

## 1 | Introduction

Worldwide innovation is seen as one of the key elements for sustainable economic prosperity. Among others this is reflected in Horizon 2020, the new EU framework programme for research and innovation [1]. A major challenge for innovation in health care is the segmentation of the domain into sectors which function separately: health care providers, enterprises, research institutions, regulatory and financing institutions. This leads to gaps in the innovation chain and often hinders the market access of innovative solutions. A systematic approach is needed to address the major hurdles. The project BSR HealthPort [2] addresses some of these gaps and the major objective is to develop an innovation ecosystem model and provide shared services in a macro-regional context.

## 2 | Background

ScanBalt Health Region (SBHR) [3] is a flagship project in the EU Strategy for the Baltic Sea Region (EUSBSR) [4]. The SBHR serves as an umbrella for a multitude of coordinated activities applied to shared visions and values. One such activity is BSHR HealthPort “Baltic Sea Health Region – Business acceleration support and training bridging innovative SMEs and health care orga-

nisations to strengthen BSR health economy”. HealthPort focuses on the interactions between Health Service providers and SMEs and is co-financed by the Baltic Sea Region programme 2007-2013. The health care sector is particularly suited for collaboration due to common societal challenges like demographic ageing and rising prevalence of non-communicable diseases and already established collaborations.

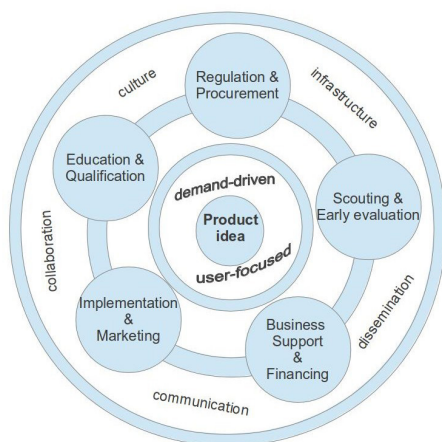
## 3 | Innovation Ecosystem for health economy

According to Metcalfe an innovation system can be seen as “...that set of distinct institutions which jointly and individually contribute to the development and diffusion of new technologies and which provides the framework within which governments form and implement policies to influence the innovation process. As such it is a system of interconnected institutions to create, store and transfer the knowledge, skills and artefacts which define new technologies.” [5]. Innovation systems can be categorized into national, regional or local innovation systems, or into technological innovation systems and sectoral innovation systems. For the domain of health economy there is no definition or clear understanding of an innovation system yet. Innovation is often the result of the interaction among a multitude of actors, and the metaphor of an

‘innovation ecosystem’ is well suited to emphasize this characteristic. The idea of applying the ecosystems analogy to policy development and innovation is not new. It has already been used in diverse contexts such as the “Digital Business Ecosystems (DBE) Integrated Project (IP)” [6] and has served as a theoretical underpinning for developing the concept of digital ecosystems. More recently the Open Innovation Strategy and Policy Group (OISPG) has adopted the ecosystems idea for policy development and the Open Innovation 2013 yearbook contains many examples of modern ecosystems thinking, both in smart city contexts as well as regional contexts. [7] “We need to move from having ‘perfect plans for yesterday’ to an innovation culture which fosters experimentation and prototyping in real-world settings. This new innovation culture leads to simultaneous technological and societal innovation and encouragement”. Somewhat similar ideas and concepts are also emphasised by a High Level Group on Innovation Policy Management commissioned by the Council of the European Union “Growth through a radical new innovation ecosystem” [8]. In October 2013 the EC organized the iNOVAHEALTH conference and published a report with the title “Building an open innovation ecosystem for health care in Europe”. [9] Whithin, in the Baltic Sea Region Health Port Project such concepts of innovation as well as a

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thorough analysis of bottlenecks for innovation in health and life sciences in the Baltic Sea Region have led to the development of an innovation ecosystem for health economy. Its basic design is summarized in Graphik 1. Its main aim is to contribute to encourage and to facilitate innovation activities in the Baltic Sea Region.



The main motivation behind the Innovation Ecosystem model is the notion that successful transformation of ideas into commercialised products and services requires a holistic approach that addresses all segments of the complete value chain. Its main elements will be described in the following chapters.

### 4 | Clinical innovation — employee driven innovation — user driven innovation

The creative process of generating, developing, and communicating new ideas is the first step in creating innovative solutions. The main idea of clinical innovation is that the most beneficial impact is derived when innovations are driven by clinical unmet needs. Healthcare practitioners and clinical personnel are thought to be the best source of innovative ideas that has been largely untapped yet. Recently user-driven innovation or employee-driven innovation has also become popular to systematically search for innovative solutions. Employee-driven innovation has been developed by the project partner Region Nordjylland and implemented in the “Ideas Clinic” of the Aalborg University Hospital [10]. The Ideas Clinic has implemented an internal open innovation process to manage the whole innovation cycle from ideation to market entry. Similar models have been implemented in Uppsala [11] and in Oslo [12].

### 5 | Early idea evaluation

Health care products and services that do not finally face the patient are a waste of money, time and human resources. Therefore mechanisms are necessary to filter out promising ideas in an

early stage and subsequent further periodical testing for validity. In the HealthPort project the method of an ideas competition has been implemented and tested to filter out promising ideas for innovations. Another idea that has not been tried out so far is the early integration of Health Technology Assessment (HTA) expertise. A discussion of innovative ideas and concepts with HTA experts in an early stage may reduce the risk of developing technologies that will be disregarded in a later stage due to deficiencies in HTA. It is self-evident, that in user-driven innovation the user is part of the innovation cycle from the very first moment. However, if the main driver of the idea is a firm it is very important to integrate potential customers or users from the very beginning.

### 6 | Training for Entrepreneurship

Clinical personnel are a largely untapped source of innovative ideas for products and service innovation in the health care domain. However, the successful transformation of their ideas into products and services on the market is often hindered by the lack of entrepreneurial expertise on part of clinical personnel and researchers. The process of transferring ideas and successful commercialization builds on the competence of higher education system and the availability of



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knowledge to promote entrepreneurship and innovation management. In the scope of the HealthPort project the University of Gothenburg performed an analysis of available courses in the greater ScanBalt region that provide knowledge in the fields of Innovation and Entrepreneurship, Procurement, Clinical Verification, Business Development, IP, Licensing and Knowledge Transfer, Venture financing and Sales and Marketing [13]. The analysis has shown that health and life sciences based innovation courses are under-represented in relation to other technology innovation courses. To fill this gap ScanBalt is preparing an educational platform to teach entrepreneurial skills in the domain of health and life sciences. A first module covers the topic of clinical trials for healthcare professionals and pharmaceutical companies which is provided by the University of Gothenburg [14].

### 7 | Pre-Commercial Procurement (PCP) & Public Procurement of Innovation (PPI)

PCP [15] and PPI [16] are two novel mechanisms that should support the development and dissemination of innovations. The OECD recently stated that “..public procurement is at centre of recent demand-side innovation policy initiatives. Because of their large purchasing power governments can pull demand for innovation and can

also create a signalling effect as lead user and influencing the diffusion of innovation broadly.”[17]. The main idea is that public procurers can drive innovation from the demand side by acting as first buyers. The public sector has a key role when it comes to procurement of health care in the Nordic countries as health services are delivered by public providers. 80 to 85 per cent of health spending in the Nordic countries is funded by public sources [18]. Innovation procurement is composed of two main aspects: If the procurement of innovative solutions requires R&D than the Pre-Commercial Procurement policies apply where the procurer can work under R&D exemption of the procurement procedure. If no further R&D is required than the normal procurement procedures apply under the Public Procurement of innovation headline. VINNOVA has produced an excellent report that discusses the topic of public procurement of innovation in health care in detail [19].

### 8 | Clinical trials and verification

Clinical trials and verification are mandatory to prove efficacy and safety of drugs, medical interventions and devices, diagnostics and e-health applications. Due to complex regulatory, organizational and experience requirements, demanding a disproportionate operational and

financial effort, many SMEs, start-ups or investigators often cannot effort clinical research to the necessarily extent. Thus, turning the clinical trial and verification topic into the most relevant bottleneck in medical technology transfer and dampening innovation. Clinical research activities are today increasingly located outside Europe. The problems related to recruitment of sufficient number of subjects has been identified as one of the reasons for the decrease in clinical trial activities. It is difficult for single countries in the Baltic Sea Region to compete alone with e.g. populations in Asia. Collaboration between BSR countries could substantially increase the competitiveness of the region in a global context.

The need for a common approach of this innovation inhibitor and the decrease in clinical trials was already recognized in particular regions of the Baltic Sea Area: NordForsk, an organization under the Nordic Council of Ministers and providing funding for Nordic research cooperation, kicked-off the Nordic Trial Alliance in 2013, to come up with joint solutions for NO, SE, DK, FI, IS [20]. In Northern Germany, a strategic approach to overcome the obstacle for medical technology transfer was drawn by the master plan Health Economy 2020 on behalf of the state government Mecklenburg-Vorpommern:

An incubator for clinical trials is intended to bundle resources from this region and the adjoining Polish Baltic Sea region, developing a business model for a Baltic ClinTrial Service Cluster [21].

### 9| Financing tools

Access to capital is a critical success factor for all entrepreneurs and start-ups. In the domain of health and life sciences this is particularly challenging due to the high standards and requirements for certification and the resulting long time-to-market. New financing tools are needed to address the different phases and demands from invention to innovation. For the very early phase start-ups need capital for idea evaluation and prototyping. Currently there is a lack of capital and appropriate tools for this stage in the translation process from idea to market. New tools like idea competitions, crowdfunding or special funds dedicated to high risk early stage development may fill this gap. The Accelerace Life project [22] addresses a later stage in the innovation cycle and focuses on near to market innovative products and combines mentoring, financing and evaluation of the company and the product.

### 10| Social Innovation and shared value creation

In many cases innovations in health and life sciences change the way of health care delivery. This sometimes is a high barrier for innovation dissemination since people and systems are reluctant to change. More and more researchers as well as politician argue, that the answer to this problem is focus innovation activities on social innovation i.e. on innovations, which are designed to meet social needs and are based on social values [23]. Porter and Kramer [24] argue that firms should enter into shared value creation that involves creating economic value in a way that also creates value for society by addressing its needs and challenges.

### 11| Conclusions

Innovation support for health and life sciences can not be decoupled from innovation in healthcare delivery and the innovative structural and organizational evolution of the health care system itself. In that sense health care innovation does have a regional, a national and a global dimension. The responsibility for health care delivery is in the regions and it will be there for the foreseeable future. Innovation in health care and the dissemination of innovative products and services is impossible without regional/local key

actors and decision makers. The support in this dimension is a sine qua non. However, research and the development of innovative solutions for the societal challenges in health care do not have borders. In a globalized world collaboration and cross-border cooperation is an imperative to find innovative solutions for health care challenges and to develop high quality, efficient and cost-effective products. An open mindset, transparency and collaboration are prerequisites for excellence in research and development for innovative products. Synergistic effects where the sum is more than the parts only can take place in cases of massive collaboration across sectors and across borders.

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