Towards Open Health Innovation.
Openness of Research, Development and Innovation Activity in Health Sector in Finland.

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Content

1 Executive summary

The study aims to analyze pre-defined political, legal and structural changes in health sector from the view of promoting or enabling open RDI-activity, present examples of openness in health sector RDI-activity, and provide insights to promote open RDI-activity and PPP-co-operation in health sector in Finland. The focus of the study was in literature review including case studies with interviews, e-survey and workshop providing some additional information.

In general, it can be noted that studied strategies and structural and regulatory reforms do not hinder openness in public-private sector co-operation or in private sector RDI-activity. All studied strategies have some link to openness also from private sector perspective. In general, the aim is to enable or promote development of innovation ecosystems in health sector for example by promoting private sector co-operation or by opening public research or by fostering development of innovation infrastructures. Priority has been in development of one-stop service provider that provides one door for all health information generated in public sector and thus enables open utilization of health data in e.g. research focused innovation activity when ethical and regulatory demands are filled. Regarding open innovation, many strategies aim to promote development of innovation ecosystems but in practical level the focus has been in other matters than in open company co-operation and open innovation. For example in development of FICAN and national genome centre the focus has been in other matters than private sector co-operation or open RDI-activity. However, it is possible that co-operation elements and models are included in the operation once centers began their activity. Utilization of openly available data is only one aspect to openness in RDI-activity - moreover, it can be argued that openly shared health data can be also utilized in closed innovation process. Promoting utilization of public data and public research in private sector, developing utilization capabilities or promoting companies to share their own data has been scarce or nonexistent. Likewise, promoting open innovation has been scarce. Most notable aims to promote companies to share their own data are included in act on organizing health and social services which prerequisites that service providers both in public and private sector co-operate, service providers have access to customer information, save customer information to common register and constantly evaluate and share information about service operation, customer safety and service quality. Also, regarding biobank and also possibly genome bank operations user of biological material is expected to provide research results to the biobank in order to avoid overlapping research per se. However, quality and method-related questions make this difficult to accomplish according to interviews and thus, in practical level no clear operating model for this yet exists.

Tools to promote openness in RDI-activity in private sector and in public-private-sector interfaces, include e.g. 1) public procurement, 2) PPP and Triple Helix-operating models, 3) public funding instruments and 4) communication and marketing. The most important tool to promote public-private-sector co-operation in RDI-activity in health sector is public procurement. Public procurement makes it possible to require openness in RDI-activity during procurement process as well as during the contract period. Development of public procurement to the ways of better promoting openness requires both knowledge, resources, and more strategic thinking. Closely connected to public procurement, public-private-partnership and triple helix models provide another tool to promote openness in private-public-sector interface and to require open RDI-activity. Also public funding instruments could better promote openness in RDI-activity. For example, a new public funding instrument with higher funding levels could be developed for RDI-projects requiring utilization of open innovation models and opening RDI-activity. Also, public research funding instruments could have specific requirements of open innovation and company co-development. Finally, market communication is needed to inform possibilities to access open data and to promote open innovation models e.g. via success stories. Open innovation requires different operating models and different mind-set and the shift to open innovation prerequisites a major cultural change in private sector, which can be promoted via marketing and by setting the example by utilizing open innovation practices in public sector development.

2 Introduction

This study is conducted based on assignment of Ministry of Education and Culture during January-March 2017. The study is based on aims manifested in Open Science and Research Initiative, Open science and research roadmap and The Health Sector Growth Strategy for Research and Innovation Activities which all will be further described in following subchapters.

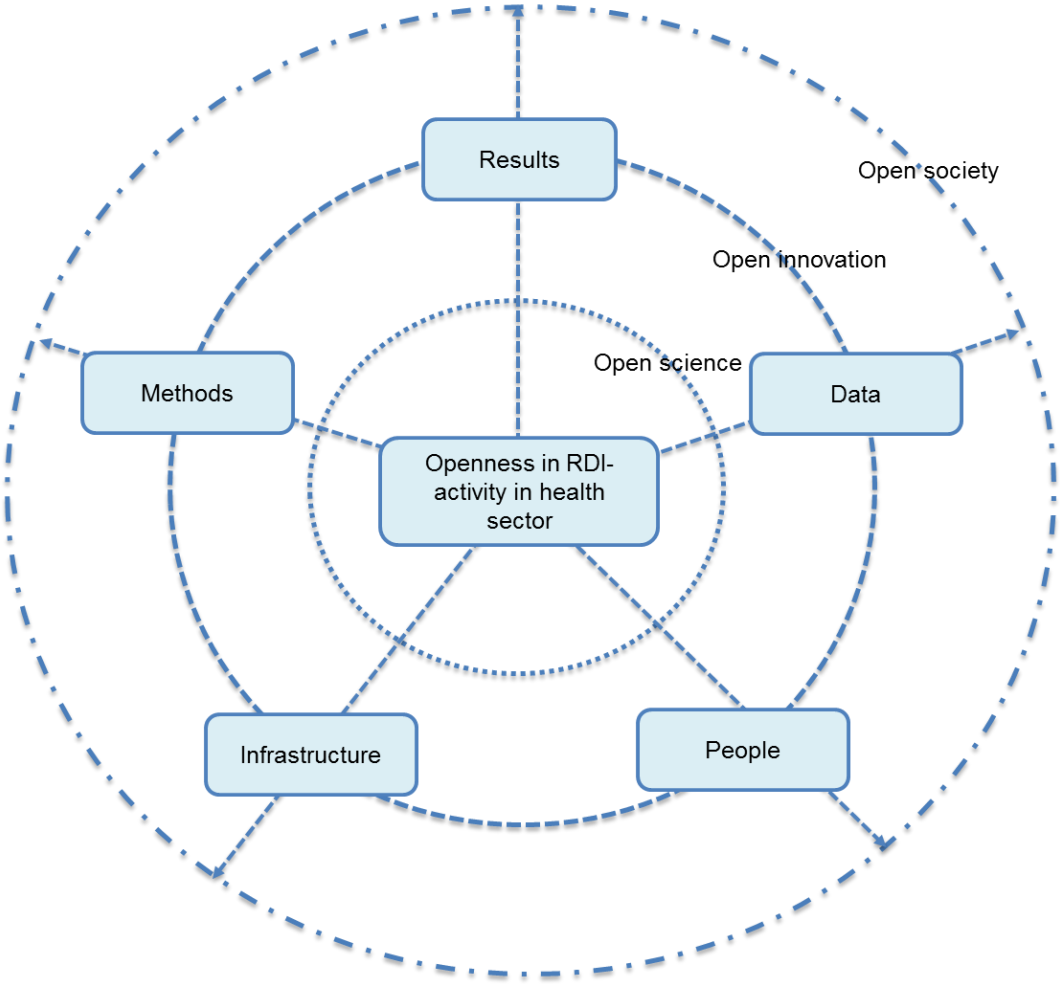
The study aims to *analyze pre-defined political, legal and structural changes in health sector from the view of promoting or enabling open RDI-activity, present examples of openness in health sector RDI-activity, and provide insights to promote open RDI-activity and public-private co-operation in health sector in Finland.*

Operating environmental factors	Objects of the study
Strategies and policies	✓ Open innovation, open science, open to the world ‐ vision for Europe (EU) ✓ Open Science and Research Initiative (FI) ✓ Open science and research roadmap (FI) ✓ The Health Sector Growth Strategy for Research and Innovation Activities (FI) ✓ Government programme ´ s key project 5 ‐ Intensified cooperation between higher education and business (FI) ✓ National Genome Strategy (FI)
Regulatory and structural reforms	✓ Health and social services reform and relating Government ´ s bills (FI) ✓ Draft government bill regarding information secure utilization of social and health care data and relating regulation (FI) ✓ EU 2016/679 regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (EU) ✓ Genome centre (FI) ✓ Comprehensive Cancer Center Finland (FICAN) (FI) ✓ Isaacus ‐ service operator project (FI) ✓ Harmonizing operations of biobanks (FI)
International and Finnish case examples	✓ The Innovative Medicines Initiative (EU) ✓ NEXT (DK) ✓ Structural Genomics Consortium and Protein Data Bank archive (CA) ✓ Biomarkers Consortium (USA) ✓ Eli Lilly and open drug development: Innocentive (USA, international) ✓ Vertical (FI) ✓ Helsinki Biobank (FI) ✓ Demola (FI, international) ✓ Astra Zeneca ´ s open innovation programs (SE, UK, international) ✓ LEO Pharma Open Innovation (DK, international) ✓ Merck Serono ´ s Open Compound Sourcing initiative (DE, international)

Table 1: Objects of operating environment analysis

The operating environment factors included in the study were defined in the assignment and are presented in the table 1. These selected factors portray by no means all-encompassing list of relevant factors affecting openness in

RDI-activity in the health sector. Factors of operating environment affecting openness of research, development and innovation activity in health sector can be classified for example according to PESTLE-model into political, economic, social, technological, legal, and environmental factors. These factors can act as barriers or drivers for openness. In this study the focus is on legal, structural and political factors. Thus, economic, social, technological and environmental factors with potential to effect on openness were cropped outside the scope of the study. However, it can be noted that for example technological development (e.g. IoT, robotisation, development of sensor technology, health technology development, development of data mining methods) and digitalization of society as a whole has a major impact on openness and open innovation. Also, the analyzed legal, structural and political factors mentioned in the table 1 do not present all-inclusive list of all legal, structural and political factors with potential to effect on openness in RDI-activity in health sector. It should be also noted, that the studied legal and structural factors are mainly currently evolving and since there are no final decisions made, the operating environment analysis provides only current view of the situation.



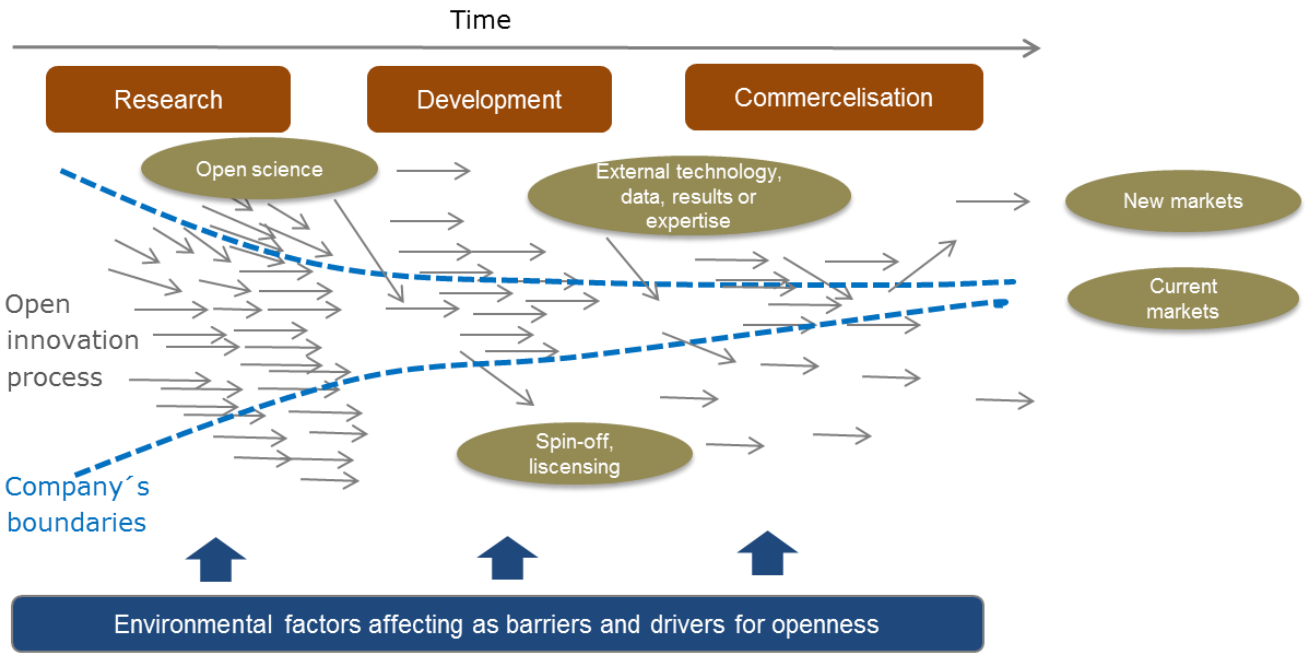
Picture 1: Framework of the study

The study was based on literature review comprising published and unpublished material related to subject of the study and mentioned strategies as well as structural and regulatory changes. Data analysis was reinforced with interviews and workshop material as well as corporate survey results. In order to broaden and deepen understanding of openness from private sector perspective 12 case studies portraying examples of open RDI-activity in health

sector were conducted. Also, e-survey to health sector companies was conducted to better understand level of openness in Finnish health sector and perceived barriers to open RDI-activity.

The framework for analyzing openness in RDI-activity in health sector is presented in picture 1. The framework links open science, open innovation and open society in the same cycle. Open society produces vast amount of e.g. health data which can be used as a raw material for open science and open innovation. Also, societal challenges and market needs provide a starting point for innovation activity and scientific research. Data, results and methods of scientific research are openly published and can be used as raw material and inspiration in open innovation activity and decision making. Open research infrastructures provide access to knowledge also for companies and they potentially portray platforms for common research and innovation activities. Open innovation activity creates new products and services to solve societal challenges and satisfy market needs.

The framework adds people as a fifth element of openly shared assets in RDI-activity. Data, methods, results and even infrastructure portray passive elements of openness in RDI-activity. Open publishing of data or methods or results is one-directional activity. Infrastructures such as databases can be seen as platforms that enable open publishing. However, people bring dynamicity to the equation. Open interaction between people, sharing of expertise in RDI-process is dynamic activity. Interaction between people can bring alive new ideas and innovations that go beyond data, methods and results. Sharing expertise and utilizing common enthusiasm can be seen as a key element in open RDI-activity. Interaction between people, between private and public sector and research organizations is needed to utilize openly shared material and joint platforms and jointly create innovations.



Picture 2: Open science and open innovation (Chesbrough 2003[1]) in health sector RDI-activity

[1] Chesbrough, H. (2003), Open Innovation: The New Imperative for Creating and Profiting from Technology, Harvard Business School Press. http://ses.sp.bvs.br/wp-content/uploads/2016/10/Book+OPen+Innovation_Henry-Chesbrough.pdf

This study is based on open science initiatives and strategies. Picture 2 aims to combine open science and open innovation. Open science can provide valuable insights for open innovation, in each phase of development process. In open innovation process legal boundaries of company do not limit exchange of ideas, data or results or utilization of innovation infrastructures. The boundary between a firm and its surrounding environment is more porous, enabling data and innovation to move easily between the two. In every phase of open innovation process company can utilize external data, results, expertise, technology or external infrastructures in development of own, joint or external products or services. Open science can provide insights that can be for example jointly commercialized with a company, through start-up-activity or based on licensing agreements or patents.

3 Background

In this chapter brief literature review relating to openness in health sector RDI-activity is presented together with main theories providing theoretical background for open science, open innovation and crowdsourcing.

3.1 Openness in health sector in OECD countries – Finland one of the forerunners in health information systems

OECD countries are ageing and increasing shares of our populations are living longer with multiple chronic and disabling conditions which places pressure on limited health care resources. To meet this challenge, health system managers and policy makers are moving toward performance-based governance to improve care quality, co-ordination and efficiency. Performance-based governance requires timely and accurate patient data that span the continuum of care, including health outcomes and costs. Such data also support re-designing and evaluating new models of health care service delivery and contribute to the discovery and evaluation of new treatments.[2]

OECD countries are making considerable investments in health data collections and information management systems. However, many OECD countries have a poor track record in bringing these investments toward their full potential in terms of information value. Further, encouraging the uptake of the most efficient and effective frameworks and practices to enable the collection, storage and use of personal health data to improve population health and to improve the effectiveness, safety and patient-centeredness of health care systems remains a significant policy challenge in many OECD countries.[3]

The OECD has been surveying countries about their health information assets and the use of these assets for statistics and research since 2011. Few countries are linking data across the pathways of health care to regularly monitor

[2] OECD (2015), Health Data Governance: Privacy, Monitoring and Research, OECD Health Policy Studies, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264244566-en
[3] OECD (2015), Health Data Governance: Privacy, Monitoring and Research, OECD Health Policy Studies, OECD Publishing, Paris. p 2 http://dx.doi.org/10.1787/9789264244566-en

health care quality and health system performance. Among 22 countries surveyed, the health information systems with the greatest data availability, maturity and use were found in Denmark, Finland, Iceland, Israel, Korea, New Zealand, Norway, Singapore, Sweden and the United Kingdom.

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Health data that can be linked to measure pathways and outcomes is often both personal and sensitive. It is personal because there is information that identifies individuals and sensitive because relates to health and health care treatments and services. Throughout the OECD, the legal framework for the protection of personal data recognizes the need for a high level of protection. To date, there is high variability across OECD countries in data availability and use. This is due to concerns and uncertainty about how best to protect patient's rights to privacy and to preserve the security of health data when data is shared linked and analyzed.[4]

To better understand how countries manage the use of personal data in health, an OECD survey has looked into different data accessibility factors that are directly linked to legislative frameworks and their interpretation in practice. These factors include whether or not identifiable national personal health data are ever shared among data custodians or government entities and whether personal health data, after de-identification, can be approved for access by applicants from different sectors of society and by foreign applicants. Overall, data sharing and accessibility is greatest in New Zealand, Sweden and the United Kingdom.

Also, OECD study identified eight data governance mechanisms to maximise benefits to patients and to societies from the use of health data and minimize risks to patients' privacy, public trust and confidence in health care providers and governments. These mechanisms are designed to work together to support countries in developing data governance frameworks and engaging in legislative reforms, including those necessary as the result of the anticipated EU Data Protection Regulation. These mechanisms build forward from existing efforts, such as the OECD Privacy Framework (OECD, 2013b) and the European Data Protection Directive (95-46-EC). Data governance mechanisms include[5]:

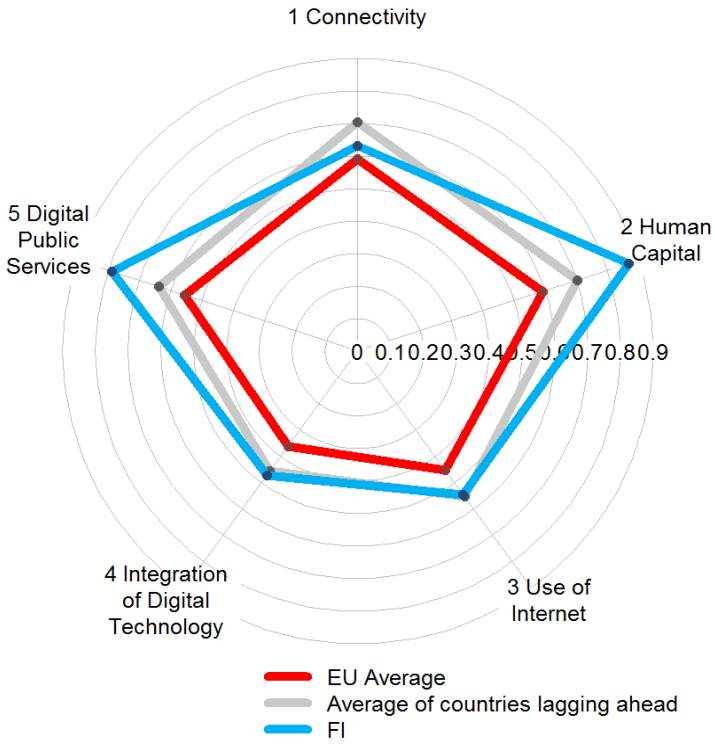
1) The health information system supports the monitoring and improvement of health care quality and system performance, as well as research innovations for better health care and outcomes.
2) The processing and the secondary use of data for public health, research and statistical purposes are permitted, subject to safeguards specified in the legislative framework for data protection.
3) The public are consulted upon and informed about the collection and processing of personal health data.
4) A certification/accreditation process for the processing of health data for research and statistics is implemented.
5) The project approval process is fair and transparent and decision making is supported by an independent, multidisciplinary project review body.
6) Best practices in data de-identification are applied to protect patient data privacy.
7) Best practices in data security and management are applied to reduce re-identification and breach risks.

[4] OECD (2015), Health Data Governance: Privacy, Monitoring and Research, OECD Health Policy Studies, OECD Publishing, Paris. p 2 http://dx.doi.org/10.1787/9789264244566-en
[5] OECD (2015), Health Data Governance: Privacy, Monitoring and Research, OECD Health Policy Studies, OECD Publishing, Paris. p 5-6 http://dx.doi.org/10.1787/9789264244566-en

3.1 Finland´s ranking in EU Index and global competitiveness reports

Openness in health sector is closely connected to digitalization and open data. Finland ranks 4th out of the 28 EU Member States in the European Commission Digital Economy and Society Index (DESI) 2016[6]. Finland belongs to the cluster of countries with high scores but slow improvements called lagging ahead. In the Digital Public Services dimension Finland is progressing faster than average despite an already high starting level. Finland is displaying very high connectivity, but very slow fixed broadband take-up compared with other countries; however, performance in mobile broadband is excellent. Finland's comparatively slow improvement in digital skills mostly reflects the very high scores already achieved and the success of other countries in catching up. The Use of Internet and the Integration of Digital Technologies are both advancing roughly at EU average rates. All in all, Finland is a world leader in digitization.[7]

Regarding open data, Finland scores 390 out of 700 in the European Public Sector Information scoreboard, against an overall score of 351 out of 700 for the European Union.

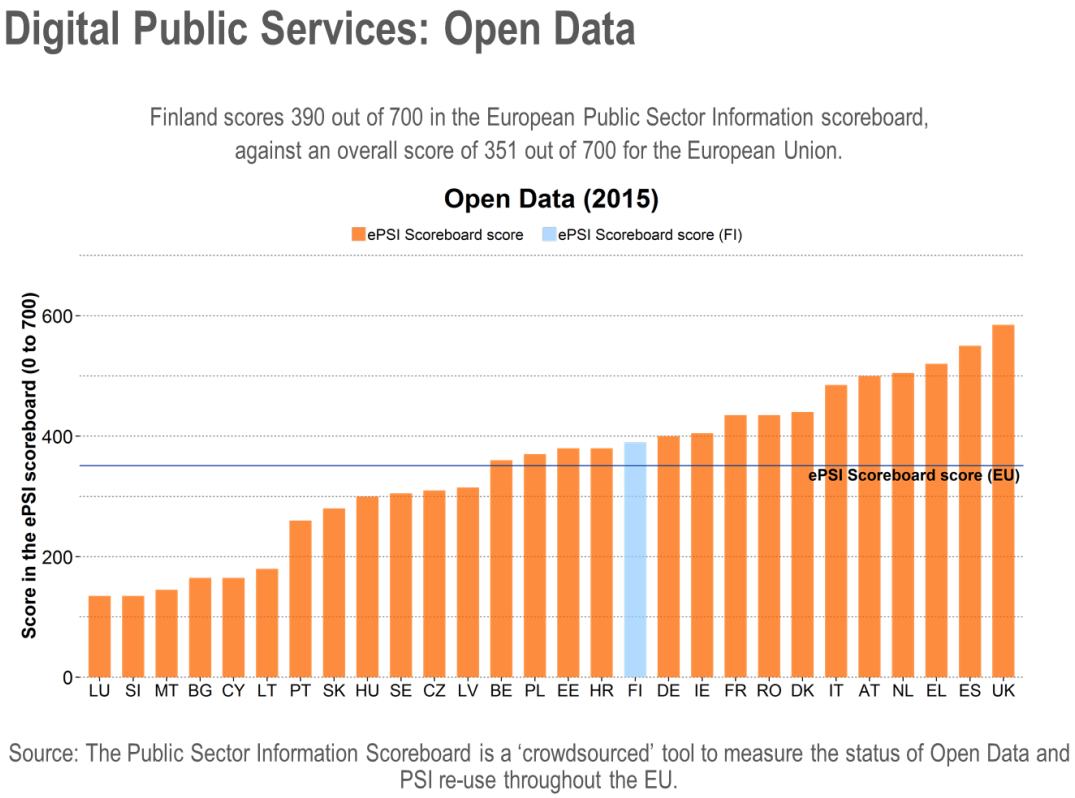


Picture 3: Finland's performance in the DESI 2016 (Source: European Comission, 2017)

In Digital public services, Finland performs very well and is still progressing faster than the EU average. In the Programme of the Government, the goal for the next ten years is that Finland will make a productivity leap in public services and the private sector by grasping the opportunities offered by digitalization, dismantling unnecessary

[6] European Commission (2017), Digital Economy and Society Index (DESI) 2016. https://ec.europa.eu/digital-single-market/en/scoreboard/finland
[7] European Commission (2017), Digital Economy and Society Index (DESI) 2016. https://ec.europa.eu/digital-single-market/en/scoreboard/finland

regulation and cutting red tape. With the help of new operating practices, public services will thus become user-oriented and primarily digital. In order to achieve this, a one-stop-shop service model will be developed and the information management legislation reformed. To make e-government services more widely available, the government is also building a National Digital Services Infrastructure, which will facilitate the introduction of a national common digital identification solution. The policy focus placed by the government on digital public services combined with the widespread availability of network access and the high level of skills in the population make Finland an ideal case for proving the benefits of digitization for public services. Regarding open data, Finland scores 390 out of 700 in the European Public Sector Information scoreboard, against an overall score of 351 out of 700 for the European Union.[8]



Picture 4: Open data in Digital Economy and Society Index 2015

ePrescriptions now make up over 90% of all prescription services in public and private health care in Finland as well as in Sweden. Joining the Finnish ePrescription Centre is mandatory and, from 2017, ePrescriptions will be the only option available for dispensing medication. A pilot project in the Tornio valley established a functioning cross-border ePrescription service between Finland and Sweden. The pilot project implemented cross-border ePrescription services in four pharmacies in Sweden and three in Finland. The challenges encountered in the project were primarily

[8] European Commission (2017), Digital Economy and Society Index (DESI) 2016. https://ec.europa.eu/digital-single-market/en/scoreboard/finland

legal and organizational in nature, though these were overcome by implementing specific amendments to the existing ePrescription laws in both countries. [9]

According to World Economic Forum´s Global Competitiveness report 2016-2017 Finland is well positioned in terms of innovation, with a high degree of collaboration between universities and industry. Regarding university-industry collaboration in R&D Finland takes second place with 5.7 score.[10]

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3.2 Open science

Theoretical background of this study is on open science, open innovation and crowdsourcing theories.

Open science is a relatively young discourse and a term which encompasses a variety of assumptions concerning knowledge creation, its future, results, and dissemination as well as assumptions concerning the researcher or the relationship between research and the society. The discourse of open science highlights the need for academic research to open up more. Today ´ s technological innovations and internet bring about new opportunities to share knowledge and data. A literature review of open science highlights the differences in the way open science is understood and defined. Mainly, three predominant categories that could be found from the literature in which the authors defined open science. These are infrastructures, public accessibility, and collaborative research. [11]

Open science, in terms of infrastructures, involves the free availability of data, methods and results of research on the Web with unrestricted access and use along with being free of charge to users. Through open platforms it is possible to copy, redistribute, extract, and modify data. The public accessibility category involves the central assumption that full and open access to information covering the entire scientific process should be made to the public. The collaborative research category assumes that collaboration among scientists would make knowledge-creation more efficient. In this sense open science is defined as operating as a collaborative process where open access to shared resources through an open repository, the ability to draw upon prior research, gaining credit from follow-on researchers, and cross-checking of information and results are viewed as highly important. Thus, open science is seen to involve data and metadata being discoverable, accessible to all, assessable, and re-usable. Based on these three categories, open science implies the open availability of resources through an open repository that is publicly-accessible,

...open science implies the open availability of resources through an open repository that is publicly-accessible, collaboration where knowledge can travel openly, and the availability of tools that will enable the previously mentioned.

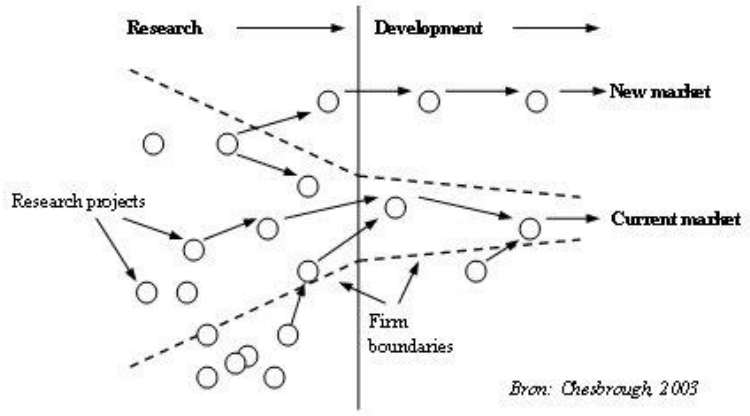
[9] European Commission (2017), Digital Economy and Society Index (DESI) 2016. https://ec.europa.eu/digital-single-market/en/scoreboard/finland
[10] World Economic Forum (2017), The Global Competitiveness Report 2016-2017. http://www3.weforum.org/docs/GCR2016-2017/05FullReport/TheGlobalCompetitivenessReport2016-2017_FINAL.pdf
[11] Ministry of Education and Culture (2016), Landscape of Open Science. http://openscience.fi/documents/10864/12232/Landscape+of+Open+Science/870316f5-2cf8-467d-a019-519239c195a6

collaboration where knowledge can travel openly, and the availability of tools that will enable the previously mentioned. [12]

3.3 Open innovation

In this new model of open innovation, firms commercialize external (as well as internal) ideas by deploying outside (as well as in-house) pathways to the market.

The definition of open innovation is based on the fact that companies are increasingly rethinking the fundamental ways in which they generate ideas and bring them to market − harnessing external ideas while leveraging their in-house R&D outside their current operations. The old model of closed innovation is based on philosophy that successful innovation requires control. Thus, companies generated their own ideas that they then developed, manufactured, marketed, distributed and serviced themselves. This philosophy of self-reliance dominated the R&D operations of many leading industrial corporations for most of the 20th century. However, toward the end of the 20th century, a number of factors combined to erode the underpinnings of closed innovation, especially in the United States. One of the main factors affecting the change was the dramatic rise in the number and mobility of knowledge workers, making it increasingly difficult for companies to control their proprietary ideas and expertise. Another important factor was the growing availability of private venture capital, which has helped to finance new firms and their efforts to commercialize ideas that have spilled outside the silos of corporate research labs. Such factors have wreaked havoc with the virtuous cycle that sustained closed innovation. Now, when breakthroughs occur, the scientists and engineers who made them have an outside option to pursue it on their own − in a startup financed by venture capital. [13]



Picture 5: Open innovation model (Chesbrough, 2003)[14]

[12] Ministry of Education and Culture (2016), Landscape of Open Science. http://openscience.fi/documents/10864/12232/Landscape+of+Open+Science/870316f5-2cf8-467d-a019-519239c195a6
[13] Chesbrough, H. (2003), The Era of Open innovation. MIT Sloan Management Review. http://sloanreview.mit.edu/article/the-era-of-open-innovation/
[14] Openinnovation.eu (2017), Open innovation. http://www.openinnovation.eu/open-innovation/

In this new model of open innovation, firms commercialize external (as well as internal) ideas by deploying outside (as well as in-house) pathways to the market. Thus, an organization should not restrict the knowledge that it uncovers in its research to its internal market pathways, nor should those internal pathways necessarily be constrained to bringing only the company´s internal knowledge to market. Specifically, companies can commercialize internal ideas through channels outside of their current businesses by e.g. startup companies and licensing agreements. In addition, ideas can also originate outside the firm's own labs and be brought inside for commercialization. No longer should a company lock up its IP, but instead it should find ways to profit from others´ use of that technology through licensing agreements, joint ventures and other arrangements. In other words, the boundary between a firm and its surrounding environment is more porous, enabling innovation to move easily between the two. [15]

Many companies have been defining new strategies for exploiting the principles of open innovation, and in doing so, have focused their activities into one of three primary areas: funding, generating or commercializing innovation. Two types of organizations, innovation investors and benefactors, are focused primarily on funding innovation. Benefactors focus on funding basic and applied research in the early stages of research discovery while innovation investors provide venture capital that helps to move ideas out of corporations and universities and into the market, typically through the creation of startup. Chesbrough (2003) identifies four types of organizations that primarily generate innovation: innovation explorers, merchants, architects and missionaries. Innovation explorers specialize in performing the discovery research function that previously took place primarily within corporate R&D laboratories. Innovation merchants´ activities are focused on a narrow set of technologies that are then codified into intellectual property and aggressively sold to others (e.g. Qualcomm). Innovation architects develop architectures that enables numerous other companies to provide pieces of the system, all while ensuring that those parts fit together in a coherent way (e.g. Nokia, Boeing). Innovation missionaries consist of people and organizations that create and advance technologies to serve a cause (e.g. Linux). Finally, two types of organization are focused on bringing innovations to market: innovation marketers and one-stop centers. Innovation marketers focus on developing a deep understanding of the current and potential needs in the market and this helps them to identify which outside ideas to bring in-house. Innovation one-stop centers provide comprehensive products and services. They take the best ideas and deliver those offerings to their customers at competitive prices.[16]

Traditionally, innovation in the pharmaceutical industry is organized according to the linear and closed innovation model. Over the decades this model lost its meaning as a result of rising costs, increased competition, new scientific developments and better-informed, more demanding users. The linear model is not well equipped to involve these new actors and to include their feedback. Starting from a systemic approach, the involvement of actors in pharmaceutical innovation processes, more in particular users, is put central.[17]

[15] Chesbrough, H. (2003), The Era of Open innovation. MIT Sloan Management Review. http://sloanreview.mit.edu/article/the-era-of-open-innovation/
[16] Chesbrough, H. (2003), The Era of Open innovation. MIT Sloan Management Review. http://sloanreview.mit.edu/article/the-era-of-open-innovation/
[17] Smits, R. and Boon, W. (2008), The role of users in innovation in the pharmaceutical industry. Drug Discov Today. 2008 Apr;13 (7-8): 353-9. https://www.ncbi.nlm.nih.gov/pubmed/18405849

3.4 Crowdsourcing, user innovation and know-how trading

Open innovation is closely related to phenomena such as crowdsourcing, know-how trading and user innovation. Know-how trading is a web-based research and design phenomenon that denotes fee-based knowledge markets that treat knowledge and expertise as commodities that can be traded for financial gain. Examples of know-how trading portals include InnoCentive, NineSigma and Starmind.

User innovation refers to innovation by intermediate users, that can be firms or consumers (individual end-users or user communities), rather than by suppliers (producers or manufacturers). The concept of user innovation was based on notion that many products and services are developed or at least refined, by users, at the site of implementation and use. End-users are also noted to be experts of their own needs and usage habits. In 1986 Eric von Hippel introduced the lead user method that can be used to systematically learn about user innovation in order to apply it in new product development.[18] In 2007 another specific type of user innovator, the creative consumer was introduced. These are consumers who adapt, modify, or transform a proprietary offering as opposed to creating completely new products.[19] User innovation has a number of degrees: innovation of use, innovation in services, innovation in configuration of technologies, and finally the innovation of novel technologies themselves. Today, many companies and web-based forums facilitate and utilize user innovation, for example Lego. Lego Mindstorms is a classic example of the "outside in" open innovation model where the company has allowed customers to create designs.

The term "crowdsourcing" was introduced in 2005 by Jeff Howe and Mark Robinson, editors at Wired, to describe how businesses were using the Internet to "outsource work to the crowd", which quickly led to the term "crowdsourcing." Howe first published a definition for the term crowdsourcing in a companion blog post to his June 2006 Wired article, "The Rise of Crowdsourcing":

"Simply defined, crowdsourcing represents the act of a company or institution taking a function once performed by employees and outsourcing it to an undefined (and generally large) network of people in the form of an open call. This can take the form of peer-production (when the job is performed collaboratively), but is also often undertaken by sole individuals. The crucial prerequisite is the use of the open call format and the large network of potential laborers."

In a February 1, 2008, article, Daren C. Brabham defined it as an "*online, distributed problem-solving and production model*."[20]

After studying more than 40 definitions of crowdsourcing in the scientific and popular literature, Enrique Estellés-Arolas and Fernando González Ladrón-de-Guevara, researchers at the Technical University of Valencia, developed a new integrating definition:

"Crowdsourcing is a type of participative online activity in which an individual, an institution, a nonprofit organization, or company proposes to a group of individuals of varying knowledge, heterogeneity, and number, via a flexible open call, the voluntary undertaking of a task. The undertaking of the task; of variable complexity and

[18] von Hippel, E. (1986), Lead Users: A Source of Novel Product Concepts. Management Science, 32(7), 791-805.
[19] Berthon, PR.; Pitt, LF.; McCarthy I. and Kates, SB. (2007), When customers get clever: Managerial approaches to dealing with creative consumers, Business Horizons 50 (1), 39-47
[20] Brabham, D. (2008), "Crowdsourcing as a Model for Problem Solving: An Introduction and Cases", The International Journal of Research into New Media Technologies, 14 (1): 75–90

modularity, and; in which the crowd should participate, bringing their work, money, knowledge and/or experience, always entails mutual benefit. The user will receive the satisfaction of a given type of need, be it economic, social recognition, self-esteem, or the development of individual skills, while the crowdsourcer will obtain and use to their advantage that which the user has brought to the venture, whose form will depend on the type of activity undertaken".[21]

Crowdsourcing is an IT-mediated phenomenon, based on broadcasting of problems to the public, and an open call for contributions to solving the problem. Members of the public submit solutions which are then owned by the entity which broadcast the problem. In some cases, the contributor of the solution is compensated by money, prizes, recognition or intellectual satisfaction. Crowdsourcing may produce solutions from amateurs or volunteers, working in their spare time, or from experts or small businesses which were unknown to the initiating organization.

One pioneer example of open innovation platforms is InnoCentive. Pharmaceutical maker Eli Lilly funded InnoCentive's launch in 2001 in order to connect with people outside the company who could help develop drugs and speed them to market. From the outset, InnoCentive threw open the doors to other firms eager to access the network's trove of ad hoc experts. Companies like Boeing, DuPont, and Procter & Gamble have posted their scientific problems on InnoCentive´s Web site for anyone to solve. The companies pay solvers anywhere from $10,000 to $100,000 per solution. The strength of a network like InnoCentive's is the diversity of intellectual background. Thus, it is noted that the most efficient networks are those that link to the broadest range of information, knowledge, and experience. [22] Today, InnoCentive portrays tens of challenges related to life science e.g. pharmaceutical development. [23]

4 Policies and strategies

In this chapter main policies and strategies relating to openness in health sector RDI-activity in Finland are briefly described. These include European Commision´s Open innovation, open science, open to the world - vision, Open Science and Research Initiative, Open science and research roadmap, Health Sector Growth Strategy for Research and Innovation Activities, Government programme´s key project, National Genome Strategy and also strategy relating to utilization of social and welfare data ("SOTE-tieto hyötykäyttöön" -strategia). We will further describe the first six strategies in regard of openness in private sector RDI-activity.

4.1 Open innovation, open science, open to the world – vision for Europe

It is noted in Open innovation, open science, open to the world - vision that the innovation can no longer be seen as the result of predefined and isolated innovation activities but rather as the outcome of a complex co-creation process involving knowledge flows across the entire economic and social environment. In order to encourage the transition from linear knowledge transfer towards more dynamic knowledge circulation, it is essential to create and support an

[21] Estellés-Arolas, E.; González-Ladrón-de-Guevara, F. (2012), "Towards an Integrated Crowdsourcing Definition", Journal of Information Science, 38 (2): 189-200
[22] Howe, J. (2006), The Rise of Crowdsourcing. https://www.wired.com/2006/06/crowds/
[23] InnoCentive (2016), Challenges, https://www.innocentive.com/ar/challenge/browse

open innovation ecosystem that facilitates the translation of knowledge into socio-economic value. In addition to the formal supply side elements such as research skills, excellent science, funding and Intellectual Property management, there is also a need to concentrate on the demand side aspects of knowledge circulation, making sure that scientific work corresponds to the needs of the users and that knowledge is findable, accessible, interpretable and re-usable (FAIR). [24]

Open Access to research results is essential part of Open Science and is also the springboard for increased innovation opportunities, for instance by enabling more science-based startups to emerge. It is noted that prioritizing Open Science does not, however, automatically ensure that research results and scientific knowledge are commercialized or transformed into socio-economic value. In order for this to happen, Open Innovation must help to connect and exploit the results of Open Science and facilitate the faster translation of discoveries into societal use and economic value. [25]

... prioritising Open Science does not, however, automatically ensure that research results and scientific knowledge are commercialised or transformed into socio-economic value.

International collaboration plays a significant role both in improving the competitiveness of Open Innovation ecosystems and in fostering new knowledge production worldwide. It ensures access to a broader set of competences, resources and skills wherever they are located, and it enables global standard-setting, allows global challenges to be tackled more effectively, and facilitates participation in global value chains and new and emerging markets.[26]

The Commission aims to ensure that the appropriate framework conditions for innovation are in place through the three pillars of its Open Innovation policy. These are: Reforming the Regulatory Environment, Boosting Private Investment and Maximizing Impacts. First, Europe needs to create the right regulatory environment that removes obstacles to innovation and encourages innovators and entrepreneurs, while rule and standard-setting must keep up with rapidly changing technologies. Second, it's clear that the European innovation ecosystem is lacking adequate private financial instruments (with far less venture capital in Europe, and venture capital funds do not have the scale or scope to grow companies). Under the third pillar, the Commission will strive to get the most out of EU-level support for innovation by developing new actions to get more innovation impact out of Horizon 2020, including through better synergies with the Structural Funds.[27]

Fostering international cooperation in research and innovation is a strategic priority for the European Union in order to access the latest knowledge and the best talent worldwide, solve global societal challenges more effectively, create business opportunities, and use science diplomacy as an influential instrument of external policy. The European Commission is active on several fronts to help ensure that European research and innovation are 'Open to the World'. This work includes leading several global initiatives, helping to develop the framework conditions that

[24] European Commission (2016) Open innovation, open science, open to the world. https://ec.europa.eu/digital-single-market/en/news/open-innovation-open-science-open-world-vision-europe
[25] European Commission (2016) Open innovation, open science, open to the world. https://ec.europa.eu/digital-single-market/en/news/open-innovation-open-science-open-world-vision-europe
[26] European Commission (2016) Open innovation, open science, open to the world. https://ec.europa.eu/digital-single-market/en/news/open-innovation-open-science-open-world-vision-europe
[27] European Commission (2016) Open innovation, open science, open to the world. https://ec.europa.eu/digital-single-market/en/news/open-innovation-open-science-open-world-vision-europe

underpin international cooperation, and maximizing synergies with the activities of Member States. Being 'Open to the World' means striving to ensure that EU research and innovation can work at a global level for all of us. [28]

4.2 Finland´s Government programme´s key project 5 in Skills and education

Government´s vision in skills and education for 2025 is that "*Finland is a country where people always want to learn new things. Skills and education levels in Finland have risen, promoting the renewal of Finnish society and equal opportunities. Finland is in the vanguard of education, skills and modern learning techniques"*. The objective is to make Finland a leading country of modern learning and inspiring education. Government term objectives for the strategic priority are following:

1. Learning environments have been modernized and the opportunities offered by digitalization and new pedagogical approaches are grasped in learning.
2. The number of young people who have dropped out of education or working life has fallen. The drop-out rate in education has declined.
3. Dialogue between educational institutions and working life is more active.
4. The quality and effectiveness of research and innovation have begun to improve.
5. Education and research have become more international and obstacles to education exports have been removed.[29]

Higher education institutes will be encouraged to cooperate with companies and intensify the impact and efforts to commercialise the research findings.

The key project 5 in skills and education is focused on intensified cooperation between higher education and business life to commercialize innovations. For cooperation between universities and business 159 million euros was allocated in the government programme. The objective of key project five is to make maximum use of scientific and research resources and to boost education exports. This objective is aimed to be reached via four measures. Firstly, higher education institutions and research institutes will be required to prepare a proposal regarding their respective responsibilities and intensified cooperation between faculties and research units. Secondly, financial support will be provided for regional and industry-specific centres of excellence. Thirdly, full consideration should be given to the effectiveness and commercialization of research results in steering public research, development and innovation funding, as well as in the provision of incentives for research institutes and higher education institutions. Fourthly, barriers to education exports should be removed at all levels.[30]

Tasks promoting openness in private sector RDI-activity include for example joint initiatives to provide a platform for the commercialization of research and establishment of new businesses in select prioritized areas. Also, an

[28] European Commission (2016) Open innovation, open science, open to the world. https://ec.europa.eu/digital-single-market/en/news/open-innovation-open-science-open-world-vision-europe
[29] Valtioneuvosto (2016) Action plan for the implementation strategic government programme. Government Publications 1/2016. Valtioneuvoston kanslia: Helsinki. http://valtioneuvosto.fi/documents/10616/1986338/Action+plan+for+the+implementation+Strategic+Government+Programme+EN.pdf/12f723ba-6f6b-4e6c-a636-4ad4175d7c4e
[30] Valtioneuvosto (2016) Action plan for the implementation strategic government programme. Government Publications 1/2016. Valtioneuvoston kanslia: Helsinki. http://valtioneuvosto.fi/documents/10616/1986338/Action+plan+for+the+implementation+Strategic+Government+Programme+EN.pdf/12f723ba-6f6b-4e6c-a636-4ad4175d7c4e

innovation bank is aimed to be established to contribute to the more efficient utilization of innovations and patents. Also, resources will be allocated to centres of excellence and corporate cooperation according to the strategic priorities and individual profiles. Innovative public procurement will be used to promote development and demonstrations of new innovations in order to promote exports. Public funding will be allocated to promote joint projects by companies and public research organizations to commercialize knowledge generated by research. Public funding will be developed to boost more efficient commercialization of research. Existing funding instruments of Tekes for commercializing research will be developed, new instruments will be adopted and cooperation between Tekes and the Academy of Finland will be reinforced. To ensure a better match between the needs of business and publicly funded research, Tekes will launch Challenge Finland. Higher education institutes will be encouraged to cooperate with companies and intensify the efforts to commercialize the research findings and the exploitation and commercialization of research will be evaluated in the future. Also, researchers' awareness of the commercial potential of research and entrepreneurship will be reinforced and funding allocated to experimentation, prototypes and high risk projects.

4.3 Finland´s Open Science and Research Initiative

The Ministry of Education and Culture of Finland has launched the Open Science and Research Initiative (ATT) for the promotion of research information availability and open science platform for the years 2014-2017. The main goal of the Open Science and Research Initiative is for Finland to become one of the leading countries in openness of science and research by the year 2017. The initiative aimed to implement the national policy agenda in a way that fosters the Finnish research system towards better competitiveness and higher quality, transparency and innovation. The ambition were to promote the trustworthiness of open science and research and to incorporate them in to the whole research process, thus improving visibility and impact of science in the innovation system and society at large. By supporting the culture of open science within the research community, the societal impressiveness of open science grows. In addition to opening up both the results and raw data, the ambition were to build a sustainable information infrastructure in conjunction with a variety of sophisticated tools and methods to promote long-term availability and accessibility of results. [31]

Practically, the aim was to provide researchers with tangible knowledge in how they as individuals can implement openness. Open science is promoted by directing special attention on three central constituents completing each other: *open scientific publications*, *open research data* and *open research methods with their corresponding storage facilities, metadata and access services*. Also cutting edge *research environments, advanced skills and knowledge, comprehensive guidelines and other diverse support services and tools* are included in the initiative. It was stated that Finland will engage in international collaboration to promote the openness of science which means that the possibilities and outcomes of open science will be widely utilized on a national level and with growing international affairs.[32]

[31] Ministry of Education and Culture (2014) Open science and research initiative in action. http://openscience.fi/open-science-and-research-iniative-in-action
[32] Ministry of Education and Culture (2014) Open science and research initiative in action. http://openscience.fi/open-science-and-research-iniative-in-action

4.4 Finland´s Open science and research roadmap 2014–2017

Open science and research roadmap is based on the work of the Open Science and Research Initiative, a cross-administrative initiative established by the Ministry of Education and Culture. The key objective is, subject to the restrictions of research ethics and the juridical environment, to publish research results, research data and the methods used, so that they can be examined and used by any interested party. Open science includes practices such as promoting open access publishing, openly publishing research materials, harnessing open-source software and open standards, and the public documentation of the research process through 'memoing'.[33]

In the roadmap it is stated that open science and research can significantly increase the quality and competitiveness of Finland's research and innovation system. Increasing openness in research aims to improve reliability, transparency, and the impact of research. It is also seen, that openness creates opportunities to participate in scientific advancement, and enables easier and more effective utilization of research results. Promoting open science and research requires not only extensive involvement from the research community, but also cooperation and coordination, internalizing new ways of working, and developments in research environments, researcher services and research infrastructures.

In the roadmap the vision for 2017 is: *Open research leads to surprising discoveries and creative insights. This means a situation in which research data and materials move freely throughout society; from one researcher or research team to another, between disciplines, to innovative businesses, and to decision-makers and citizens. Information flow is facilitated by clear policies and best practices, and by providing services to safeguard the availability of scientific and research results. Openness is a joint operating model. Openness has given Finnish research an international competitive edge*.[34]

…open science creates new opportunities for researchers, decision-makers, business, public bodies and citizens.

Thus, it is seen that innovative businesses benefit from open research results and data by gaining new insights and discoveries. Roadmap claims, that research results (publications, data, methods and the tools required to publish) will be openly and permanently available in data networks via standardized interfaces in accordance with ethical principles and respecting legal operating environments. Openness within research infrastructures will be pursued when it is legally and contractually possible. Further use of research results is not unnecessarily restricted and dialogue in science and research will be promoted on many levels.

The roadmap will be implemented via four sub-objectives, which are[35]:

- ✓ reinforcing the intrinsic nature of science and research, so that openness and repeatability increase the reliability and quality of science and research.
- ✓ strengthening openness-related expertise, so that those working in the Finnish research system know how to harness the opportunities afforded by openness to boost Finland's competitive edge.

[33] Ministry of Education and Culture (2014), Open science and research roadmap. http://openscience.fi/documents/14273/0/Open+Science+and+Research+Roadmap+2014-2017/e8eb7704-8ea7-48bb-92e6-c6c954d4a2f2

[34] Ministry of Education and Culture (2014) Open science and research initiative in action. http://openscience.fi/open-science-and-research-iniative-in-action

[35] Ministry of Education and Culture (2014) Open science and research initiative in action. http://openscience.fi/open-science-and-research-iniative-in-action

- ✓ ensuring a stable foundation for the research process, so that good, clear basic structures and services enable new opportunities to be harnessed at the right time and ensure a stable basis for research.
- ✓ *increasing the societal impact of research*, so that open science creates new opportunities for researchers, decision-makers, *business*, public bodies and citizens.

Thus, the final sub-objective connects open science to openness in private sector RDI-activity. The aim is to increase impact of open science also in business sector so that research results will be more rapidly utilized and open data will provide raw material for innovation. Research results may lead to the birth of new innovations and their commercialization. It is noted in the roadmap that high-quality research is closely linked to expertise and innovation, which have a great impact on economic growth and the greatest economic opportunities are to be found in radical new products, services and markets. Through a more open approach, ideas will multiply and develop. It is also noted that immaterial rights fundamentally support the free movement of information since copyright give authors the incentive to publish new works for the benefit of society. Inventions can be protected with patents and utility models before the open publication of results even in the case of contractual research.[36]

4.5 Finland´s Health Sector Growth Strategy for Research and Innovation Activities

As a result of long-term investments in education, research, innovation and research infrastructures of health sector, the health sector in Finland has grown and become international faster than many other sectors in recent years. The quality of the Finnish health care system is among the best in the world. Health technology has turned into a high-tech export sector and nationally important employer.[37]

The Health Sector Growth Strategy for Research and Innovation Activities published in 2014 was prepared in collaboration by three ministries (Ministry of Employment and the Economy, Ministry of Social Affairs and Health, and Ministry of Education and Culture), funding providers for research and innovation i.e. Tekes and Academy of Finland as well as health sector actors. The Growth Strategy aims for expertise-driven improvement of citizens' health and well-being, for example, by using the possibilities created by the advancement of science and technology. At the same time, it aims to promote Finland as an internationally renowned forerunner in health sector research and innovation, investment and new business.[38]

Roadmap gives details about the implementation of the growth strategy. The aim of the roadmap is to strengthen the operating environment and thus improve Finland's position as an internationally renowned forerunner in health sector research and innovation, investment and new business. At the same time, an improvement is sought in people's health and wellbeing through the opportunities offered by research and technology to ensure Finland's high standard of health care also in the future. The State has a central role in the building of an ecosystem favorable to research and innovation. The measures include innovation friendly regulation, coordinated funding for research and innovation, and providing opportunities for innovative solutions in structural. Reform of the Finnish health and

[36] Ministry of Education and Culture (2014), Open science and research roadmap. http://openscience.fi/documents/14273/0/Open+Science+and+Research+Roadmap+2014-2017/e8eb7704-8ea7-48bb-92e6-c6c954d4a2f2

[37] Ministry of Work and Employment (2016), Innovating together. Health sector growth strategy for research and innovation activities. Raodmap 2016-2018. http://urn.fi/URN:ISBN:978-952-327-142-5

[38] Ministry of Work and Employment (2016), Innovating together. Health sector growth strategy for research and innovation activities. Raodmap 2016-2018. http://urn.fi/URN:ISBN:978-952-327-142-5

social services system will increase the opportunities for innovative public procurement and for Finland to act as a lead market.

The strategy aims that Finland is an internationally known pioneer country in research and innovation, investments and new business in the health sector. The strategy states that as a pioneer Finland is

- ✓ A source of and able to utilize the high-level scientific research and innovations that are born out of that
- ✓ A dynamic operating environment for growth companies in the sector
- ✓ A model country for matching the health services system and innovation activities
- ✓ An attractive co-operation partner and a target country for investments in the health sector
- ✓ A forerunner in personalized health care and utilization of genome data

Key action areas of growth strategy that are related to openness in private sector include e.g. [39]:

- Universities and cities with university hospitals agree on action plans to *develop hospital cluster research and innovation ecosystems and related cooperation with companies*.
- Higher education institutions and research institutions in the central university cities will *strengthen collaboration in technology transfer and commercialization* with a particular aim to reinforce sectoral cooperation on national level.
- Through cooperation between Tekes and the Academy of Finland, funding instruments will be developed further, taking the special features of the health sector into consideration in order to *facilitate the utilization of research*.
- a) *Access to personal health data and patient documents* will be enabled for research purposes. b) National genome centre will be established, including legislation and guidelines for the *utilization of genome data*.
- A joint operation model will be drawn up to *reinforce the work of relevant ministries and the business sector* for exerting influence in the EU.
- *Introduction of innovative solutions will be encouraged* when renewing health technology and pharmaceutical regulation as well as in the strategies of the health sector institutions. Innovative public procurement will be supported.
- *To support market entry of small and medium sized companies developing health technology and pharmaceuticals*, training and advisory activities for regulation as well as standards will be enforced.

Universities and cities with university hospitals agree on action plans to develop hospital cluster research and innovation ecosystems and related cooperation with companies.

Actions 2016-2018 related to promote openness include e.g. supporting cooperation between higher education institutions (HEI), research institutes and companies in ecosystem initiatives that provide a platform for commercializing research and competences, starting new companies, and generating international business in selected priority areas, including the health sector. Actions also include directing the resources of HEIs and research institutes at creating competence hubs and business cooperation as indicated by their profiles (players in health sector competence hubs) as well as encouraging health sector actors to pilot the implementation of research organizations' joint commercialization and innovation services.

[39] Ministry of Work and Employment (2016), Innovating together. Health sector growth strategy for research and innovation activities. Raodmap 2016-2018. http://urn.fi/URN:ISBN:978-952-327-142-5

4.6 Finland´s National Genome Strategy

The Ministry of Social Affairs and Health (MSAH) set up a working group to formulate a National Genome Strategy in healthcare during the period of 1.9.2014 – 30.4.2015. The strategy aimed to establish the conditions that are required for the effective utilization of genomic data in Finnish healthcare. It also promoted genomics research and the development of applications for genomic data in the field of human health.[40]

The strategy is based on the fact that the novel research methods in genetics will open up new possibilities to identify the causes of human health and disease, as well as to create new means for disease prevention and targeted care. The use of genomic data, i.e. information about an individual's whole genetic makeup, is rapidly increasing in healthcare. In the future, health promotion and the treatment of diseases will be increasingly based on individual genetic makeup. Genomic data will enable us to make better individualized choices, to target the screening of the diseases more precisely, to make more accurate diagnosis and to select the most effective care. [41]

Due to the rapid increase in genomic data, there is a need for a National Genome Strategy. This would enable healthcare to pave the way for the effective use of genomic data without compromising the legal protection and fair treatment of individuals and would also ensure that Finland becomes an attractive country for top level international research and innovation utilizing genomic data.[42]

The aim of the strategy is to make Finnish healthcare more effective. This will be achieved by providing people with better and more targeted care. Healthcare professionals will gain access to more comprehensive genomic data for application in clinical care. Researchers, for their part, will have entirely new opportunities for utilizing genomic data in scientific research. Society may benefit from a containment of healthcare costs and better allocation of resources. In addition, the aim is to transform Finland into an internationally attractive environment for research and business in the field of genomics.

The strategic vision is "*in 2020, genomic information will be effectively used in Finland to achieve population health benefits". The guiding principle of the strategy is "Improving health through the use of genomic data*". A particular focus of the strategy is on data utilization. The aim is that Finland would concentrate on using genomic data to produce high added value. Another area of focus is creating a single body, a genome centre, for the management of genomic data and to serve as a national service point for stakeholder groups using genomic data.[43]

The needs for revision of the legislation are identified in the strategy and the necessary regulatory amendments are prepared. The applicable data protection regulations are mapped out, and the purpose of collecting and using genomic data, among others, is defined.[44]

[40] Ministry of Social Affairs and Health (2015), Finland´s Genome Strategy. https://issuu.com/sitrafund/docs/finland_genomestrategy
[41] Ministry of Social Affairs and Health (2015), Finland´s Genome Strategy. https://issuu.com/sitrafund/docs/finland_genomestrategy
[42] Ministry of Social Affairs and Health (2015), Finland´s Genome Strategy. https://issuu.com/sitrafund/docs/finland_genomestrategy
[43] Ministry of Social Affairs and Health (2015), Finland´s Genome Strategy. https://issuu.com/sitrafund/docs/finland_genomestrategy
[44] Ministry of Social Affairs and Health (2015), Finland´s Genome Strategy. https://issuu.com/sitrafund/docs/finland_genomestrategy

5 Structures and regulation relating to openness

In this chapter structural and regulatory reforms relating to openness of health sector RDI-activity are briefly summarized. Structural changes include e.g. health and social services reform, establishment of genome centre and a national cancer centre, and harmonizing operations of biobanks. Legislative reforms include for example the Countries Act; Health, Social Service and Regional Government bill; the bill on customers' freedom of choice; the Act on Organizing Health and Social Services; Biobank Law; EU regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and General Data Protection Regulation.

5.1 Health and social services reform and relating Government´s bills

The structure of health and social services will be reformed in order to reduce inequities in wellbeing and health between people, and to manage costs. The reform aims to bridge a large part of the sustainability gap in general government finances. The Government's aim is to save EUR 10 billion, of which approximately EUR 3 billion should be covered through the reforms in the branch of government of the Ministry of Social Affairs and Health. Responsibility for providing public healthcare and social services will be assigned to autonomous regions that are larger than municipalities. Healthcare and social services will be brought together at all levels to form customer-oriented entities, and basic public services will be strengthened. This also means that financing will be simplified and customers will have more freedom of choice in the services. Besides structural reforms, the steering and operating models in healthcare and social welfare will be thoroughly modernized. The aim is to achieve better services that are not only more customer-oriented, effective and cost-efficient than before but also better coordinated.[45]

On 29 June 2016 the Government published **draft bills on reforming health and social services and on establishing counties**. On 21 December 2016, the Government published a draft of the legislation detailing how customers will be able to select from among the health and social services that are within the scope of freedom of choice. Additionally, the Government published changes made to the **Health, Social Service and Regional Government bill**. According to government, a **government proposal on the simplification of multisource financing** will be drawn up in 2017.[46] The bill on customers' freedom of choice was circulated for comments in early 2017 and some elaborations are anticipated based on constitutional law in order to safe equal accomplishment of basic rights.[47]

In the **Act on Organizing Health and Social Services** following paragraphs include aspects that link to openness between private and public sector: 1 § , 13 § , 15 § , 23 § , 25 § , 33 § , and 34 § . In the act it is noted that integration of services prerequisites that service providers both in public and private sector co-operate, have access to customer information (Kanta) and save customer information to common customer or patient register (Kanta) in the county level. Regarding self-assessment it is required that service provider constantly evaluates it´s operations, customer safety and service quality. Also, in order to compare service production both in public and private sector it is noted that the Ministry should be able to collect data regarding service quality (e.g. customer feedback), service efficiency

[45] Alueuudistus (2017), http://alueuudistus.fi/en/social-welfare-and-health-care-reform/about-the-reform
[46] Alueuudistus (2017), http://alueuudistus.fi/en/policy-outlines
[47] Alueuudistus (2017), http://alueuudistus.fi/documents/1477425/4278701/valinnanvapauslain-luonnoksen-valtiosaantooikeudellinen-arvio-15.2.2017.pdf/0c0f4f66-c55b-4915-aef9-502f9170fc45

and patient safety from service providers in private and public sector. According to interview, the most significant implications to openness in private sector, are based on requirements of service providers to share quality-related data to public.

5.2 Government bill for secure use of health and social data and relating regulation

Government bill for secure use of health and social data and relating regulation [48] aims that in the future, personal client data saved in health and social services' databases can be used more efficiently to support, for example, social decision-making and development of health and social services. According to 1 § personal client data saved in health and social services´ databases and other personal data saved for research, statistical, steering or monitoring purposes can be used as flexible as possible also in other purposes, such as research, development and innovation, teaching, knowledge management and public service planning or monitoring. Development and innovation activity refers to application of scientific knowledge together with technical and business information in order to develop new or significantly improved products, services or processes.[49]

... personal client data saved in health and social services´ databases -- can be used as flexible as possible also in other purposes, such as research, development and innovation…

The legislative changes would make it possible to use client data from health and social services and other personal data relating to health and wellbeing in a more flexible and effective way. The data can nowadays be used, on conditions laid down by law, for scientific research, compilation of statistics, steering and enforcement duties of authorities and for other official duties like planning, analysis and assessment. Teaching, *information management and development and innovation activities* would be new fields of use. The draft act takes account of data security and protection of individual privacy of clients when data is used. These would be further improved, specifically through requirements for secure handling. [50]

The new act would bring together all provisions concerning the use of health and social care data from personal data files and other data regarding wellbeing. Now the provisions are scattered in different statutes. When there is need to combine data from different data controllers or use data from private health and social services, all permits to use the data would be granted by the same permit authority. After having granted a usage permit, the permit authority would collect the data from different registers, combine them and deliver them to the permit holder. [51]

According to the draft act, the National Institute for Health and Welfare (THL) would operate as the permit authority. The duties of the permit authority would be carried out by a special unit set up for that purpose at the Institute. Data

[48] Ministry of Health and Social Services (2016), http://stm.fi/documents/1271139/3091050/Luonnos-HE--Sote-tietojen-tietoturvallinen-hy%C3%B6dynt%C3%A4minen.PDF/7e6eb683-437f-4fbd-9684-82d8032a9d5b
[49] Ministry of Health and Social Services (2016), http://stm.fi/documents/1271139/3091050/Luonnos-HE--Sote-tietojen-tietoturvallinen-hy%C3%B6dynt%C3%A4minen.PDF/7e6eb683-437f-4fbd-9684-82d8032a9d5b
[50] Ministry of Health and Social Services (2016), http://stm.fi/artikkeli/-/asset_publisher/sosiaali-ja-terveystietojen-tietoturvallista-hyodyntamista-parannetaan?_101_INSTANCE_yr7QpNmlJmSj_languageId=en_US
[51] Ministry of Health and Social Services (2016), http://stm.fi/artikkeli/-/asset_publisher/sosiaali-ja-terveystietojen-tietoturvallista-hyodyntamista-parannetaan?_101_INSTANCE_yr7QpNmlJmSj_languageId=en_US

controllers would include, for example, the National Institute for Health and Welfare, the Social Insurance Institution of Finland, Statistics Finland, Population Register Centre, and all public organizers of health and social services.[52]

An electronic permit portal would be set up to enable permit handling and communication between the permit authority and permit applicants. Data-secure operating environments and communications would be created for sending and handling the data. Additionally, data controllers and the permit authority should organize an advisory service to help those who wish to use personal data.[53]

The government bills would bring the provisions on handling personal data into conformity with the EU Data Protection Regulation, which entered into force on 25 May 2016. The reforms are due to come into force in stages, starting from 1 January 2018.

5.3 Genome centre

The Government decided in April 2016 that a genome centre and a national cancer centre will be set up in Finland. At the same time the practices of public biobanks will be harmonized to make them more effective. The Government also aims to ensure that there will be close cooperation between the biobanks and the genome centre. The Government has proposed in its Budget that these operations will be allocated a total of EUR 17 million in 2017–2020. [54] of which 5.8 million euros will be allocated for the year 2017[55]. These measures are aimed at ensuring Finland becomes a leader and internationally desired partner in healthcare, high-level research and global business utilizing genome data.[56]

… the centre's tasks would include taking responsibility for the creation and development of a national genome database as well as facilitating the efficient use of the database in clinical care, research, and product development.

The Ministry of Social Affairs and Health has appointed a working group to prepare the setting up of a genome centre. This work was based on the assumption that in the future, information on the human genome can be used more efficiently in verifying, treating and preventing illness and disease. Thus, the centre's tasks would include taking responsibility for the creation and development of a national genome database as well as facilitating the efficient use of the database in clinical care, *research, and product development*. The working group is to prepare a proposal for the establishment of a genome centre and for the responsible use of genome data. The working group will also validate the ethical principles for the use of genome data and prepare a proposal for the operating models for national reference and variation databases and for genome data interpretation services. Another task of the working group is to draw up a proposal for the structures and processes of the genome centre's other operations that

[52] Ministry of Health and Social Services (2016), http://stm.fi/artikkeli/-/asset_publisher/sosiaali-ja-terveystietojen-tietoturvallista-hyodyntamista-parannetaan?_101_INSTANCE_yr7QpNmlJmSj_languageId=en_US
[53] Ministry of Health and Social Services (2016), http://stm.fi/artikkeli/-/asset_publisher/sosiaali-ja-terveystietojen-tietoturvallista-hyodyntamista-parannetaan?_101_INSTANCE_yr7QpNmlJmSj_languageId=en_US
[54] VNK (2016), http://valtioneuvosto.fi/artikkeli/-/asset_publisher/hallitus-sopi-julkisen-talouden-suunnitelmasta-vuosille-2017-2020?_101_INSTANCE_3wyslLo1Z0ni_groupId=10616
[55] VM (2017), Budjettikatsaus vm.fi/dms-portlet/document/0/463259
[56] Ministry of Social Affairs and Health (2016), The working group to prepare establishment of a genome centre http://valtioneuvosto.fi/artikkeli/-/asset_publisher/1271139/tyoryhma-valmistelemaan-genomikeskuksen-perustamista?_101_INSTANCE_3wyslLo1Z0ni_languageId=en_US

aim to facilitate the efficient use of genome data in healthcare, research and development and the promotion of health and wellbeing.[57]

The process of working group is ongoing at the time of writing the report, and there is no published information for further developments of genome centre.[58] However, in interviews it was noted that development of genome center requires regulatory changes. Genome law has been prepared in close coordination with other laws relating to secondary use of personal and health data as well as laws relating to biobank harmonization. In interviews it was also noted that budget allocated for genome centre is merely a seed funding to proceed the development. Preliminary operating models discussed are similar with biobanks e.g. requirements of returning research results back to genome bank to avoid overlapping research and better utilize previous research results, but many operational questions are unsolved. Also, it was noted in the interviews that genome data is becoming more important also from cancer treatment perspective and thus, cancer treatment is becoming more tailored based on patients´ genomic data. Thus, development of genome center has close links to cancer center development.

5.4 Comprehensive Cancer Center Finland (FICAN)

The working group was appointed in 2012 to assess, in accordance with the Government Programme, options and possibilities for establishing a national comprehensive cancer center. The working group proposed in their report published in 2014 that the Finnish comprehensive cancer center comprise a national coordinating centre and five regional centres which could function in close association with existing university hospitals and the catchment areas for providing specialist care. The center would be managed by a contracted member or shareholder-based organization or by some other type of competent organization. [59]

In the report it is planned that in the next phase, the National Institute for Health and Welfare and other key actors would enter into cooperation agreements with the comprehensive cancer center. Negotiations with universities would be initiated promptly to explore how they could participate in the center's operations. The working group suggests that the coordinating center be located in Helsinki. The organization as a whole would be named Comprehensive Cancer Center Finland (FICAN). The implementation of the proposed reform will require incentives particularly during the inception phase. Initially, operations would need to be funded mainly from the state budget and would require funding from a main title of expenditure of the Ministry of Social Affairs and Health for a minimum period of three years. After activities have become well-established, core funding for the coordination of patient care could be based on capitation. FICAN should have the ability to coordinate the use of and channel available resources for cancer treatment and to finance cancer research. It could also earn income. The better the center is able to integrate nationally diagnostics and care with high quality research and teaching, the more significant

[57] Ministry of Social Affairs and Health (2016), The working group to prepare establishment of a genome centre http://valtioneuvosto.fi/artikkeli/-/asset_publisher/1271139/tyoryhma-valmistelemaan-genomikeskuksen-perustamista?_101_INSTANCE_3wyslLo1Z0ni_languageId=en_US

[58] University of Eastern Finland (2016), Genomikeskus tarvitsee yliopistojen osaamista https://www.uef.fi/-/genomikeskus-tarvitsee-yliopistojen-osaamista

[59] Voipio-Pulkki, L-M.; Koskela, A.; Helander, T.
(2014) Final report by working group on founding of Comprehensive Cancer Center Finland. Ministry of Social Affairs and Health: Helsinki. https://www.julkari.fi/bitstream/handle/10024/116154/URN_ISBN_978-952-00-3490-0.pdf?sequence=1

FICAN's added value will be. FICAN will ensure equitable access to high quality care for cancer patients in Finland beyond 2020.[60]

Regarding company co-operation Owal´s final report [61]on FICAN´s operating models (December 2016) portrays three levels of co-operation and four possible co-operation models. It has been noted in the report that development of FICAN has focused on the core activity including universities and university hospitals. Some company groups have been mentioned in the report as potential co-operation partners, these include 1) companies providing diagnosis services, 2) companies providing cancer treatments, 3) biobanks and 4) research organizations and companies. Company co-operation could exist in three levels. Firstly, companies could be co-owners of FICAN, which could take a form of cooperative or limited company. Second, companies could provide as strategic partners for example diagnosis tools as a part of FICAN´s service portfolio. Thirdly, companies could operate as network partners with no organizational or contractual agreements with FICAN. Company co-operation models presented in the report include 1) joint treatment and diagnosis capacity, 2) co-operation forums, 3) innovation and demonstration platforms, and 4) start-up business accelerator co-operation. In development of national cancer treatment chains also private sector treatments and diagnosis tools can be seen as equal possibilities for cancer treatment. Co-operation forums could provide open platforms for development of new products and co-operation models. FICAN could actively provide platforms for innovations and demonstrations of new products and services. As a part of promoting public research commercialization, FICAN could jointly provide start-up accelerator services together with business accelerator operator or programme.

After publishing these two, previously mentioned reports some further development has occurred and preliminary presented models are not valid in all aspects any more. However, no further information about the progress is publicly available. The planning of comprehensive cancer center is in the Ministry of Health and Social Services estimated to be more progressive than in other structural changes. Planning has in the ministry´s side been strongly focused on biomedical aspects. It was also mentioned from the ministry´s side, that FICAN has received strong corporate interest with weekly contacts from large companies. Thus, the value of biological and cancer data has been noted in the ministry. However, final decisions about the operational model of comprehensive cancer center has not yet made and thus, models of private sector co-operation are not yet fixed. Thus, it is difficult to assess the effects of FICAN on openness in RDI-activity and public-private sector co-operation.

5.5 Isaacus – service operator project

Sitra is preparing a one-stop-shop operator that will collect and co-ordinate well-being data on the Finnish population for example research purposes. The working title of this operator is Isaacus ‑ the Digital Health HUB. Together with its partners, Sitra has launched several pre-production projects listed below. The experiences from these projects will be utilized in the action plan for the operator to enable the launch of its operation in 2018.[62]

[60] Voipio-Pulkki, L-M.; Koskela, A.; Helander, T.
(2014) Final report by working group on founding of Comprehensive Cancer Center Finland. Ministry of Social Affairs and Health: Helsinki. https://www.julkari.fi/bitstream/handle/10024/116154/URN_ISBN_978-952-00-3490-0.pdf?sequence=1
[61] Owal (2016), Kansallisen syöpäkeskuksen toimintamallit. Loppuraportti.
[62] https://www.sitra.fi/en/projects/isaacus-pre-production-projects/#what-is-it-about

The Metadata project develops a national description system for digital materials. Metadata refers to descriptive information and search terms which makes finding and analyzing data easier. The National Institute for Health and Welfare and CSC ‑ IT Center for Science are central parties in the co-operation. The project also co-operates with the Datapool project of HUS (the Hospital District of Helsinki and Uusimaa). [63]

The Datapool projects implement a solution based on open source code to collect the data scattered in various sources. Huge amounts of data on patients and administrative raw data will be brought into the data pool, and metadata will be generated from it. The platform provides individual-level patient data for scientific research, treatment process guidance, development work and quality control for researchers and development organizations. The projects are being implemented by the Hospital District of Helsinki and Uusimaa (HUS), the Hospital District of Southwest Finland and the City of Kuopio.[64]

The National authorization, information and support service project creates a Finnish permit service operating on a one-stop-shop basis, from which researchers can apply for authorization to use different materials, such as social welfare and healthcare data in the public sector, biobank data, and official registers and statistics that contain well-being data. In addition, the project will implement a support portal, which will provide information on healthcare materials with restricted access and on their use for research and other purposes. Project organizer is National Archives of Finland.[65]

The Clinical data service project processes data generated in the datapool projects so that it can be used to support the treatment of individual patients and to assess the effectiveness of treatment. Healthcare professionals will be able to view the data related to treatment better. By combining statistical research and data analytics, it is possible to create easy-to-use data visualization tools for doctors, financial administration professionals, researchers and management. Project organizer is Hospital District of Southwest Finland.[66]

The pilot project entitled Well-being information on children and young people aims at collecting and putting together information from many systems, such as healthcare, student welfare, family services and child protection. The information on the child will then be available to different services, which makes it easier to move from one service to another and ensures that children, young people and their families are not excluded from support or treatment. Project organizer is City of Kuopio.[67]

According to interview, service operator project has proceeded as planned. Sitra´s project has provided information that is also utilized in legislative processes. Both Isaacus and legislative processes have been open to public and interactive. Service provider´s data would include data from e.g. Kanta, Omakanta, biobanks, genome bank, national registers and statistics as planned. The question of pricing models and diversion of economic benefits has not yet been solved. Thus, it can be noted that the aim is to create structures that are eventually economically self-sufficient or even profitable. Service operator model is aimed to permit utilization of healthcare data for innovation purposes when criteria for research focus is reached.

[63] Sitra (2016), What is it about? https://www.sitra.fi/en/projects/isaacus-pre-production-projects/#what-is-it-about
[64] Sitra (2016), What is it about? https://www.sitra.fi/en/projects/isaacus-pre-production-projects/#what-is-it-about
[65] Sitra (2016), What is it about? https://www.sitra.fi/en/projects/isaacus-pre-production-projects/#what-is-it-about
[66] Sitra (2016), What is it about? https://www.sitra.fi/en/projects/isaacus-pre-production-projects/#what-is-it-about
[67] Sitra (2016), What is it about? https://www.sitra.fi/en/projects/isaacus-pre-production-projects/#what-is-it-about

To conclude, comprehensive health information service operator model promotes utilization of public data in research and research-focused RDI-activity and thus, enables openness in RDI-activity. Finnish permit service model operating on a one-stop-shop basis is aimed to make applying different materials, such as social welfare and healthcare data and biobank data, easier and faster per se and thus promote utilization of public data in research-focused activities. However, practical solutions regarding operating model, requirements and pricing models have huge impact on the attractiveness of the health data utilization in RDI-activity in the end. Also, it can be noted that the focus in development has been in other aspects than promotion of open development and innovation activity and open corporate co-operation.

5.6 Harmonising operations of biobanks

Biobanking as a distinct discipline has been increasingly developed for about the last 15 to 20 years, and is today considered a key activity to create and maintain critical resources that enable biomedical research, specifically translational investigation. The parallel rapid evolution of genetic and genomic technologies that took place during this period, with the need of increasingly larger sample sizes to meet the statistical challenges of genome-wide research projects has further accentuated the need for large, well-annotated collections of biospecimens and associated clinical and phonotypical data.[68]

In the report of the Expert Group (EG) Appointed to Evaluate the Integration of Finnish Biobanks it is stated that Finland represents a particularly attractive and powerful opportunity for the development and deployment of biobanks, based on its unique population structure, the availability of a well-curated and comprehensive medical record system, the first of its kind of a national biobanking law, and the presence of a highly educated population with a generally supportive and enlightened attitude towards biomedical research.[69]

It is noted that the Finnish Biobanking Act provides a unique and robust legal framework for biobanking activities, including the permission to re-contact study subjects for follow-up data collection across all domains of biomedicine. This is of particular relevance in the context of applying biobanking resources to pharmaceutical research, where more sophisticated phenotypic characterization of carriers of genetic variants of interest is viewed as being of particular impact.[70] However, it should be noted that according to interviews regulatory changes regarding harmonization of biobank activities are assessed, and these possible regulatory changes are combined with development of genome law and regulation regarding information secure utilization of social and health care data. Thus, the future regulation is estimated to set norms for utilization of genomic data and development of infrastructure (genome centre).[71] The main challenge in utilization of genomic data, as well as utilization social and health care data as a whole, relies in definition of scientific research which also comprises e.g. technological development and

[68] Report of the Expert Group Appointed to Evaluate the Integration of Finnish Biobanks (2016), http://stm.fi/documents/1271139/3226819/FBB-EG-Report1_woannex.pdf/b36e3f31-8d43-4e64-973c-0f8c5426672b

[69] Report of the Expert Group Appointed to Evaluate the Integration of Finnish Biobanks (2016), http://stm.fi/documents/1271139/3226819/FBB-EG-Report1_woannex.pdf/b36e3f31-8d43-4e64-973c-0f8c5426672b

[70] Report of the Expert Group Appointed to Evaluate the Integration of Finnish Biobanks (2016), http://stm.fi/documents/1271139/3226819/FBB-EG-Report1_woannex.pdf/b36e3f31-8d43-4e64-973c-0f8c5426672b

[71] Liede, S. (2017), Etiikka tutkimuksen ja tuotekehityksen rajalla. Oikeudellinen näkökulma – patentit. Esitys Etiikan päivässä. http://www.etiikanpaiva.fi/sites/etiikanpaiva.fi/files/Etiikan_paiva_2017_Liede.pdf

applied research and thus, somewhat fades boundaries between academic and commercial use of data. This challenge is included also in EU regulation 2016/679, recital 159.

Based on Report of the Expert Group Appointed to Evaluate the Integration of Finnish Biobanks [72] the requirements for realizing the full value of the Finnish biobank potential are:
(1) Coordination, integration, and standardization of Finnish biobanks;
(2) Establishment of intimate linkage between biobank specimens and detailed electronic medical record and other health care-relevant data;
(3) Dedicated funding to allow the overall biobanking resources as described above reach the critical mass necessary to deliver value (i.e., availability of 100s of 1000s of prospective specimens).

In the report it is stated that among regional biobanks, Turku (AURIA) and in Helsinki have established the requisite informatics and operational infrastructures, and are at an early, nascent stage of specimen collection, whereas the other biobanks are still at various stages of planning. The biobanking resources represented by the registries agglomerated under the auspices of THL represent a sizeable resource but re not linked to the EHR/EMR.

...leveraging the full potential of biobanking in Finland will only be realized if individual biobank resources are integrated as parts of an overarching ecosystem that, by virtue of creating interoperability, results in critical mass. Thus, the activities of individual biobanks need to be harmonized to allow utilization of resources in the most impactful fashion.

The Expert Group (EG) concluded, in agreement with responses received from all biobanks that leveraging the full potential of biobanking in Finland as a national resource will only be realized if individual biobank resources are integrated as parts of an overarching ecosystem that, by virtue of creating interoperability, results in critical mass. Thus, the activities of individual biobanks need to be harmonized to allow utilization of resources in the most impactful fashion. Such a harmonization effort is also expected, by providing economy of scale and cost efficacies, to accelerate the requisite scaling up of the overall effort and make it more cost-effective.

The EG recommends a model of national coordination of biobanks, which would be established in the form of a new legal entity representing a formal consortium of all biobanks, with an appointed Managing Director and a Board of Directors that represents the individual biobanks. This entity will be the official representation of all Finnish biobanking activities, and be responsible for transparency and accountability with regard to the public, and for assurance of compliance with all applicable ethical, legal, and societal considerations, in particular data safety and access control. The EG was advised that, based on a number of considerations, the best legal entity option is a Cooperative (421/2013).

While the individual biobanks will continue to operate independently on a local level, as is consistent with the vision that biobanking will become an integral part of health care system activities, they will do so adhering to standardized processes. They will be accountable to the consortium leadership in this regard by committing to utilize for their operation the services of a Single Service Provider (SSP) or as later called Joint Operator (JO). Thus, essentially a two-layer structure was proposed consisting of a formalized consortium as a new legal entity governing the biobanks, and a joint operator ensuring standardized and harmonized operations, was recommended as the currently optimal

[72] Report of the Expert Group Appointed to Evaluate the Integration of Finnish Biobanks (2016), http://stm.fi/documents/1271139/3226819/FBB-EG-Report1_woannex.pdf/b36e3f31-8d43-4e64-973c-0f8c5426672b

solution. Notwithstanding governance under a consortium structure, provisions should be made for individual biobanks to carry out local projects, applying joint operator provided standardized operating procedures and returning data generated to the general database.[73] Thus, the joint operator would provide standardized tools and services, as specified by the consortium leadership, thus ensuring harmonization across biobanks as well as recognition of economies of scale and it would also serve as a single point of contact for interested customers of the biobanking resources and will safeguard the principle that value from data and specimens shall be created in Finland, thus conserving a national resource in support of Finnish economy and scientific interests. Lastly, it can serve as a central procurement agent for instrumentation, equipment, reagents and consumables as well as certain outsourced services (e.g. DNA extraction).[74]

The EG recommends that due consideration is paid to ensure adequate funding for setting up the SSP or JO as well as for the build-up of a critical-mass biobanking resource. Consideration should be given how this will be supported as part of the plans for the Finnish Genome Center, although the currently approved funding under this plan was considered not to be sufficient to achieve an internationally competitive biobank volume. The Finnish biobanks have been largely in favor of this model as the preferred scenario for national coordination of efforts, a concept that all of them supported in principle. However, there was a strong sentiment that local presence and control of day-to-day operations is essential to maintain the momentum and motivation among both biobank operators and participants. This would appear to be aligned also with the emerging recognition that biobanking will increasingly become an integrated part of all health care systems. For these reasons, concerns against a fully centralized "national operator" model were raised by all but the THL and Helsinki biobanks.[75]

Further development has occurred after publishing previously mentioned reports. Government of Helsinki University Hospital has agreed on establishment of Finnish Biobank Cooperative. [76] The value promise of Biobank Finland Joint Operator is to utilize Finnish biobanks´ resources for the good of individuals and national health. Five Finnish universities and university hospital districts will be members of Joint Operator cooperative. Joint Operator will enable utilization of standardized and common methods. Joint operator will increase cost efficiency of biobank activity and serve as one-stop-operator for external clients seeking large, integrated population resources. External clients such as researchers, public health care operators and companies including biomedical and diagnostics industry are expected to agree on terms relating to corporate development and marketing. [77]

It can be noted that the planned joint operator model is based on recognizing increasing interest of academia and industry in population records where sample collections are linked to medical record data. Also, unique power of Finnish population structure and socio-cultural ecosystem (EMR, national ID, well-educated, receptive population)

[73] Report of the Expert Group Appointed to Evaluate the Integration of Finnish Biobanks (2016), http://stm.fi/documents/1271139/3226819/FBB-EG-Report1_woannex.pdf/b36e3f31-8d43-4e64-973c-0f8c5426672b
[74] Report of the Expert Group Appointed to Evaluate the Integration of Finnish Biobanks (2016), http://stm.fi/documents/1271139/3226819/FBB-EG-Report1_woannex.pdf/b36e3f31-8d43-4e64-973c-0f8c5426672b
[75] Report of the Expert Group Appointed to Evaluate the Integration of Finnish Biobanks (2016), http://stm.fi/documents/1271139/3226819/FBB-EG-Report1_woannex.pdf/b36e3f31-8d43-4e64-973c-0f8c5426672b
[76] HUS (2017), Hallitus, pöytäkirja 27.2.2017. http://husd360fi.oncloudos.com/cgi/DREQUEST.PHP?page=meetingitem&id=2017242203-4
[77] HUS (2017), Hallitus, pöytäkirja 27.2.2017. http://husd360fi.oncloudos.com/cgi/DREQUEST.PHP?page=meetingitem&id=2017242203-4

are assessed as a high value resource for biomedical research. Broad national endorsement of biobanking enhances the possibilities for this development. Thus, it can be noted that there are biobanks at each university or university hospital district. Opportunity recognized and supported at top governmental and public policy level. Challenges include that a critical-mass, integrated asset needed to leverage opportunity (100-thousands of participants). Also, biobanking efforts are currently fragmented across many centers. There are ineffective and costly duplications and non-harmonized efforts. A joint operator model is seen as a solution. This would include harmonized logistics and operational support for all biobanks. The mission of the joint operator is to provide harmonized, cost-effective services to Finnish biobanks to create an integrated, critical-mass population resource asset and market asset to external users by optimally leveraging its value for science and revenue. The vision is to become key contributor to making Finnish population resource a global brand for advancing public and personal health and leverage resource value.[78]

Finally, it should also be noted that Finland is one of BBMRI-ERIC (Biomolecular Resources Research Infrastructure – European Research Infrastructure Consortium) partners. BBMRI-ERIC will establish, operate and develop a pan-European distributed research infrastructure of biobanks and biomolecular resources in order to facilitate the access to resources as well as facilities and to support high quality biomolecular and medical research. There are thousands of national biobanks in the world[79]. BBMRI-ERIC operates on a non-economic basis and activities are guided by the following values: pan-European in scope, combined with scientific excellence, transparency, openness, responsiveness, ethical awareness, legal compliance and human values. BBMRI-ERIC consists of 19 Member States and one International Organization, making it one of the largest research infrastructures in Europe. Members include Austria, Belgium, Czech Republic, Estonia, Finland, France, Germany, Greece, Italy, Latvia, Malta, the Netherlands, Norway, Poland, Sweden, and the United Kingdom. [80]

5.7 EU 2016/679 regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data

EU 2016/679 provides rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data. The regulation protects fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data. The rules on the protection of natural persons with regard to the processing of their personal data should, whatever their nationality or residence, respect their fundamental rights and freedoms, in particular their right to the protection of personal data. The regulation is intended to contribute to the accomplishment of an area of freedom, security and justice and of an economic union, to economic and social progress, to the strengthening and the convergence of the economies within the internal market, and to the well-being of natural persons. The regulation aims that the free movement of personal data within the Union shall be neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data. [81]

[78] Lindpaintner, Klaus (2017), Biobanks Finland Joint Operator. Presentation.
[79] Tekes (2014), Biobankkien liiketoimintamahdollisuudet https://www.tekes.fi/globalassets/global/nyt/uutiset/2014/tekes_biobanks__13_11_2014_pdf.pdf
[80] BBMRI (2016), About us, http://www.bbmri-eric.eu/BBMRI-ERIC/about-us/
[81] European Union (2016), Regulations. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=FI

On the other hand, directive 95/46/EC of the European Parliament and of the Council seeks to harmonize the protection of fundamental rights and freedoms of natural persons in respect of processing activities and to ensure the free flow of personal data between Member States. [82]

The right to the protection of personal data must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality. The processing of personal data should be designed to serve mankind. The regulation respects all fundamental rights and observes the freedoms and principles recognized in the Charter as enshrined in the Treaties, in particular the respect for private and family life, home and communications, the protection of personal data, freedom of thought, conscience and religion, freedom of expression and information, freedom to conduct a business, the right to an effective remedy and to a fair trial, and cultural, religious and linguistic diversity. [83]

… the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration…

The regulation notes that the economic and social integration resulting from the functioning of the internal market has led to a substantial increase in cross-border flows of personal data. The exchange of personal data between public and private actors, including natural persons, associations and undertakings across the Union has increased. National authorities in the Member States are being called upon by Union law to cooperate and exchange personal data so as to be able to perform their duties or carry out tasks on behalf of an authority in another Member State. Rapid technological developments and globalization have brought new challenges for the protection of personal data. The scale of the collection and sharing of personal data has increased significantly. *Technology allows both private companies and public authorities to make use of personal data on an unprecedented scale in order to pursue their activities.* Natural persons increasingly make personal information available publicly and globally. *Technology has transformed both the economy and social life, and should further facilitate the free flow of personal data within the Union and the transfer to third countries and international organizations, while ensuring a high level of the protection of personal data.* Those developments require a strong and more coherent data protection framework in the Union, backed by strong enforcement, given the importance of creating the trust that will allow the digital economy to develop across the internal market. Natural persons should have control of their own personal data. Legal and practical certainty for natural persons, economic operators and public authorities should be enhanced.[84]

In the section 159 it is pointed out that *the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research. Scientific research purposes should also include studies conducted in the public interest in the area of public health. To meet the specificities of processing personal data for scientific research purposes, specific conditions should apply in particular as regards the publication or otherwise disclosure of personal data in the context of scientific research purposes. If the result of scientific research*

[82] European Union (2016), Regulations. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=FI
[83] European Union (2016), Regulations. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=FI
[84] European Union (2016), Regulations. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=FI

in particular in the health context gives reason for further measures in the interest of the data subject, the general rules of this Regulation should apply in view of those measures.[85]

Article 6 states that processing personal data for a purpose other than for which they have been collected and is not based on the data subject's consent, the controller shall take into account (a) any link between the purposes for which the personal data have been collected and the purposes of the intended further processing; (b) the context in which the personal data have been collected, in particular regarding the relationship between data subjects and the controller; (c) the nature of the personal data, in particular whether special categories of personal data are processed, (d) the possible consequences of the intended further processing for data subjects; (e) the existence of appropriate safeguards, which may include encryption or pseudonymisation.[86]

Article 9 states that e.g. processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited. However, this shall not apply if e.g. the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, or processing is necessary for the purposes of preventive or occupational medicine, or for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, or for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.[87]

6 Case studies

In order to analyze openness in RDI-activity in the health sector the case study approach was selected to portray examples of open innovation initiatives, open innovation and crowdsourcing platforms as well examples of companies using open innovation in strategic level.

There seems to be plenty of examples of open innovation platforms in international level especially in pharmaceuticals development. Also, many big pharmaceutical companies have developed their own open innovation platforms or other open innovation operation models in order to benefit from external innovation capabilities more flexibly.

Companies open up their innovation process in order to stimulate growth and to reduce cost and save time in RDI-process. In the pharmaceutical industry, the concept of open innovation has received attention, but it has not yet been broadly implemented by the pharmaceutical industry. Also, many different variations of practical execution exists with various degrees of openness and associated legal and business constraints. One specific aspect of open

[85] European Union (2016), Regulations. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=FI
[86] European Union (2016), Regulations. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=FI
[87] European Union (2016), Regulations. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=FI

innovation in the pharmaceutical industry involves sourcing of external compounds to provide alternative chemistry for screening campaigns or to more easily explore collaborations.[88]

6.1 The Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. The origins of the Innovative Medicines Initiative (IMI) lie in the European Technology Platform on Innovative Medicines that was supported under the European Commission's Sixth Framework Programme for Research (FP6) as a gathering of stakeholders, led by the pharmaceutical industry. IMI was launched in 2008 with the goal of '*significantly improving the efficiency and effectiveness of the drug development process with the long-term aim that the pharmaceutical sector produce more effective and safer innovative medicines.*' [89]

IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe. IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA. [90]

IMI is the world's biggest public-private partnership (PPP) in the life sciences. Through the IMI 2 programme, it has a €3.3 billion budget for the period 2014-2024. Half the budget comes from Horizon 2020, the EU's framework programme for research and innovation. €1.425 billion is committed to the programme by EFPIA companies and up to €213 million can be committed by other life science industries or organizations that decide to contribute to IMI 2 as members or Associated Partners in individual projects.[91]

EFPIA companies do not receive any EU funding via IMI; the EU funding supports the participation of the 'public' partners in IMI projects, i.e. universities, small biotech companies, patient groups, regulators, etc. EFPIA companies and Associated Partners contribute to the projects 'in kind', for example by contributing their researchers' time or providing access to research facilities or resources. Organizations can suggest ideas for IMI projects by filling a form and these can ultimately be used in an IMI Call for proposals. [92]

IMI IP provisions allow companies, universities and other organisations to share compounds, data and knowledge with one another.

IMI can be seen as a platform that enables open science and open innovation and allows individual projects to determine their level of openness. In practice, the IMI IP provisions allow companies, universities and other organizations to share compounds, data and knowledge with one another.

For example, in the *European Lead Factory*, a range of companies are contributing their own compounds and targets to the project to create a *Joint European Compound Collection*. The EU Lead Factory is an IMI-funded project that

[88] Nilsson, N. & Felding, J. (2015), Open innovation platforms to boost pharmaceutical development. Future Med. Chem. 2015: 7(14), 1853-1859 http://www.future-science.com/doi/pdf/10.4155/fmc.15.122
[89] IMI (2016), History http://www.imi.europa.eu/content/history
[90] IMI (2016), http://www.imi.europa.eu/
[91] IMI (2016), http://www.imi.europa.eu/
[92] IMI (2016), http://www.imi.europa.eu/content/get-involved

aims to create new chemistry based on crowd-sourced ideas and boost applicants' drug discovery programmes at no upfront costs. The European Lead Factory is a collaborative public-private partnership aiming to deliver innovative drug discovery starting points. Having established the first European Compound Library and the first European Screening Centre, the EU Lead Factory gives e.g. free access to up to 500,000 novel compounds and a unique industry-standard uHTS platform. [93] Organizations can run screenings to see if they can identify potential drug candidates or high‐quality pharmacological tools for the experimental validation of drug targets. The EU Lead Factory's Honest Data Broker (HDB) is a bespoke HTS triage and project management application developed to support the unique scientific and IP requirements of the Lead Factory. It enables scientists to select the best compounds emerging from the HTS screens while ensuring that all activities remain within the IP framework agreed by the project partners. The HDB is hosted on Biovia's ScienceCloud and comprises a full suite of cheminformatic tools to enable filtering, clustering, similarity searches, activity modelling, multiparameter optimization and is seamlessly linked to established visualization tools on the same cloud platform.[94]

On the other hand, the companies involved in *NEWMEDS* have pooled their data to create the largest-known database of studies on schizophrenia, including information from 67 studies. The database represents a unique resource that is helping the project partners identify new, more effective ways of running clinical trials and analyzing clinical trial results. The project has focused on developing new animal models which use brain recording and behavioral tests to identify innovative and effective drugs for schizophrenia. It also has developed new approaches for shorter and more efficient trials of new medication‐trials that may require fewer patients and give faster results. [95] While in the *eTOX* project, participating organizations are pooling their existing data on toxicity to develop novel, computer-based tools to test potential drugs for damaging effects on the heart and other vital organs. [96] The eTOX project aims to develop a drug safety database from the pharmaceutical industry legacy toxicology reports and public toxicology data; innovative in silico strategies and novel software tools to better predict the toxicological profiles of small molecules in early stages of the drug development pipeline.[97]

6.2 NEXT

Danish pharmaceutical and biotech industries is one of the leading in the world with companies such as Leo Pharma and Novo Nordisk and so called Medicon valley area. Denmark has promoted development of the sector with initiatives and public-private-partnerships. [98] One example of this is NEXT‐National Experimental Therapy Partnership, which is a public-private partnership within clinical research consisting of the regions of Denmark, universities, twelve pharmaceutical companies and GTS - Godkendt Teknologisk Service institute. February 2017 NEXT extended by three companies as associated partners. The partnership was established on November 2014 as an INNO+ partnership, with the Innovation Fund Denmark investing DKK 50 million in the partnership over a five year period and the partners investing DKK 114 million. On April 2016, NEXT was granted an extra investment

[93] European Lead Factory (2017), Concept. https://www.europeanleadfactory.eu/about/concept/
[94] European Lead Factory (2017), Honest Data Broker. https://www.europeanleadfactory.eu/about/assets/honest-data-brooker/
[95] NewMeds (2017) About NewMeds. http://www.newmeds-europe.com/
[96] IMI (2017), IP in practice – driving success in IMI projects. http://www.imi.europa.eu/content/intellectual-property-policy
[97] eTOX (2017) Welcome to eTOX website. http://www.etoxproject.eu/
[98] AbbVie (2016), Research and collaboration – uniqueness of Denmark. http://www.investindk.com/~/media/Images/News%202015/AbbVie_Research_and_collaboration.ashx

from the Innovation Fund of DKK 42,4 million over a period of four years and the partners contributed with DKK 162 million.[99]

NEXT aims to make Denmark the pharmaceutical industry's first choice for early clinical trials of new drugs for patients and with particular focus on Proof of Concept trials. NEXT aims to optimize all processes from start-up to close out of clinical trials by prioritizing legal and regulatory processes. Thus, NEXT offers a one stop shop for the pharmaceutical industry and hospital researchers - it provides an easy access to Denmark's strongest clinical research environment within experimental research in the early phases, national recruitment of patients and establishment of patient databases as well as optimized administrative and regulatory processes. NEXT has established centers within Oncology and Haematology, Dermatology, Respiratory Medicine, Infectious Diseases and Bioinformatics. Companies seeking help to locate collaborators within other disease areas can get help at the regions "One entry point" Clinical Trials Office Denmark. NEXT's current goal is to increase fourfold the amount invested by pharmaceutical companies in early clinical trials in Denmark. [100]

NEXT, The Danish Association of the Pharmaceutical Industry (Lif) and Invest in Denmark have published a report made by Copenhagen Economics which quantifies the value generated by clinical trials in Denmark. The report shows that clinical trials by pharmaceutical companies deliver value to the Danish society. On average, a clinical trial improves GDP by DKK 0.9m and the public budget by DKK 1.2m. The positive economic effects arise from better healthcare, highly productive jobs and new research in life sciences.[101]

6.3 Structural Genomics Consortium and Protein Data Bank archive

The SGC (Structural Genomics Consortium) is a not-for-profit, public-private partnership with the directive to carry out basic science of relevance to drug discovery. The SGC is home to approximately 200 scientists, visiting scientists and other support staff. The core mandate of the SGC is to determine 3D structures on a large scale and cost-effectively - targeting human proteins of biomedical importance and proteins from human parasites that represent potential drug targets. In these two areas respectively, the SGC is now responsible for over 25% and over 50% of all structures deposited into the *Protein Data Bank* each year; to date (Sep.2011) the SGC has released the structures of over 1200 proteins with implications to the development of new therapies for cancer, diabetes, obesity, and psychiatric disorders.[102]

The Worldwide PDB (wwPDB) organization manages the PDB archive and ensures that the PDB is freely and publicly available to the global community. wwPDB data centers serve as deposition, annotation, and distribution sites of the PDB archive.

Since 1971, the Protein Data Bank archive (PDB) has served as the single repository of information about the 3D structures of proteins, nucleic acids, and complex assemblies. The Worldwide PDB (wwPDB) organization manages the PDB archive and ensures that the *PDB is freely and publicly available to the global community*. wwPDB data centers serve as deposition, annotation, and distribution sites of the PDB archive. Each site offers tools for searching, visualizing, and analyzing PDB data.

[99] NEXT (2017), About Next. https://nextpartnership.dk/en/about-next-2/
[100] NEXT (2017), About Next. https://nextpartnership.dk/en/about-next-2/
[101] NEXT (2017), News. https://nextpartnership.dk/en/news/
[102] SGC (2017), FAQ, http://www.thesgc.org/about/mini_faq

[103] According to statistics for PDB structures that are deposited and processed by year, number of deposits during last five years have been around 10 000 per year with total number of over 130 000 deposits. [104] At the same time number of annual downloads have been over 3 mrd.[105]

Currently, the SGC is funded by 13 separate organizations: AbbVie, Boehringer Ingelheim, the Canada Foundation for Innovation, the Canadian Institutes for Health Research, Genome Canada, GlaxoSmithKline, Janssen, Lilly Canada, the Novartis Research Foundation, the Ontario Ministry of Economic Development and Innovation, Pfizer, Takeda, and the Wellcome Trust. The SGC operates from three academic institutions - the University of Toronto, the University of Oxford and the State University of Campinas (Unicamp) in Brazil - ensuring the SGC labs a remarkable level of engagement and exchange with their respective local academic communities. In these three SGC labs, there are in excess of 230 scientists, visitors, collaborators and support personnel at any time working on several research areas. The SGC Karolinska laboratory is housed within the Department of Medicine at Karolinska Institutet, and located at the Centre for Molecular Medicine. The lab was opened in 2015. Work at SGC Karolinska is focused on patient-derived cell assays for auto-immune diseases as well as the production of high quality antibodies and biological probes.[106]

The structures of human proteins in essence is part of the information that defines what it is to be human. It is very expensive to determine a new protein structure, but with improvements in methods, computers and with access to the complete sequence of DNA (the human genome), it is possible to adopt more systematic approaches, and thus reduce the time and cost to determine the shapes of proteins. Structural genomics aims to determine the three-dimensional structures of proteins at a rapid rate and in a cost-effective manner. Structural information provides one of the most powerful means to discover how the protein works. Because of the fundamental nature and importance of the information, *SCG places it´s results immediately and without restriction into the public domain*. This not only provides the public with this fundamental knowledge, but also *allows commercial efforts and other academics to utilize the data freely and without any delay*. The result is greater knowledge about the human body and about the mechanisms of disease. The information also promotes faster drug discovery, bringing potentially life-saving drugs to market sooner and more cheaply.[107]

SCG places it´s results immediately and without restriction into the public domain. This not only provides the public with this fundamental knowledge, but also allows commercial efforts and other academics to utilize the data freely and without any delay.

6.4 Biomarkers Consortium

The Biomarkers Consortium (BC), launched on November 2006 in the United States, is a public-private partnership whose goal is to identify and qualify new biological markers to accelerate the detection, diagnosis, and treatment of a range of diseases, including cancer. The Consortium is made up of a diverse list of partners with this common goal. The Biomarkers Consortium is managed by the Foundation for the National Institutes of Health (FNIH). The Consortium brings together the expertise and resources of various partners to rapidly identify, develop and qualify

[103] WWPDB (2017), http://www.wwpdb.org/
[104] WWPDB (2017), http://www.wwpdb.org/stats/deposition
[105] WWPDB (2017), http://www.wwpdb.org/stats/download
[106] SGC (2017), Labs, http://www.thesgc.org/labs
[107] SGC (2017) FAQ, http://www.thesgc.org/about/mini_faq

potential high-impact biomarkers particularly to enable improvements in drug development, clinical care and regulatory decision-making. [108]

Consortium includes the Foundation for the National Institutes of Health (FNIH), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS), the Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Industry Organization (BIO), and representatives of the public, including patient advocacy organizations. [109]

The NIH and its partners have long recognized a need for robust and objective measures of disease risk, underlying pathobiological processes, diagnosis and stage of disease, prognosis, treatment response, recurrence, and clinical outcomes. However, despite significant advances in our molecular understanding of many diseases and treatment outcomes, there are very few biomarkers that are qualified for clinical use and used widely to address medical needs. Some of the most widely accepted biomarkers in use today include blood pressure, total cholesterol, and high-density lipoprotein to low-density lipoprotein (HDL/LDL) ratios as markers of cardiovascular risk and response to treatment; and HIV viral load and CD4+ T-cell counts to assess HIV/AIDS disease severity, stage, and treatment response.[110]

The BC is structured to provide a fair and inclusive platform to discover, develop, and qualify biomarkers in a precompetitive environment, devoted to the generation of public resources.

The availability of such biomarkers would not only enable research, but also serve to streamline clinical care and potentially speed the development and availability of new drugs. Although the need is clear, there are several important impediments to developing reliable biomarkers. Biomarker development requires insight into disease risk, natural history, and outcomes. It also requires a sufficiently large number of adequate samples taken from well-characterized patients and handled in a standardized fashion. Analytical platforms that effectively and reproducibly measure the biomarker must also be available and standardized. Analytical approaches that assess the utility of biomarkers as signs or predictors of underlying biology or future outcomes must also be developed for the promise of biomarkers to be translated into clinical usefulness. Once such biomarkers and analytical approaches are developed, they will prove useful to promote and foster more discovery science and facilitate the conduct of translational and clinical research, all of which are activities central to the mission of the NIH. [111]

The goals of the Biomarkers Consortium are to:
1. promote the discovery, development, qualification, and regulatory acceptance of biomarkers;
2. make research results and data arising under a Project Team ("PT") activity broadly available, subject to agreed upon data sharing plans; and
3. to help speed disease-specific research.

The BC is structured to provide a fair and inclusive platform to discover, develop, and qualify biomarkers in a precompetitive environment, devoted to the generation of public resources. Biomarkers Consortium activities support the expeditious development of biomarkers to ensure that safe, innovative, and effective new medicines and diagnostics are developed to address healthcare needs, improve medical care, and promote and improve public

[108] FNIH (2017), http://www.fnih.org/what-we-do/biomarkers-consortium/about
[109] The Onkologist (2016), http://theoncologist.alphamedpress.org/content/12/3/250.short
[110] The Onkologist (2016), http://theoncologist.alphamedpress.org/content/12/3/250.short
[111] The Onkologist (2016), http://theoncologist.alphamedpress.org/content/12/3/250.short

health. The FNIH serves as the managing partner and provides a home for this activity, consistent with its mandate to support the activities of the NIH.[112]

All Participants agree to implement the Intellectual Property and Data Sharing Principles of the Biomarkers Consortium. In the context of individual projects, Participants agree to explore all mechanisms available, consistent with their individual missions and the interests of the public health, to do so most effectively. The principles address the following issues:

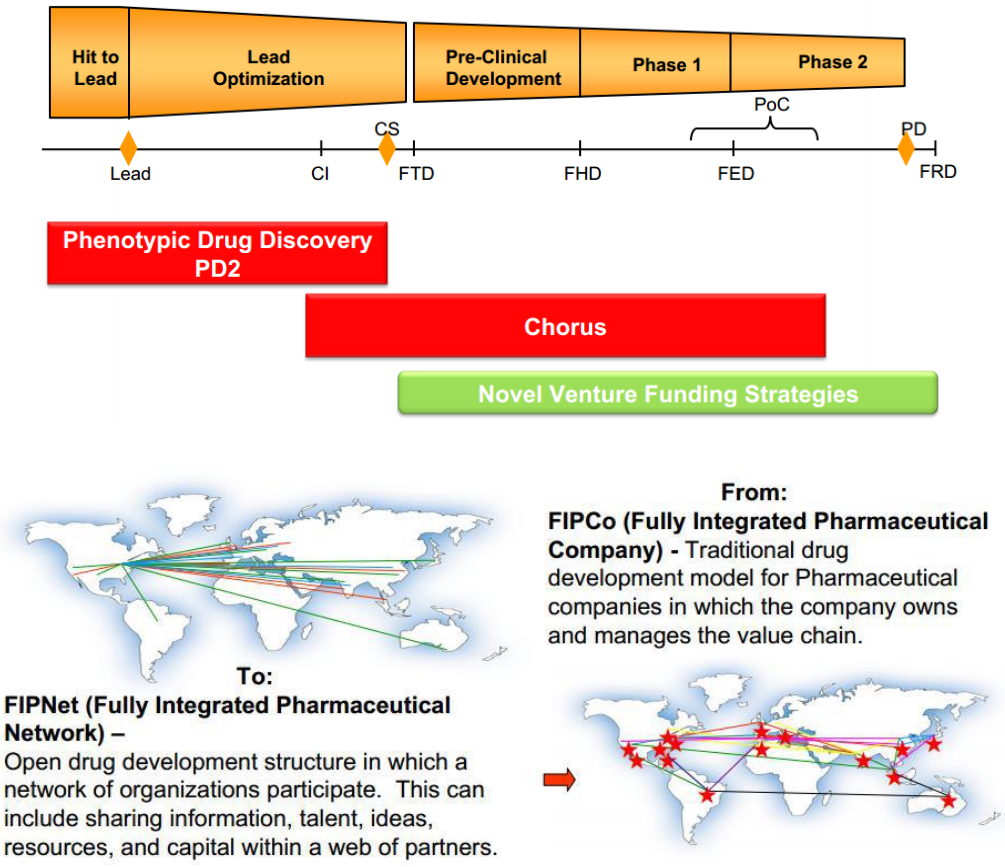
- The advance planning and approval of specific projects;
- The management of pre-existing Data and other Intellectual Property, including, for example, confidential research Data or patented inventions shared by members for specific Biomarkers Consortium projects; and
- The management of new Data and Intellectual Property arising from Biomarkers Consortium-sponsored projects.[113]

6.5 Eli Lilly and open drug development: Innocentive

Eli Lilly and Company was founded in 1876 in Indianapolis, USA, by Colonel Eli Lilly, a pharmaceutical chemist and veteran of the American Civil War, after whom the company was named. The company, initially a medical wholesale company, quickly became successful, which allowed Lilly to expand its business and rapidly evolve from drug manufacturer and wholesale, into an innovative drug developer. Today, Lilly is one of the world's biggest pharmaceutical companies. [114]

The pharmaceutical industry suffered of a productivity crisis since the first decade of the 21st century. Lilly, despite its advantageous position, was not an exception. Lilly had a long tradition of collaborating with external actors (e.g. the mass-production of penicillin together with the University of Toronto, in 1940s) and adoption of open innovation models to boost RDI-activity seemed to be thus somewhat more natural to Lilly. Lilly developed various open innovation models including *FIPCo & FIPNet*, *Chorus*, *Innocentive* and *open innovation drug discovery programs PD2 and TD2* to save time and money in different phases of drug development process (see pictures below).[115]

[112] The Onkologist (2016), http://theoncologist.alphamedpress.org/content/12/3/250.short
[113] Biomarkers Consortium (2017), General Intellectual Property and Data Sharing Principles. http://www.fnih.org/what-we-do/biomarkers-consortium/about/policies
[114] Raja, B.H. and Sambandan, P. (2015), Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. Masters thesis. KTH School of Industrial Engineering and Management (ITM): Stockholm. http://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf
[115] Raja, B.H. and Sambandan, P. (2015), Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. Masters thesis. KTH School of Industrial Engineering and Management (ITM): Stockholm. http://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf



Picture 6: Examples of Eli Lilly´s open innovation models in drug development[116]

Chorus aims to boost the productivity of the R&D process by relying in a virtual team, based on existing Lilly's network of external vendors, manufacturers, scientist and consultants, and establishing a collaborative product development model. Despite of the managerial complexity that such a virtual organization can imply, Lilly has managed to run this alternative R&D model with low costs.[117]

Innocentive was the first internet-based platform designed to help connect Seekers, those who had difficult research problems, with Solvers, those who came up with creative solutions to these problems.

The idea of *Innocentive* was born in the year 1998 at Lilly. In 2001 Innocentive was launched with majority of the seed funding from Lilly. Innocentive is claimed to be the first internet-based platform designed to help connect "Seekers", those who had difficult research problems, with "Solvers", those who came up with creative solutions to these problems. Innocentive ´ s clients at the start were mostly R&D intensive companies whose innovations were based upon chemistry, biochemistry, biology and material science which were typically industries like

[116] Raja, B.H. and Sambandan, P. (2015), Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. Masters thesis. KTH School of Industrial Engineering and Management (ITM): Stockholm. http://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf

[117] Raja, B.H. and Sambandan, P. (2015), Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. Masters thesis. KTH School of Industrial Engineering and Management (ITM): Stockholm. http://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf

pharmaceutical, chemical, consumer goods and petrochemicals. The scientist could post their problems anonymously and seek solutions from a global community of independent scientists and scientific organizations that were associated with Innocentive. The best possible solution which satisfied the criteria jointly set by the Innocentive employees and the client scientists or the seekers were be awarded. The model of Innocentive has since then been adopted by a wide array of industries and in recent times it has been extended to other disciplines. The seekers are not only private organizations but also non-for profit and public sector organizations. On the other hand, Solvers can be private, non-for profit and public sector organizations as well as private people (e.g. retired scientists). Innocentive has for a long time been in partnership with organizations like AstraZeneca, Cleveland Clinic, and Lilly & Company. Innocentive had 2015 more than 355,000 registered solvers from 200 different countries. The success rate in solving challenges is estimated to be around 85%.[118]

How Innocentive has helped Lilly in speeding up its R&D process and develop intermediate compounds in the drug development process at a reduced cost? Here is one example case. Dr.Chris Schmid was the R&D operations manager in the chemical process group at Lilly. He and his group were working on the synthesis of a new chemical compound for which they had determined the raw material but to start from the scratch was a tedious and time consuming process. Hence, they wanted somebody else to synthesize the intermediate compound so that they can take it from there to the final compound. Schmid posted their problem on Innocentive and in just 3 months they got it solved through a solver scientist involved with Innocentive for award money of 25,000 USD. The solver scientist was a retired chemist from the R&D operation in Lilly. The process was iterative meaning with Innocentive as the mediator the process went through several feedback loops before it was finally accepted and rewarded by Lilly. According to Schmid they could have not solved the problem in-house for just 25,000 USD. The retired chemist had mentioned that he did it for not only monetary benefits but also for the intellectuals' aspects of it which brought him satisfaction.[119]

Other examples of open innovation models of Lilly include *Open innovation drug discovery programs PD 2 and TD2* that rely on the idea of opening up Lilly's resources and expertise to trigger an exchange of knowledge. PD2, Phenotypic Drug Discovery launched in 2009 and TD2, Target Drug Discovery launched in 2011. In these programmes *Lilly opens up the R&D process to external collaboration by sharing without charge its internal resources*. Basically, *Lily shares molecules in company's portfolio to be used as starting points on drug discovery and development with external scientist who are mainly representatives of academia and small biotechnology companies*. In exchange, Lilly will profit from external skills and expertise applied on the shared resources by having access to the results that external collaborators came up with after carrying out R&D efforts based upon the molecules initially provided

In open innovation drug discovery programs PD 2 and TD2 --- Lilly opens up the R&D process to external collaboration by sharing without charge its internal resources. Basically, Lily shares molecules in company's portfolio to be used as starting points on drug discovery and development with external scientist.

[118] Raja, B.H. and Sambandan, P. (2015), Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. Masters thesis. KTH School of Industrial Engineering and Management (ITM): Stockholm. http://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf

[119] Raja, B.H. and Sambandan, P. (2015), Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. Masters thesis. KTH School of Industrial Engineering and Management (ITM): Stockholm. http://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf

by Lilly's PD2 and TD2. Specifically, Lilly's goal here is to receive quality inputs from the outside rather than a high quantity of proposal submissions. [120]

The set of molecules offered through PD2 focuses on endocrinology and oncology diseases such as diabetes and cancer. The key value of PD2 is that it allows scientists to have their compounds screened against phenotypic, disease-relevant assays that were already established within Lilly, so that they focus on phenotypic drug discovery (the earliest step in the R&D process). Since its creation, Lilly has created a network of 70 small biotechnology companies and 174 academic institutions, and it has helped the company to diversify its portfolio of compounds.[121]

TD2 offers resources to focus within the same therapeutic areas as PD2, but also extends to cardiovascular and neuroscience areas. Also, the resources it proposes to external collaborators are not limited to molecules, but also relevant computational methods to let investigators carry out structure-based research on the initial results. The key difference is that TD2 emphasizes the collaboration effort on the drug optimization step of the R&D process by sharing molecules that are target-based, already-validated.[122]

The external investigator, who needs to sign up and accept a Material Transfer Agreement to become a member of the platform, will submit back to Lilly his R&D results for evaluation. Based on this evaluation, Lilly and the investigator will negotiate how to leverage the discovery, i.e. through licensing or collaboration. In this negotiation, Lilly holds the priority to first reach an agreement with the scientists while, in the other hand, the investigator keeps the IP rights on the molecule solution and is free to leave with the patent.[123]

...Lilly holds the priority to first reach an agreement with the scientists while, in the other hand, the investigator keeps the IP rights on the molecule solution and is free to leave with the patent.

6.6 Vertical

Accelerators provide another aspect to openness of RDI-activity in health sector. Accelerator activity is typically based on the idea of co-development together with peer companies, investors and experts from accelerator programme. Thus, openness inside accelerator programme is usually inherent. One example of accelerator activity in health sector in Finland is Vertical.

Vertical is a startup accelerator that is solely focused on health technologies and smart life. The accelerator program is run twice a year for 4 months at a time. Each time up to 15 early stage companies within the domain of health

[120] Raja, B.H. and Sambandan, P. (2015), Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. Masters thesis. KTH School of Industrial Engineering and Management (ITM): Stockholm. http://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf
[121] Raja, B.H. and Sambandan, P. (2015), Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. Masters thesis. KTH School of Industrial Engineering and Management (ITM): Stockholm. http://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf
[122] Raja, B.H. and Sambandan, P. (2015), Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. Masters thesis. KTH School of Industrial Engineering and Management (ITM): Stockholm. http://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf
[123] Raja, B.H. and Sambandan, P. (2015), Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. Masters thesis. KTH School of Industrial Engineering and Management (ITM): Stockholm. http://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf

technologies and wellness are chosen for the program. The accelerator offers companies an environment where to develop and grow their business: together with selected partners, the accelerator offers members a co-working space, a state-of-the-art training program which focuses on going from minimum viable product to minimum meaningful product, organizing of financing, assistance, and connections within marketing and international product distribution. Vertical´s partners work with startups to help them with technology, market insights, distribution and beyond.[124]

On the other hand Vertical provides established and large companies possibility to work with start-ups in order to gain new insights and boost RDI-activity. From this aspect, Vertical functions as outsourced startup collaboration partner that helps to find the most suitable startup partners and empower companies´ experts to work in collaboration with the best entrepreneurs. Vertical also serves as a glue between companies´ needs and the startups offering to create joint offerings to the market. Thus, Vertical offers range of learning and innovation services, ranging from enabling companies to engage with startups and learn how entrepreneurs think, to cooperation services helping them to facilitate hands-on cooperation between corporates and startups.[125]

The accelerator offers companies an environment where to develop and grow their business: together with selected partners, the accelerator offers members a co-working space, a state-of-the-art training program which focuses on going from minimum viable product to minimum meaningful product, organizing of financing, assistance, and connections within marketing and international product distribution.

Finally, Vertical links venture capital and start-ups providing business angels and VC investors investment possibilities and start-ups venture capital to boost the business. Vertical has partnered up with experienced investors from around Europe to bring start-ups closer to the next round. Investor partners include e.g. LEO innovation lab, Inventure, Superhero Capital, and Invesdor. [126]

6.7 Helsinki Biobank

Helsinki Biobank is a hospital based biobank founded by the Hospital District of Helsinki and Uusimaa (HUS), the University of Helsinki, Kymenlaakso Social and Health Services (Carea) and the South Karelia Social and Health Care District (Eksote). Helsinki Biobank covers now 1,9 million inhabitants and next year it will cover 200 000 inhabitants more. Helsinki Biobank obtained the license to operate from Valvira, the National Supervisory Authority for Welfare and Health on April 21, 2015.[127]

According to the Finnish Biobank Act (688/2012), biobanks are infrastructures supervised by the authorities in which samples and related data are processed and stored for future medical research needs. Biobank research investigates how genetic, environmental and lifestyle factors impact the etiology of diseases. It also studies disease prevention and the development of safe, more effective and personalized therapies and diagnostics. Biobanks provide data for academic research as well as research-focused company RDI-activity filling ethical requirements.[128]

[124] Vertical (2017), What is Vertical? http://www.vertical.vc/faq/#.WImsi1OLSM8
[125] Vertical (2017), Enterprises, http://www.vertical.vc/enterprises/#.WLj90G_yiM8
[126] Vertical (2017), Enterprises, http://www.vertical.vc/enterprises/
[127] HUS (2016), Helsinki Biobank http://www.hus.fi/en/about-hus/helsinkibiobank/Pages/default.aspx
[128] HUS (2016), Helsinki Biobank http://www.hus.fi/en/about-hus/helsinkibiobank/Pages/What-is-a-Biobank.aspx

Helsinki Biobank provides samples from its sample repository, with associated clinical information, for medical research and R&D purposes. The largest retrospective sample collection contains diagnostic FFPE samples from 1,4 million individuals collected during years 1982-2013. In addition, prospective cohorts, including multiple longitudinal sample types from 2000 patients with urological malignancies, are available. [129]

Requests for sample and data access, and project proposals are reviewed by Helsinki Biobank's Scientific and Ethical Review Committee. The recommendation will be based on following items[130]:

- linkage of the proposed research project with Helsinki Biobank's research focus and aims
- the scientific merits of the proposed research project
- the amount of material requested in relation to its availability within Helsinki Biobank sample repository
- the qualification and resources of the team carrying out the proposed research project

Helsinki Biobank has operated since August 2016 and there has been 17 requests so far for a sample of which three were from companies. Kimmo Pitkänen, director of Helsinki biobank, estimates that the number of company applications will be around 20-30% as in Auria biobank. Helsinki Biobank had also agreed on co-operation with Bayer AG as a form of contract agreement [131]in order to speed up application process and make it in some aspects more flexible (e.g. regarding due diligence matters). Kimmo Pitkänen estimates that the number of requests will be 30-40 per year. Applicants receiving samples are expected to return research results back to the biobank in order to avoid overlapping research. However, due to methodological issues the model for this is still under construction.

Although there is not yet public record of Helsinki biobank´s requests, companies applying samples from biobanks in Finland seem to be mainly large pharmaceutical companies. On the other hand, in Helsinki Biobank half of company applications were from SME´s. In Auria biobank based on web-site information, 37 % of biobank research is company research and the majority is academic research. [132] Year 2016 there were 11 studies according the Auria´s website of which 7 were company driven studies. Companies conducting these studies were Bayer Pharma AG (Germany, three studies), Bayer Oy, Medaffcon Oy and AstraZeneca, Roche Oy and Boehringer Ingelheim. [133] Thus, companies utilizing biobank data and samples seem to be mainly international large pharmaceutical companies which mainly also have own open innovation platforms and databases (e.g. AstraZeneca).

According to Kimmo Pitkänen Helsinki biobank has gained interest also among Finnish SME sector. Helsinki biobank have had contacts weekly from SME´s interested to learn more about biobank operation and co-operate. Many of these contacts are focused on possibility to provide analysis tools for companies utilizing samples and data. One option for the future could maybe be that Helsinki biobank wouldn´t only provide samples and raw data for pharmaceutical companies or universities but also analysis tools and final research results together with other service providers. This sort of public-private sector co-operation could promote business and export especially in SME

[129] HUS (2016), Helsinki Biobank http://www.hus.fi/en/about-hus/helsinkibiobank/forresearchers/Pages/default.aspx
[130] HUS (2016), Helsinki Biobank http://www.hus.fi/en/about-hus/helsinkibiobank/forresearchers/scientific%20and%20ethical%20review%20committee/Pages/default.aspx
[131] HUS (2016), Helsingin Biopankki on solminut Bayerin kanssa puitesopimuksen biopankkiyhteistyöstä http://www.hus.fi/hus-tietoa/uutishuone/Sivut/Helsingin-Biopankki-on-solminut-Bayerin-kanssa-puitesopimuksen-biopankkiyhteisty%C3%B6st%C3%A4-.aspx
[132] Auria (2017) Biopankkitutkimukset https://www.auriabiopankki.fi/palvelut/biopankkitutkimukset/
[133] Auria (2017) Biopankkitutkimukset vuonna 2016 https://www.auriabiopankki.fi/palvelut/biopankkitutkimukset/biopankkitutkimukset-vuonna-2016/

sector. Also, it would be interesting whether the operating model itself could be developed as an export product as such, notes Kimmo Pitkänen.

6.8 Demola

In pharmaceutical industry there seem to be quite many company driven open innovation platforms which are typically goal oriented and focused. There are also public sector driven open innovation initiatives which are more research oriented. Another aspect to open innovation is health sector is open innovation platforms driven by education institutions. One example of these is Demola.

Demola is the open innovation platform of the higher education institutions that today operates in Tampere, Helsinki, Oulu and internationally in several locations. It offers companies an opportunity to develop and test their ideas together with students.

Demola is the open innovation platform of the higher education institutions in Tampere. It offers companies an opportunity to develop and test their ideas together with students.

In Tampere approximately 60 Demola projects are conducted each year in collaboration with students of Tampere University of Technology, the University of Tampere and Tampere University of Applied Sciences.

Demola projects are carried out to develop for example technological applications, services, digital solutions, social innovations and business concepts. Demola suits for companies and organizations that are seeking multidisciplinary and new perspectives on their activities and are interested in co-operation with universities and students. The company provides a topic or a challenge for a project that students typically work on for 3-4 months with support from a facilitator and the partner company. Each partner has a clear role, and the work is guided by simple procedures. The result may be a demo, a new concept, or a prototype or something else that validates the feasibility of the original idea. The copyright to the resulting demo belongs to the students. Demola projects are free of charge for companies. If the partner company finds the outcome useful, the company can license or purchase the outcome, and take it for further development. So far, some 75 per cent of the results have been licensed by partner companies.[134]

Today the Demola platform (www.demola.net) is an international organization that facilitates co-creation projects between university students, companies and researchers, both locally and internationally. One example of health care cases Demola has solved is children´s disease map. The City of Tampere gathers the data of how children´s diseases spread. With an easy way to check the actual disease status in Tampere region, children's parents would be able to take the needed precaution act in order to stop the diseases. There are already some implementations on flu meters (e.g. Nuhasää by Terveystalo). The regional public health data would be an excellent platform for a version where the main purpose would be to tackle the spreading of children's diseases. The project goal in the case was to create a concept and demo/prototype of monitoring the spread of TOP3 children's disease. The City of Tampere provided the needed material and data, tapping into the Pegosos diagnosis register. The data included location information, based on diagnosis postal coding. Potentially, the system would provide parents the way to decide not to take their children to daycare on specific dates. This would stop the diseases, boil down to healthier

[134] Tampere University of Technology (2016), Multidisciplinary, fresh perspectives on your project http://www.tut.fi/en/business-and-industry/engage-with-our-students/demola-projects/index.htm

people and as well shorten waiting queues in health stations. The service should as well include an easy instruction to protect from actual spreading diseases (e.g. rest, remember to drink water, wear gloves).[135]

6.9 Astra Zeneca´s open innovation programs

AstraZeneca´s aim is to push the boundaries of science to deliver life-changing medicines. Their Open Innovation platform provides an open, collaborative approach to link their expertise, unique research tools, optimized molecules, technologies and challenges with external partners´ research capabilities and interests. AstraZeneca collaborates with research partners across all stages of drug discovery; from the initial idea through to early clinical development. AstraZenaca´s Innovative Medicines and Early Development (IMED) biotech unit focuses on scientific advances in small molecules, oligonucleotides and other emerging technologies and drug discovery platforms while MedImmune focuses on biologics research. Global Medicines Development (GMD) is a science unit focused on large Phase III clinical trial programmes that support the approval, launch and reimbursement of new medicines, as well as lifecycle management.[136]

The AstraZeneca Open Innovation program seeks to utilize terms that facilitate participation, open collaborative brainstorming, problem solving and are consistent with well-established and tested academic-industry agreement structures (e.g., Lambert/miCRA templates in U.K. and NIH/NCATS CRA in U.S.), for example [137]:

- Pre-existing IP remains with the original owner
- New IP follows ownership framework taking into account the contribution of each party and where possible using the well-established academic-industry templates
- Publications are encouraged after allowing AstraZeneca to comment, patent(s) to be filed (if applicable), AstraZeneca confidential information protected
- If the collaboration generates positive findings, AstraZeneca has option to negotiate a license to advance further towards patient benefit and commercialization
- For compounds 'live' in development, AstraZeneca minimally receives non-exclusive, royalty-free, fully paid license, with the right to sublicense without limitation, for all purposes for project IP.
- In general, Collaborative Research Agreement (CRA) and/or Clinical Trial Agreement (CTA) are/is negotiated for an agreed upon Full Project Proposal/Plan.

Ownership of project IP and rewards (e.g., royalties) if positive data found are based on multiple factors including regional/country standards, IP policies and the current development stage/status of the compound. AstraZeneca has at least an option to negotiate a license for project IP.[138]

Astra Zeneca launched the open innovation platform, New Molecule Profiling, for testing compounds in early 2014. AstraZeneca tests compounds in their screening campaigns against disease-relevant targets. The initial phase of the process includes signing a contract with AstraZeneca's third party service provider to explore the properties and therapeutic innovation potential by using advanced in silico cheminformatic analysis. The external partner is invited

[135] Demola (2015), Childrens disease map. http://tampere.demola.net/projects/childrens-disease-map
[136] AstraZeneca (2017), https://openinnovation.astrazeneca.com/about-us.html#why
[137] AstraZeneca (2017), https://openinnovation.astrazeneca.com/
[138] Nilsson, N. & Felding, J. (2015), Open innovation platforms to boost pharmaceutical development. Future Med. Chem. 2015: 7(14), 1853–1859 http://www.future-science.com/doi/pdf/10.4155/fmc.15.122

to sign another contract after the digital evaluation is successfully completed and compounds are accepted by AstraZeneca for screening.

The New molecule profiling initiative offers testing of compound libraries, up to 1000 as part of standard process and 1000+ after agreement. The partner is provided with the results, which it may publish. The primary focus is AstraZeneca's key therapeutic areas such as cardiovascular and metabolic diseases, oncology and respiratory, inflammation and autoimmunity. There are no obligations and the external partner is always in complete control of the decision to move to the next step, if such opportunity is presented. From a business contract perspective, AstraZeneca retains the rights of first negotiation, should it become relevant.[139]

6.10 LEO Pharma Open Innovation

LEO Pharma Open Innovation [140] was launched in March 2015 in order to explore potential collaborations by allowing external partners access to disease-relevant *in vitro* assays. The offered *in vitro* assays are fully disclosed with a focus on inflammatory skin disorders and include the use of primary human keratinocytes stimulated to express disease-like phenotypes. The disclosure of assay details makes it possible for external partners to suggest compounds with novel mode of action, which provides insights both from a compound and a target perspective. Cytotoxicity is also measured and evaluated in parallel in order to strengthen the confidence in the primary disease-relevant readouts. [141]

LEO Pharma Open Innovation was launched in March 2015 in order to explore potential collaborations by allowing external partners access to disease-relevant in vitro assays.

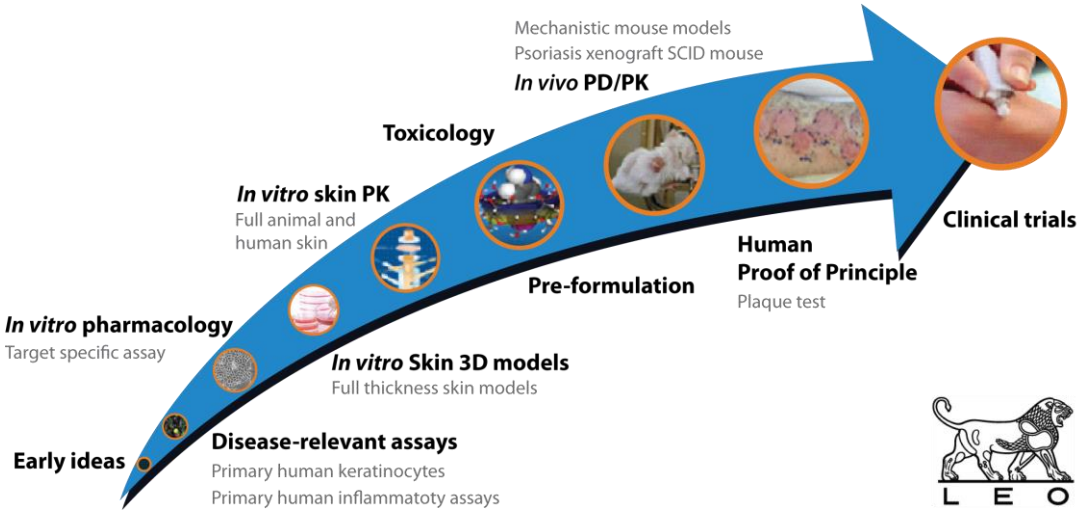
Engaging with LEO Pharma Open Innovation requires signing a simplified contract. After this compounds are digitally submitted without disclosing the structures. Vials are shipped to the external partner and returned with compounds to LEO Pharma. All data generated will be returned to the external partner and, if relevant, further collaboration will be discussed. In general LEO Pharma is looking for small molecules that could be relevant for business collaboration, science and disease exploration, or provide a starting point for a collaborative project. There are no limiting business terms attached to the contract and the external partner always retains IP rights as well as the decision to continue the collaboration or not.[142]

Thus, the LEO Pharma Open Innovation platform enables access to disease-relevant in vitro assays free of charge for external partners. The external partner retain intellectual property rights and LEO Pharma shares the data and results with the external partner. If something interesting comes up, LEO Pharma has the possibility to further explore the collaboration or develop a business partnership. Such a continued collaboration could include further profiling and application of LEO Pharma's translational disease platforms including methodology and technology such as:

- ✓ Additional in vitro pharmacology and profiling

[139] Nilsson, N. & Felding, J. (2015), Open innovation platforms to boost pharmaceutical development. Future Med. Chem. 2015: 7(14), 1853-1859 http://www.future-science.com/doi/pdf/10.4155/fmc.15.122
[140] http://openinnovation.leo-pharma.com/
[141] Nilsson, N. & Felding, J. (2015), Open innovation platforms to boost pharmaceutical development. Future Med. Chem. 2015: 7(14), 1853-1859 http://www.future-science.com/doi/pdf/10.4155/fmc.15.122
[142] Nilsson, N. & Felding, J. (2015), Open innovation platforms to boost pharmaceutical development. Future Med. Chem. 2015: 7(14), 1853-1859 http://www.future-science.com/doi/pdf/10.4155/fmc.15.122

- ✓ In vitro 3D skin models
- ✓ Pharmacokinetic evaluations
- ✓ In vivo disease models
- ✓ Pre-clinical toxicology
- ✓ Clinical testing[143]



Picture 7: LeoPharma Open innovation model [144]

6.11 Merck Serono´s Open Compound Sourcing initiative

Merck Group´s Open Innovation Portal [145] invites external partners to participate in open innovation initiatives by taking advantage of the various programs including Biopharma Innovation Cup, Merck ' s Biopharma Speed Grant, Open Lab, Biotechnology Showcase Europe, Mini Library, Compound Sourcing, Open Target Sourcing, Open Antibody Sourcing and Be a scout for Merck !

Demola is the open innovation platform of the higher education institutions in Tampere. It offers companies an opportunity to develop and test their ideas together with students

Merck Serono ´ s Open Compound Sourcing initiative was established in 2012 with the purpose of inviting potential partners to submit compounds to be included in high-throughput screening libraries. Through Open Compound Sourcing initiative, Merck Serono invites potential partners to submit their compounds to be included in our high throughput screening library and utilized in efforts to identify new therapeutics. Merck Serono is looking for novel

[143] Leo Pharma (2017), http://openinnovation.leo-pharma.com/What-is-Open-Innovation/Possibilities-and-Intentions.aspx
[144] Leo Pharma (2017), http://openinnovation.leo-pharma.com/What-is-Open-Innovation/Possibilities-and-Intentions.aspx
[145] Merc Group (2017), Open innovation portal, http://biopharma.merckgroup.com/en/partners/open_innovation_portal/index.html

small organic chemical compounds for testing in their screening campaigns for potential therapeutic activity. [146] Many of these compounds might otherwise never be tested for potential therapeutic benefits. In case of a match, specific compounds could become the next new chemical entity (NCE) or starting point for further optimization in one of our strategic therapeutic areas of focus: Oncology, Neurodegenerative Diseases and Rheumatology. [147]

With the compound sourcing process, Merck Serono is specifically looking for novel organic chemical compounds for testing in screening campaigns to provide starting point for further optimization. There is public access to the OI portal front page, but any details about specific programs, such as Open Compound Sourcing requires registration and Merck Serono's approval. Upon digital submission of structural information, chemical and physical properties, an in silico evaluation determines if the compounds are to be accepted and incorporated in the screening libraries. If the submitted compound (in the form of 20 mg in crystalline powder) passes an additional quality check, the external partner will receive a reward of €200 for an exclusive compound and €100 for a nonexclusive compound. If the compound is identified during screening, a subsequent collaboration and patent application including five analogs could result in a total financial reward of €20000. Biological data from screening campaigns will not be shared to the external partner. The legal contract Participation and Material Supply Agreement (P&MSA) covers legal, IP and commercial aspects of transferring novel small organic compounds to Merck Serono, who claims perpetual rights to use obtained data. [148]

7 Survey and workshop results

7.1 Survey results

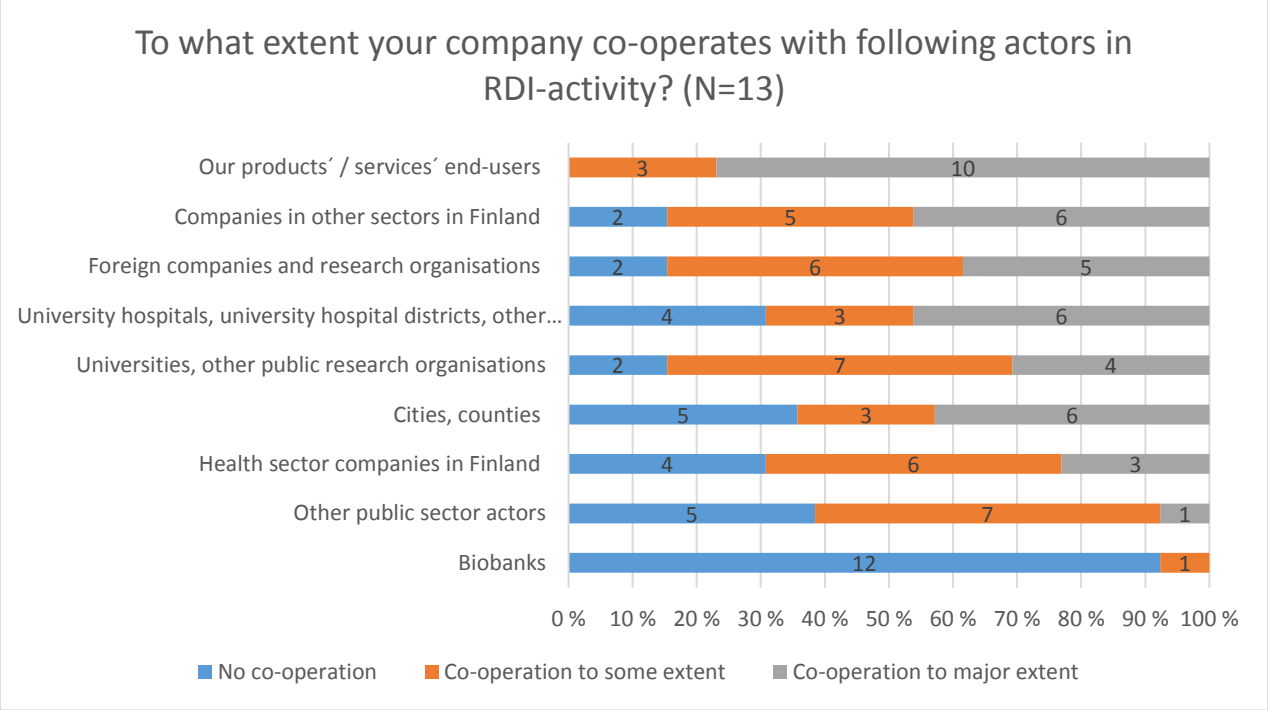
As a part of the study an e-survey among the health technology companies was conducted. Companies were selected from Team Finland´s database comprising about 100 companies mainly from health technology sector. These companies are mainly SME´s that can be characterized as "forerunner companies". These include mainly young companies with high level of RDI-activity. Thus, these are companies that can be expected to be more interested, than average, in open data, open innovation and co-development. Since the total population of recipients was somewhat low, it was anticipated that the number of answers would also remain small. Answering rates was around 10% (N=13) which is in normal level in company surveys. The survey was also send to corporate networks of the Ministry of Economic Affairs and Employment, comprising over a hundred recipient, but no additional answers were received.

Despite the low number of answers, results provide overall picture of openness in RDI-activity in health sector in Finland. Co-operation in RDI-activity with other companies seems to be quite common among these forerunner companies. Companies mainly utilize public funding such as Tekes, Finnvera, and EU-funding, in their RDI-activity

[146] Merc Group (2017), Compound sourcing, http://biopharma.merckgroup.com/en/partners/open_innovation_portal/OCS/compound_sourcing.html
[147] Nilsson, N. & Felding, J. (2015), Open innovation platforms to boost pharmaceutical development. Future Med. Chem. 2015: 7(14), 1853–1859 http://www.future-science.com/doi/pdf/10.4155/fmc.15.122
[148] Nilsson, N. & Felding, J. (2015), Open innovation platforms to boost pharmaceutical development. Future Med. Chem. 2015: 7(14), 1853–1859 http://www.future-science.com/doi/pdf/10.4155/fmc.15.122

(average 4.0), and they also participate in public funded research projects (average 3.5) and utilize public research results in their RDI-activity (3.1). Companies also share openly their research results with other companies (average 3.7). However, other aspects relating to openness remain in neutral or below neutral level. Co-operation with biobanks and other national databanks in unfamiliar to companies, and companies are on average unaware of available material and data (average 1.9). This result is in line with data from Helsinki biobank and Auria biobank – applications directed to biobanks seem to be mainly from large pharmaceutical companies. Also, information about open research infrastructures, open public data or public research results seems to be quite scarce in even forerunner health technology companies.

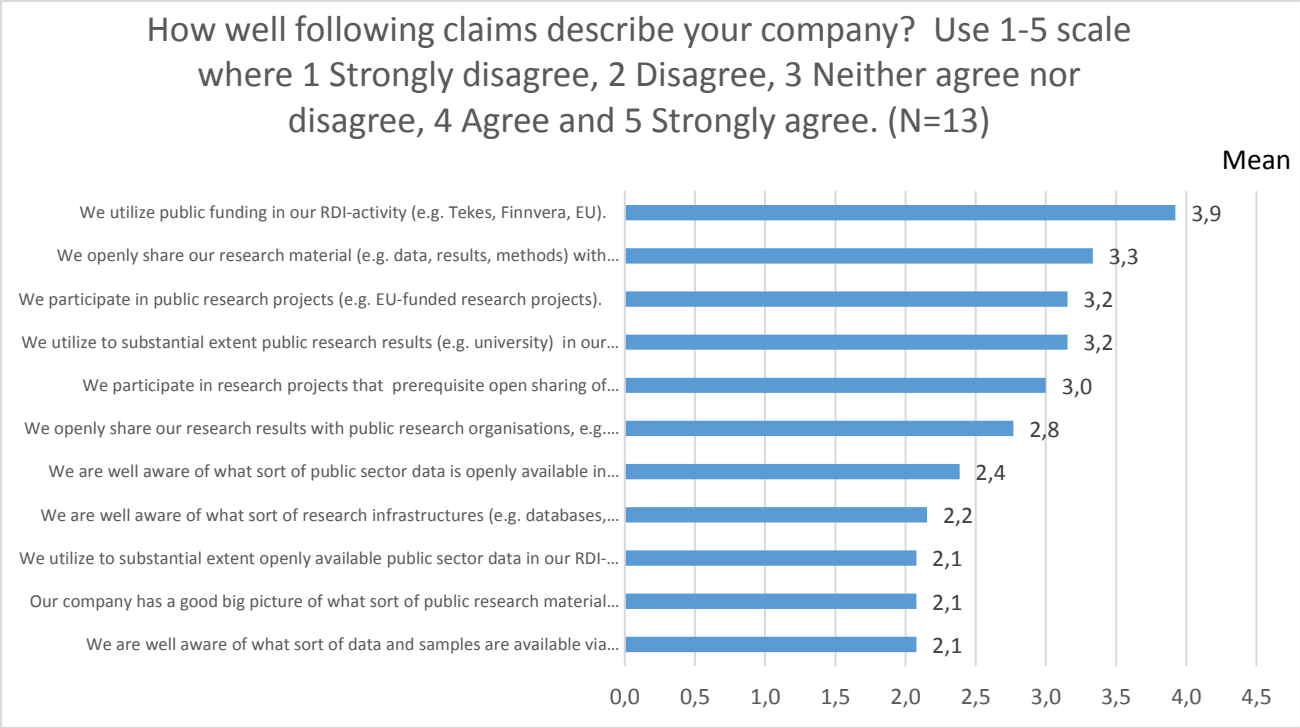
Innovation partners provide an interesting aspect of openness of RDI-activity in health sector. With whom Finnish forerunner companies in health sector co-operate in order to develop new services, products or solutions? The most positive result is that all companies participate end-users in development process – 9 companies evaluate that they co-operate with end-users in significant amount in their RDI-activity and 2 companies co-operate with them for some amount. Co-operation with other than health sector companies also seem to be quite common. 6 companies co-operate in significant amount, 4 in some amount and one company doesn´t co-operate at all with other than health sector companies in RDI-activity. Co-operation with cities and counties in RDI-activity varies a lot. 6 companies co-operate with cities in significant amount, 2 in some amount and 4 companies don´t co-operate with cities at all in RDI-activity. None of the answered companies did co-operation in RDI-activity with biobanks. Co-operation with university hospitals and other public health actors such as health sector districts varies. 5 of the companies co-operate with them in significant amount in RDI-activity, 3 in some amount and 3 don´t co-operate with them at all. Co-operation with universities and public research organization also varies; 4 companies co-operate with them in significant amount, 5 in some amount and two not at all. Co-operation with other public sector organizations is somewhat scarce.



Picture 8: Corporate survey results – co-operation in RDI-activity

Companies see that open procedures help to boost RDI-activity (4.3). Companies also believe that Finland is an attractive research and innovation hub in health sector (3.5). Regarding assessments of other aspects of openness in

health sector averages fall below neutral. Public procurement gain the most critical assessment. Thus, companies rarely see that public procurement promote demonstrations of innovative solutions in public health services (1.7). It should be noted, that public procurement law includes a new procurement model, innovation partnership, which promotes co-development and demonstration of innovative solutions. While maintaining existing instruments, the new rules aimed to encourage companies to develop their capacity for innovation. A new procedure called the innovation partnership will enable public purchasers to select partners on a competitive basis and have them develop an innovative solution tailored to their requirements. In public procurement reform, it was noted that public procurement plays a key role in innovation in areas that are the preserve of the public sector such as health services and education, firefighting or planning. Thus, the quality of public procurement is critical to the quality of the field covered by the contract and the extent to which innovation flourishes there. If purchasers remain conservative, economic operators will not be encouraged or even allowed to innovate. An innovative solution will be more attractive because of its higher quality and/or more competitive price. It will optimize public service operation by integrating new processes, technologies or materials. [149] Also, public procurement has an ability to promote openness, in research, development or innovation activity or in service production (e.g. service quality).



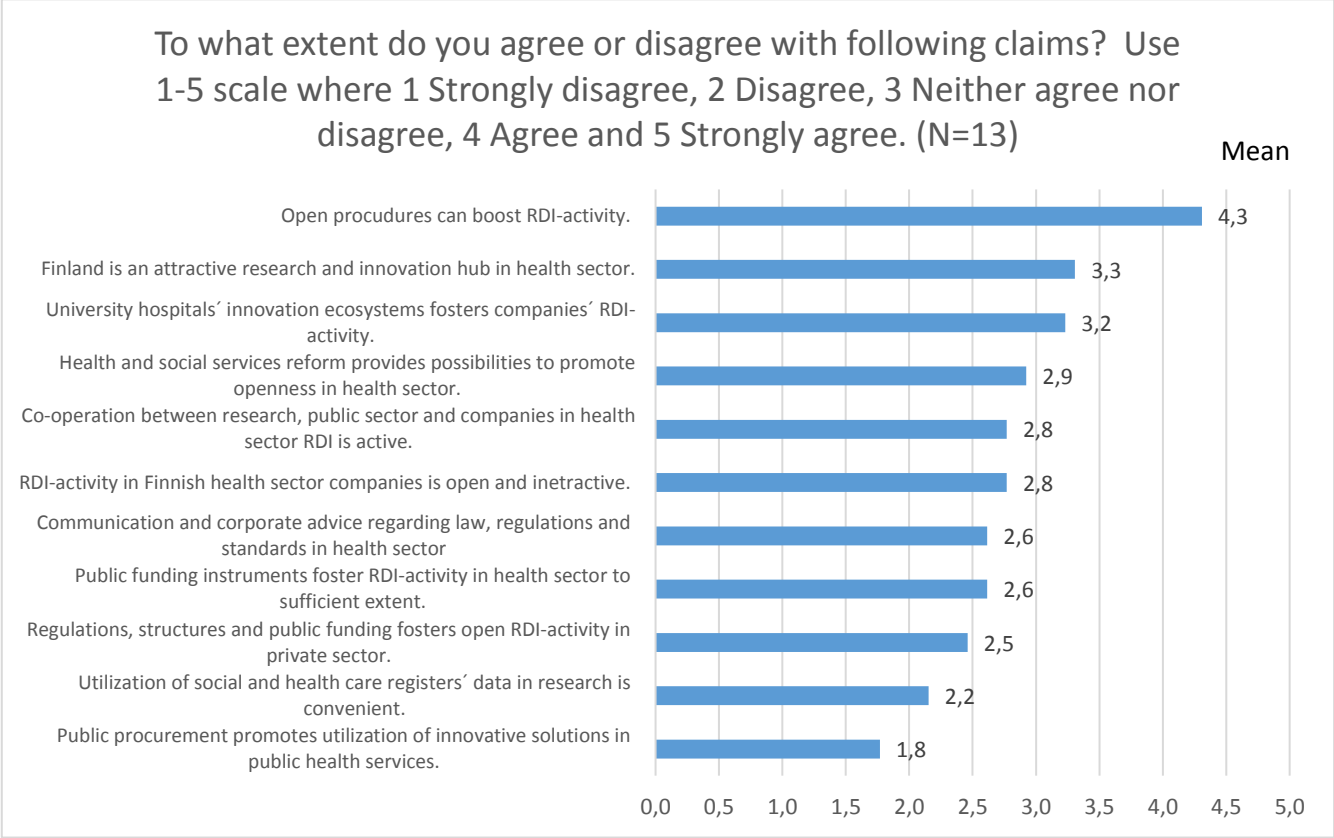
Picture 9: Corporate survey results – level of openness in different aspects of RDI-activity

Also, claim "law, structures and public funding promote open RDI-activity in private sector" received neutral assessment with average 2.5. Public funding promotes sufficiently RDI-activity in health sector also received neutral estimate with average 2.5. Communication regarding law, regulations and standards in health sector was in average evaluated to be insufficient with high standard deviation. Companies also grade critically openness of RDI-activity in health sector. Claim "RDI-activity in Finnish health sector companies is open and interactive" received neutral estimation with average 2.7 but respondents´ views varied a lot. Also, claim "co-operation between research, public

[149] http://ec.europa.eu/internal_market/publicprocurement/docs/modernising_rules/reform/fact-sheets/fact-sheet-09-innovation_en.pdf

sector and companies in health sector RDI is active" received neutral scores (2.8) with high standard deviation. Also, possibilities to promote openness in health sector via health and social services reform are estimated neutral (2.7).

Significance of openness in RDI-activity was estimated mainly low in open answers. Co-development with end-users and technology subcontractors was of significant importance for one respondent. Some respondents also mentioned the benefits of open procedures, such as faster market delivery, better focus in RDI-activity and stronger competitive advantage. Perceived barriers for openness in RDI-activity included traditional working models and suspicion towards co-operation and networks. Some companies also perceived that counties develop their operations according to closed innovation model and keeping distance to companies. Companies have no information about their plans and have no access to innovation process. Public procurement was also perceived price-focused with a little market interaction. Regarding possibilities to develop openness in public-private-sector interface and RDI-activity, public procurement was perceived important in most answers.



Picture 10: Corporate survey results – perceptions of Finnish health sector openness

The survey results seem to be in line with interview results. Co-operation with companies is seen scarce also from public sector view. For example, compared to Denmark, in Team Finland Health the co-operation could include more concrete export promotion actions. Co-operation with private sector could be stronger in ministries, not only in Ministry of Social and Healthcare, but also other ministries would benefit from stronger market orientation and corporate perspective. Public sector focus has been on promoting development of innovation ecosystems through various programs and strategies (e.g. INKA), and some development has occurred, but it still can be argued whether there are international level innovation ecosystems or healthcare clusters in Finland with regional level specialization. Public-private-co-operation needs structures, operating models and time. Public-private-sector co-operation should not be limited to testing final solutions, but co-operation should occur in earlier levels of

development process. There are no legislative barriers for private sector co-operation, but operating models for example in public procurement hinder co-development. There has been aim to direct public procurement towards innovation procurement especially in health sector, but this has not accomplished as aimed. Promoting procurement of innovative solutions requires strategic leadership and management and holistic view. However, public procurement is typically practiced in administrative silos. Innovative public procurement does not suit for every tendering process, and it requires know-how from tenderer´s side. However, there should be more strategic and holistic thinking and courage in public procurement.

7.2 Workshop results

As a part of the study a workshop was conducted to gain insights for preliminary results and activate discussion relating openness in RDI-activity in health sector. The workshop was held 21st March 2017 in Helsinki. Summary of workshop results based on individual worksheet memos is presented in the appendix 1. During the workshop two discussions were conducted. The first discussion related to possibilities to foster open RDI-activity from company´s perspective and the second discussion focused on public sector actions to promote open RDI-activity in private sector and open innovation in public-private sector interfaces.

Firstly, possibilities to foster utilization of public research was discussed. Companies are interested in on-going research projects. However, even inside one university the possibilities to create holistic picture of all ongoing research projects is somewhat challenging. Strategic focus areas of universities and research organizations give some picture of research areas in national level. Also, a short summary of publicly funded projects can be found from websites of different organizations (e.g. Tekes, Academy of Finland, universities), but this information is scattered and not all-inclusive. However, there are aims to create common platform for information on public research projects by the MoEC.

It was also noted that open publishing of research results rarely serves private sector needs as such since companies usually need information in different format and from different perspective than provided. Also, researchers often need to popularize their results and present their research results differently to different audiences. Often so called “research language” forms a barrier for utilization of results – terminology used in research and in companies is different and thus, companies can perceive that they don´t speak the same language with the researcher. It was also noted, that in many cases the interaction between the companies and researchers is more beneficial than simply proving the results. Companies rarely have time to mine relevant information out of vast amount of research data. Dynamic interaction can also lead to new insights for both researchers and companies and thus benefit both but this requires time, effort, and willingness to open discussion.

RDI-activity was perceived fragmented in health sector as a whole – companies mainly develop their own products separately and by using closed innovation model. More effort is needed to develop holistic solutions by integrating services and products of various companies. This is especially important when considering export.

More interaction and co-operation between public sector parties is needed. Also, public-private-co-operation models are needed to boost development of innovation ecosystems. Companies perceive that they have too little information about public sector operating models and IT-infrastructures in order to build compatible solutions. On the other hand, it was noted that co-operation between universities and university hospitals has been fostered during recent years. Today, some university hospitals can be seen as significant RDI-hubs with active corporate co-operation.

Law and regulations need to be harmonized and the interpretation of regulation should not unnecessarily prevent open RDI-activity and open flow of information between public and private sector and universities. Plans of

changing regulations and standards should be informed more openly and more in advance. Marketing and communication was seen essential both from public research utilization perspective and also from public data utilization perspective. Simply providing the data or research results isn´t enough. Substantial market communication effort, or selling effort, is needed to foster utilization of data and research results. This is especially critical when considering new one-stop-shop operator that will collect and co-ordinate well-being data in Finland. New operator needs branding and marketing to gain visibility in national and international level. It was also emphasized in the discussion that national health data needs to be stored and remained in Finland even though the utilization could also happen in international level. It was noted in the discussion that in France and Russia national health data is stored inside the country.

From company perspective technological interfaces are of vast importance. MyData models and compatible interfaces are needed - INTERRHI, CDS/ADL, MAPLE-15, ROG-18 and GDPR were mentioned in the discussion. Also, operating models for application of data are essential. The cost of data and the effort of applying it strongly affects the attractiveness of one door health data service. The price of data should be competitive and applying processes should be fast and convenient from company perspective.

8 Conclusions and implications

In this study operating environment analysis of policy instruments, legislative and structural factors affecting openness in public-private-sector interface was accomplished. Based on client´s specification a number of strategies, laws and structural reforms were analyzed from the view of promoting or enabling private sector openness. Also, 12 case studies portraying various examples of openness in RDI-activity in health sector was presented. The focus of the study was in literature review including case studies with interviews, e-survey and workshop providing some additional information.

In general, it can be noted that studied strategies and structural and legislative reforms do not hinder openness in public-private sector co-operation or in private sector RDI-activity. All studied strategies have some link to openness also from private sector perspective. In general, the aim is to enable or promote development of innovation ecosystems in health sector for example by promoting private sector co-operation or by opening public research (open science) or by creating innovation infrastructures. However, as noted in Open science, open innovation, open to the world –strategy, prioritizing open science does not automatically ensure that research results and scientific knowledge are commercialized or transformed into socio-economic value. In order for this to happen, open innovation must help to connect and exploit the results of open science and facilitate the faster translation of discoveries into societal use and economic value. However, utilization of discoveries of open science requires capabilities and resources both in academia and in business life. Universities have put effort on development of open science operating practices, infrastructures and capabilities to communicate and commercialize research results. However, also in private sector there is a need to develop capabilities to better utilize public research and public data and to invest resources in open RDI-activity, e.g. university co-operation. Moreover, it can be argued that main challenge lies in RDI-operating models, which seem to be, based on this study, still somewhat closed in Finnish health sector. Open innovation requires different operating models and different mind-set. Thus, the shift to open innovation prerequisites a major cultural change in private sector.

The link from data to successful utilization is of vast importance. However, the focus has been on creating structures that enable openness. Priority has been in development of one-stop service provider that provides one door for all health information generated in public sector (including e.g. biobanks, genome bank, cancer center data) and thus enables open utilization of health data when ethical and regulatory demands are filled. On the other hand, it can be noted that openly shared health data can be utilized in closed innovation process. Utilization of openly available data is only one aspect to openness in RDI-activity. Promoting utilization of public data and public research in private sector and promoting companies to share their own data has been scarce or nonexistent. Likewise, promoting open innovation has been scarce. Most notable aims to promote companies to share data are included in act on organizing health and social services which prerequisites that service providers both in public and private sector co-operate, service provider have access to customer information, save customer information to common register and constantly evaluate and share information about service operation, customer safety and service quality. These aspects of openness however, focus on sharing of data regarding operational service production, not opening RDI-activity or sharing RDI-relevant data. Also, regarding biobank and also possibly genome bank operations user of biological material is expected to provide research results to the biobank in order to avoid overlapping research. However, quality and method-related questions make this difficult to accomplish according to interviews and thus, in practical level no clear operating model for this yet exists.

..openly shared health data can be utilized in closed innovation process. Utilization of openly available data is only one aspect to openness in RDI-activity. Promoting utilization of public data and public research in private sector and promoting companies to share their own data has been scarce or nonexistent. Likewise, promoting open innovation has been scarce.

There has been no statistical analysis of utilization of public data or public research in health sector companies in Finland. One aspect to utilization of data can be seen in biobanks. Utilization of biobank materials seem in somewhat modest level even in most established biobank, Auria, with a limited number of studies utilizing biobank materials (2016: 11 studies, 2015: 25 studies; 2014: 6 studies) of which 37 % were company projects mainly from pharmaceutical companies[150]. However, it should be noted that the number of studies is only one measure to evaluate utilization activity and thus, provides only partial view of the situation.

Regarding open innovation, many strategies aim to promote development of innovation ecosystems but in practical level focus has been in other matters than in company co-operation and open innovation. Owal´s final report "National cancer center operating models" [151]includes some aspects of FICAN´s possible company co-operation in RDI-activity. For example, co-operation forums, innovation platforms / demonstration platforms and start-up accelerator activity are mentioned as possible co-operation models. However, these are only briefly described and aspects of openness are thus difficult to assess. Also, similarly as in biobank and genome bank development, possibilities of providing private sectors diagnosis and analysis tools are assessed. At time of writing the report, no final decisions have been made regarding private sector co-operation or operating models according to interviews. The focus has been in other matters than private sector co-operation or open RDI-activity. However, it is possible that co-operation elements and models are included in the operation once centers began their activity.

When considering tools to promote openness in RDI-activity in private sector and in public-private-sector interfaces, at least following should be noted: **1) public procurement, 2) PPP / Triple Helix-operating models, 3) public**

[150] Auria (2017), Biopankkitutkimukset. https://www.auriabiopankki.fi/palvelut/biopankkitutkimukset/
[151] Owal (2016), Kansallisen syöpäkeskuksen toimintamallit. Loppuraportti.

funding instruments and **4) communication and marketing**. These aspects of promoting openness somewhat fall out of the scope of this study, but are briefly discussed for the basis of further studies.

Maybe the most important tool to promote public-private-sector co-operation in RDI-activity in health sector is public procurement. Public procurement hasn´t been as such in the focus of the study, but it has been included in many strategies especially as an aim to promote innovative public procurement. Based on previous studies it can be noted that public procurement has been seen a major instrument that could promote development of innovative solutions, enable demonstrations of innovations and boost development of markets. In health and social services sector public procurement is of a vast importance. Public procurement makes it possible to require openness in RDI-activity during procurement process as well as during the contract period and service production phase. However, it has also been noted that despite of possibilities generated by regulations, only a small portion of public procurement uses innovation procurement methods (e.g. innovation partnership) or for example utilizes the possibility for market interaction in order to better meet the needs to the possibilities in the market. Even though, public procurement provides a concrete tool to promote open RDI-activity in private sector e.g. based on contract terms that demand continuous improvement of services together with end-users and other companies, there are only some examples of such innovative public procurement (e.g. in procurement of assisted living services for disabled persons in City of Vantaa, for Huvikumpu group home [152]). Development of public procurement to the ways of better promoting openness and fostering pursued impacts of services (e.g. quality, efficiency, innovativeness, end-user impacts e.g. wellbeing) requires both knowledge, resources, and more strategic thinking.

Closely connected to public procurement, public-private-partnership and triple helix-models provide another tool to promote openness in private-public-sector interface and to require open RDI-activity. For example in Denmark there are many examples of PPP-operating models in health sector and other sectors (e.g. cleantech). One successful example of these is CLEAN [153]. CLEAN is a world-leading cleantech cluster with a mission to accelerate the green and sustainable transition while realizing growth for the Danish cleantech sector. CLEAN is a triple-helix non-profit organization, a facilitator of high-value cooperation between parties, by bringing members closer to markets, customers and peers[154]. Other examples of PPP-models were presented among the case studies. PPP-models have been included in some aspects in structural changes. For example, in Owal´s final report (2016) of FICAN´s operating models, company co-operation is assesses in three levels, of which the first means that selected companies are co-owners of FICAN which could take a form of co-operative or limited company. PPP-operating models as a starting point require some level of openness between public and private sector parties and they usually aim to promote better public-private-sector co-operation in the field.

Thirdly, public funding instruments could include aspects to promote openness in RDI-activity as well as co-operation with public sector and public research. For example, some Tekes programmes do require co-operation with public research or public sector clients (e.g. former programmes Liito, Innovaatiot sosiaali- ja terveyspalveluissa). Also, participation of customers or for example lead users in development project is typically assessed positively in Tekes funding decision, but there are no specific requirements of opening RDI-process to customers or users. Also, it should be noted that large companies are expected to create secondary impact on innovation ecosystems, especially in SME-sector and this usually requires some level of interaction e.g. through

[152] PTC Services (2014), Espoossa muotoiltiin vammaispalvelujen hankinnat uusiksi http://www.ptcs.fi/fi/blogi/palvelumuotoilu-vammaispalvelujen-hankinnoissa
[153] European Commission (2016), Copenhagen Cleantech Cluster http://ec.europa.eu/regional_policy/en/newsroom/news/2016/12/12-07-2016-copenhagen-cleantech-cluster
[154] CLEAN (2017) ,About CLEAN http://cleancluster.dk/en/aboutclean/

sub-contracting. However, requirements regarding openness in RDI-activity do rarely exist. Companies are required to report to Tekes about proceeding of the project and it´s general results and impacts. But otherwise, there usually are no requirements regarding openness towards other parties.

An interesting question is, should there be public funding instruments that require open innovation? Strategies in national and EU-level promote openness and effort is put into creating infrastructures that enable openness. However, open innovation is not required. The case examples of pharmaceutical industry, as well as other open innovation examples, show that open innovation and co-development boosts RDI-process in many ways. In the spirit of fast trials and learning by doing, a funding instrument requiring open innovation could be developed for a limited period of time to gain insights of results and impacts and to promote open innovation in selected sectors. A new public funding instrument with higher funding levels (e.g. 70% funding) could require utilization of open innovation models in RDI-project and prerequisite opening RDI-process for open co-operation with external parties. Also, public research funding instruments could be developed with specific requirements regarding company co-development and open science-based open innovation activity.

Finally, marketing and communication is needed both to inform and to inspire companies. Private sector should be better informed about the possibilities to utilize open science and open public data and e.g. about the access to open research infrastructures. Also, joint branding, marketing and sales of Finnish health innovation platform and one stop operator services of Finnish health information is needed to boost export and promote foreign investments. It should be notes that utilization of open data and open science requires capabilities and resources. Capabilities to utilize open science in RDI-activity could be enhanced in private sector e.g. by boosting interaction with public research organizations and researchers. RDI-activity has been in health sector somewhat closed and the transition to open innovation means a major cultural change that could be promoted e.g. by providing inspiring case-examples and success stories. Also, utilizing open innovation practices in public sector development could foster transition to open innovation culture in Finnish health sector.

Activities to promote openness in RDI-activity in health sector
Innovative public procurement Promoting innovative public procurement in health and social services sector ✓ market interaction in early procurement planning phase ✓ utilizing innovation partnership ✓ utilizing procurement methods that enable to provide innovative solutions for specified need (e.g. reverse action, planning contest) ✓ accepting alternative solutions in the call for tenders ✓ use of contract terms requiring continuous improvement through co-development with end-users and customer ✓ use of contract terms requiring open innovation models in continuous improvement ✓ use of contract terms requiring openness (e.g. open sharing of customer feed-back or other service quality data, sharing of result or impact data)
PPP and Triple Helix Using PPP (Public-Private-Partnership) and Triple Helix-models (Public-Private-Academic) in health sector development ✓ Promoting open interaction between public and private sector and universities in RDI-activity and innovative public procurement in health sector ✓ PPP-operating models in new structures (biobanks, genome bank, FICAN, Isaacus..), e.g. combining public and private sector service production (e.g. combining public data and private analysis tools or combining public and private diagnosis and treatment services) and joint, open development of common services ✓ PPP-organisations as facilitator of innovative public procurement (e.g. CLEEN) ✓ Cluster organization fostering collaborative development and open innovation and fostering development of innovation ecosystems
Public funding ✓ Developing new public funding instrument for RDI-projects requiring utilization of open innovation models with higher funding levels (e.g. 70% funding) in order to boost health sector innovation activity ✓ Public research funding instruments with specific requirements of open innovation and company co-development
Marketing and communication Market communication to inform possibilities to access open data, material, infrastructure, methods or results in RDI-activity ✓ Marketing national health data operator services and communicating about the possibilities to access public data and open science materials ✓ Joint branding, marketing and sales of Finnish health innovation platform to boost export and promote foreign investments ✓ Continuous impact assessment of marketing and selling efforts to identify best practices Promoting development of public research and public data utilization capabilities in private sector ✓ Fostering open science utilization capabilities in private sector and enhancing interaction with public research organizations and researchers Promoting transition to open innovation culture in health sector in Finland ✓ Boosting transition to open innovation culture by providing inspiring case-examples and success stories ✓ Utilizing open innovation practices in public sector development

Table 3: Summary of proposed activities to further promote openness in RDI-activity in health sector

9 Interviews and workshop attendents

Interviews and discussions

- ✓ Kimmo Pitkänen, HUS
- ✓ Hannu Hämäläinen, STM
- ✓ Saara Leppinen, STM
- ✓ Liisa-Maria Voipio-Pulkki, STM
- ✓ Jaakko Yrjö-Koskinen, STM

Registered in the workshop held 21st March 2017

- ✓ Aki Salo, Suomen Akatemia
- ✓ Anssi Linnankivi, Roche Oy
- ✓ Eeva Kaunismaa, Opetus- ja kulttuuriministeriö
- ✓ Erja Heikkinen, Opetus- ja kulttuuriministeriö
- ✓ Helena Viita, Tekes
- ✓ Heli Paavola, Tempo Economics Oy
- ✓ Jarmo Iisakka, Aino Health Management Oy
- ✓ Juho Nyman, Tempo Economics Oy
- ✓ Mari Renlund, Janssen Suomi
- ✓ Pasi Nurmela, Seniortek Oy
- ✓ Pirjo-Leena Forsström, CSC
- ✓ Rauno Saarnio, SE Innovations Oy
- ✓ Riina Vuorento, Opetus- ja kulttuuriministeriö
- ✓ Riku Louhimo, Työterveyslaitos
- ✓ Saara Leppinen, STM
- ✓ Sami Niinimäki, OKM
- ✓ Sari Räisänen, Kansalliskirjasto
- ✓ Tero Oinonen, Helsingin Yliopisto
- ✓ Veli-Matti Kosma, Itä-Suomen yliopisto

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Appendix 1: Workshop – discussion results

Millä julkisen sektorin toimilla avointa TKI-toimintaa voitaisiin paremmin edistää?	Miten yritysnäkökulmasta avointa TKI-toimintaa voitaisiin paremmin toteuttaa yrityskentässä sekä julkisen ja yksityisen sektorin rajapinnoilla?
Laki ✓ säännösten mahdollisimman salliva tulkinta ✓ säännösten keskinäinen linjaaminen ✓ lainsäädännön uudistaminen huomioiden TKI-toimijoiden tarpeet **Rajapinnat** ✓ laadukkaammat rajapinnat, käyttöympäristöt, metadata, lisenssit ✓ Rajapintamäärittelyt ✓ MyData ✓ GDPR ✓ Interrai – well kept secret ✓ Tietojen on pysyttävä Suomessa – tuloksia voidaan esittää ja julkaista ✓ Yhden luukun periaatteet tiedon saantiin **Yhteistyö** ✓ osaamiskeskittymien rakentaminen ✓ kiinteämpi yhteistyö eri julkisten toimijoiden välillä **Viestintä** ✓ viestintä- ja markkinointiosaamisen kehittäminen	**Tutkimushankkeiden hyödyntämisen edistäminen** ✓ Avoimuus testaus-vaiheessa, esim. Ranskan autoteollisuus, jossa törmäysdata jaetaan kaikkien kesken, kaikki hyötyvät, ei keneltäkään pois ✓ Popularisointiosaaminen (tutkimustulosten hyödyntämisen edistämisessä) ✓ Rahoitushakemusten avoimuus – hukattua potentiaalia ✓ Tiedon tarjoajan dilemma: 1) miten data näkyväksi? 2) resurssointi ja infrastruktuuri, 3) miten data haluttaisiin? ✓ Eri ryhmille viestiminen eri tavalla. ✓ Tiedon hyödynnettävyys ja käytettävyys Avoimuus yrityksen sisällä ja suhteessa ulkopuolisiin toimijoihin ✓ Avoimuuden ja tiedonjaon lisääminen yritysten sisällä uusien innovaatioiden aikaansaamiseksi. yritysten kaikkien työntekijöiden osallistaminen. **Yhteistarjooma** ✓ Suurempien palvelukokonaisuuksien tarjoaminen. Ei yksittäisen yrityksen yksi tuote, vaan useiden yritysten toisiaan täydentävien tuotteiden kokonaisuus – yhteinen hyöty, paremmat mahdollisuudet. **Laki** ✓ Lainsäädännön harmonisointi EU-tasolla PP-yhteistyö ✓ Kohtaavatko työntö julkiselta sektorilta ja tarve yksityiseltä sektorilta? ✓ Kuka tai mikä voi perustaa luotetun partnerin? ✓ Isänmaan etu lähtökohtana? ✓ Verkostotyyppisen toimintamallin toteuttaminen **Avoin data** ✓ Julkishallinnon tietovarantojen avaaminen lainsäädännön ja tutkimusetiikan rajoissa, myös kaupallinen käyttö sallittava ✓ Monet lääketutkimukset tehdään erilaisilla henkilöillä kun todelliset potilaat ovat. Rekisteritiedot tarjoavat ainutlaatuisen mahdollisuuden koska esim. lääkkeiden haittavaikutuksia ja tehokkuutta voidaan tutkia koko populaatiolla.

	Rajapinnat ja teknologia ✓ Yhtenäiset rajapinnat ✓ Tekoälyn käyttö ja big data ✓ MyData: parempi tiedon hallinta, paras suoja, tiedot pidettävä maan sisällä ✓ INTERRHI: kansalliset ja kv. rajat, CDS/ADL, MAPLE-15, ROG-18 ✓ GDPR ✓ Rajapinnat: softa, hardware, wearables, sensorit ✓ Standardit, protokollat, tietokantamääritykset ✓ REST, rajapinnat ✓ Sitra, ihan koodi