas
- Developing growth sectors and regional opportunities
- Creating the conditions for a region that is competitive and low-carbon.

Especially the priority of HIE leads to several interesting initiatives with regard to innovation and entrepreneurship. Such initiatives are independently supported by, or are in partnership with, HIE. Two of them will discussed in this case-analyses: Pathfinder and Business Gateway. It should be noted that these initiatives are relatively young and detailed information with regard to success rates or financial gains were not published yet.

7.7.1 Case: Pathfinder

Pathfinder is a quite new accelerator program, it was first offered in 2014 at the Centre for Health Science, Inverness (30). Pathfinder offers expert assistance to entrepreneurs within a concentrated environment for businesses working, quite similar to the environments described in previous case studies, such as YES!Delft and imec. Pathfinder essentially helps startups to develop an idea and to explore its commercial viability before attempting market penetration. It is mainly designed for innovation in Life Sciences and Technology.

Pathfinder consists of a 12-week intensive program that is dedicated to: testing ideas and employ proven business techniques for startups. Developing a strategy and business plan, and pressure-testing the robustness of the innovation, is the main aim of those 12 weeks. After that, the program continues with three months of coaching and support from mentors.

During the program, tailored workshops and seminars are offered, and office space is provided.

Another important component in this accelerator program is, as seen before, the networking component. By helping entrepreneurs to build their network, the chances of successful market penetration and collecting investments can be significantly improved.

Now, at least three startups have completed the program. The program is free for all participants, and ten places are available throughout the year. To qualify for the program, entrepreneurs need to sign up for a selection procedure, and are evaluated for eligibility. To get a taste of the program, entrepreneurs can also join Pathfinder Bootcamps, a one day event to get a quick idea of the program. By offering this program, HIE has found an innovative way to propel innovation in the region forward, and to increase the chance of sustainable entrepreneurship in their region. Also, beneficial side effects of this program may be experienced in the region, such as an increase in employment rates, and people and businesses migrating towards the region.

7.7.2 Case: Business Gateway

Business Gateway is profiled as a public service, which also received public funding, to contribute to the economic wellbeing of Scotland. It has a partnership with HIE, and is delivered by local authorities (31). The service provides access to business support services for entrepreneurs, free of charge. Experts at Business Gateway give impartial consultation to entrepreneurs in the form of:

- online support (an informative website with business guides)
- workshop program and event calendar
- tailored advice from business consultants
- business information: practical information on how to start and grow a business

Business Gateway also offers an annual review of the users of its services and of the local region, to enhance their relevance to the region and offer services that are useful to the public. In a recent investigation, it was demonstrated that young business that have connected with Business Gateway have a significantly better three-year survival rate than the national average.

This is not surprising in the sense that the online support through the website already provides young companies with a complete entrepreneurial portal: information about every aspect of starting and growing a business can be found online, including finances, employing staff, sales and marketing, risk management and continuity plans, and market analysis.

Through the events and workshop program, entrepreneurs can develop skills in these areas, such as through a bookkeeping event and business planning workshops. For companies that need to grow and mature, it offers several case studies in

different sectors (successful predecessors), including art, construction, distilling and education (31). For companies looking to expand, Business Gateway offers, among others, detailed market reports of the UK and international markets, company credit checks, property searches, and data on statistics and demographics.

Advisors working at Business Gateway are located throughout Scotland: it has a network of 57 local offices with over 300 consultants (31). The fact that these services are free and provided for through public funds, demonstrates the dedication of the Scottish government to support entrepreneurs and innovation in the region.

7.8 Case: Israel ecosystem

While this study focuses on the health innovation ecosystem the South-Holland, Flanders and Scotland regions, it is interesting to put things into a broader perspective and explore success criteria and drawbacks mentioned by entrepreneurs from a successful startup ecosystem of comparable size in another region of the world. First, we examine what the world most successful startup ecosystems are, secondly, we select Tel-Aviv for a deep dive into that ecosystem, thirdly we elaborate on startup success criteria given by entrepreneurs and others from the Tel-Aviv ecosystem, and fourthly we give a brief reflection.

7.8.1 What are the world's most prolific startup ecosystems?

First, when discussing startup ecosystems, the consensus is to not compare countries, but compare regions, generally described either as a single large city (London), or a certain metropolitan area (Silicon Valley).

According to the leading *global startup ecosystem report 2015*, these are the top 20 startup ecosystems in the world, ranked by performance, funding, market reach, talent, and startup experience (Figure 6).

Figure 6, the global startup ecosystem ranking (32).

Silicon Valley is the obvious number one ecosystem, with four large US cities occupying the top four. The first non-US ecosystem is Tel-Aviv. The first European ecosystem is London, followed by Berlin and Paris and at 19th place Amsterdam. The Amsterdam Region is defined as the 'triangle between Amsterdam, The Hague, and Eindhoven', so it includes (the larger part of) the South Holland area. Belgium and Scotland are not found in the top 20.

When looking at the amount of successful investment exits, we see the dominance of Silicon Valley, and a true long-tail shaped graph. In terms of exits, Silicon Valley still almost accounts for 50% of the global startup market (Figure 7) (32).

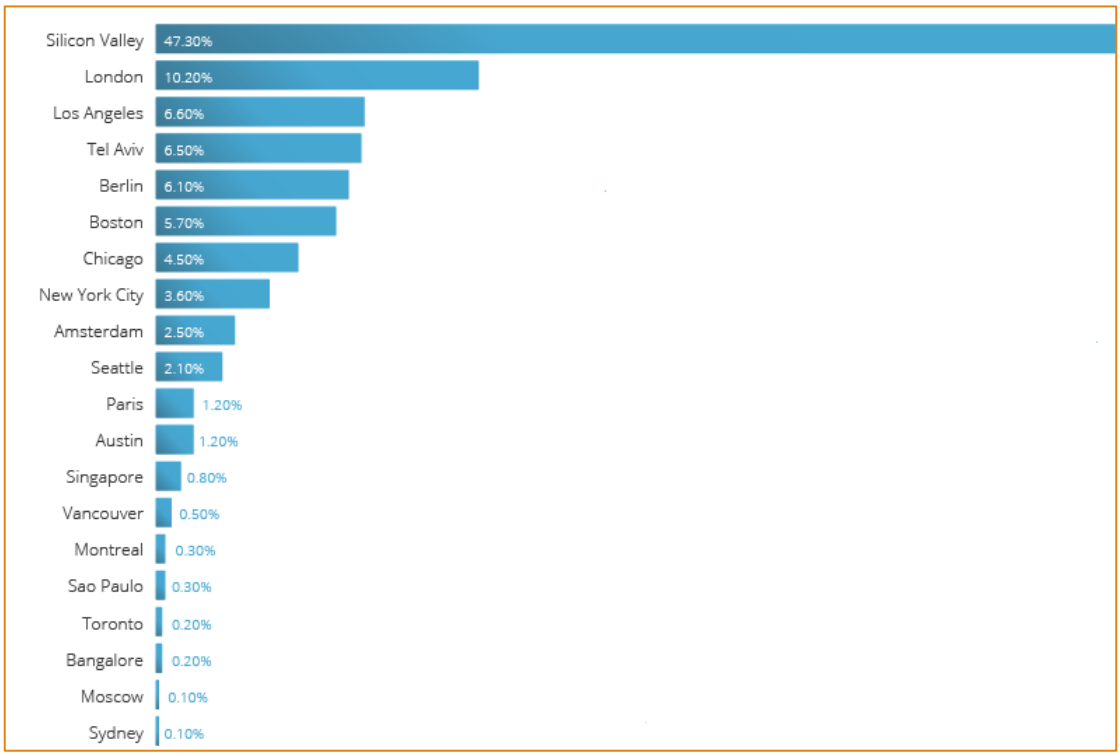


Figure 7, Total market exit 2013 & 2014 in USD (32).

7.8.2 Why Tel-Aviv?

Out of this list, we chose the Tel-Aviv startup ecosystem to describe in more detail. Tel-Aviv stands out, because it has achieved a remarkable high global startup ecosystem ranking in comparison to its modest size. Tel Aviv has 410.000 inhabitants, with 3.8 million living in its agglomeration. Israel roughly sits in between Belgium and Scotland in terms of GDP and population (32).

	GDP 2015 (billion USD)	population 2015 (million)
California	2.448	37,3
Netherlands	769	16,9
Belgium	470	11,3
Israel	311	8,3
Scotland	233	5,4

7.8.3 General description of the Tel-Aviv startup ecosystem

Tel-Aviv is Israel's second largest city. It has a renowned startup ecosystem for software and IT startups, with health innovation, and eHealth is mentioned as the number one field of new opportunity for Israeli startups (33).

7.8.4 What are strengths and weaknesses for the Tel-Aviv startup ecosystem?

Kon, Hazzan et al. performed a study into what makes the Israeli startup ecosystem tick (33). For that, they did 48 face-to-face interviews with Israeli startup founders, CTOs, CEOs, developers, angel investors, VCs, academics, and incubator and accelerator managers, most from the Tel-Aviv area.

From these interviews, they gathered a list of ingredients that have a positive or negative influence on the startup ecosystem, as well as some that pose opportunities or threats. Below, we give our simplification of their overview (33).

Military service

Israel has full military conscription for both man and women. Many respondents mentioned both the technical skills learned in the military engineering corps as well as the strong network that is developed during conscription as hugely beneficial in the formation of successful startups. Second, the military spends a large amount of R&D funding on Israeli high-tech universities, research centers, and corporates, which leads to a tech-heavy environment.

Cultural aspects

Many cultural aspects are mentioned. Most Israelis tend to be audacious (*chutzpa*), risk taking, and have a high tolerance for failure. The isolated location of the country, its hostile environment and the absence of natural resources are claimed to have formed a culture of innovation, collaboration and resilience, while the constant influx of immigrant Jews from all over the world has created an open and collaborative mindset.

Easy access to capital

Tel-Aviv is considered a startup ecosystem for tech-heavy, early stage startups. It has a thriving private capital market, but one of the reasons for the success of the Tel-Aviv ecosystem is said to be a program where the Israeli government doubled any private investment into startups, starting in the 1990's. This led to a boom in VC-investment. Later, government added soft loans as a successful funding instrument. However, several startups complained about bureaucracy and rules about IP needing to stay in the country as a drawback. Many startups get their first round of funding from other successful serial entrepreneurs following the 'pay it forward' credo.

High quality education and technical skills

Israel has since its conception always needed to depend on human capital instead of on natural resources. It has always had a high quality technical education. In recent years, the increase of immigrants from Russia and former Soviet republics – famous for delivering highly trained technical students - have led to a new, fresh inflow of human capital.

Branding as a global tech center

Respondents indicate that the mere fact that a startup is from Tel-Aviv gives a certain assurance of technical quality to a foreign investor. What *made in Switzerland* is for quality in the physical engineering, *made in Israel* is for software engineering.

Distance to large market

The isolated location of Israel and its small home market means that it is far from a large market. From a positive side, Israeli startups tend to have a global market in mind when designing their service from day one. However, testing an early version in the large market setting is therefore more difficult. A negative aspect is that different time zones, the Hebrew language, and different cultural aspects make entry into a foreign market difficult.

Focus on exits rather than on growing a business

Respondents express worry that a culture is emerging where entrepreneurs start companies aimed at an early exit, rather than aimed at growing the company to change the world. People fear this short-term focus might lower the quality or viability of Israeli startups

Focus on high tech instead of on business or marketing

Due to their high-tech focus, Israeli companies run the risk of not spending sufficient effort on business, marketing or user experience design.

War or peace

The constant threat of war, or the promise of peace is influencing the fabric of the Tel-Aviv startup scene. War or instability in the region would scare foreign investors away, while peace and normal trade agreements with the Arab countries surrounding Israel would open a large, close by market that is currently relatively untapped.

Brain drain

Countering the influx of Jews from the Russian and ex-Soviet states, still many well trained Israeli move to the US or EU. Higher salaries, better quality of life and a less geopolitical instability are mentioned as key reasons.

Demographics and socio-political changes

In Israel, Orthodox Jews and Arabs - the population segments with traditionally few entrepreneurial activity- are growing the fastest, due to high birth rates. There are concerns that an increase religion and superstition in daily live and politics might have a negative impact on science and high-tech industries.

7.8.5 Reflection

Based on the interview results performed by Kon, Hazzan et al, but also from many other sources mentioned in this manual, we can identify many ingredients for a vibrant and successful startup ecosystem, but we cannot create a standard recipe. In the overview from Israel, we observe that many aspects of Tel-Aviv's success have strong ties with Israel's history, and are strongly intertwined with its culture.

This case-study is partly based on a report by Yuklea et al (33).

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