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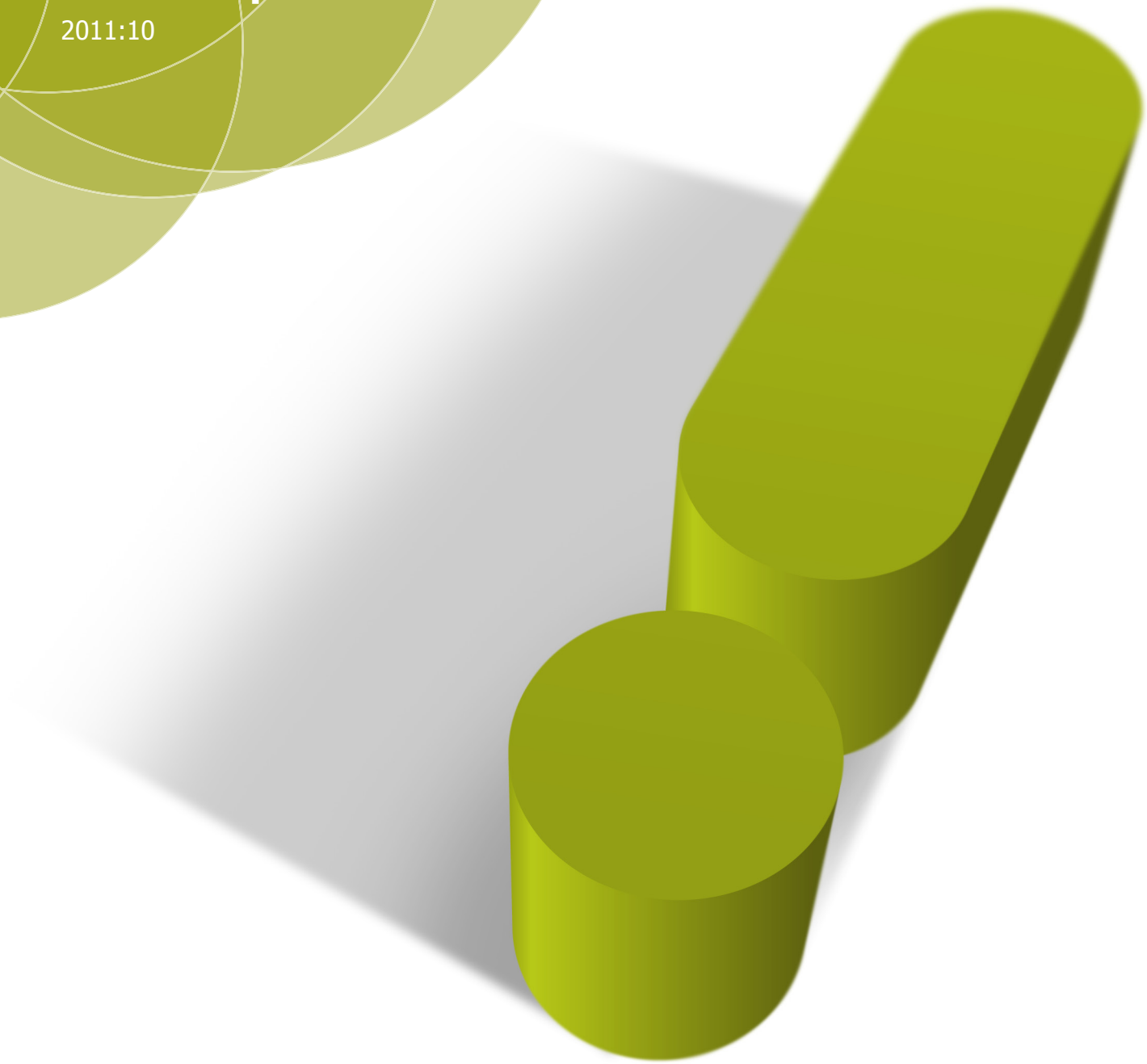

Test Beds in Health Care in the United States, Canada and Japan

- Some examples

This short report on Test Beds in health care in the United States, Canada and Japan has been commissioned by VINNOVA and in turn relates to a commission from the Swedish government to VINNOVA. The purpose of the report has been to describe any national strategies relating to test beds in health care as well as to describe good examples.

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Foreword

This short report on Test Beds in health care in the United States, Canada and Japan has been commissioned by VINNOVA and relates to a commission from the Swedish government to VINNOVA: *Uppdrag att genomföra en satsning med syfte att utveckla testbäddar inom hälso- och sjukvård och äldreomsorg* (N2011/3000/FIN). (Sic: Assignment to perform a program to develop test beds in health care and elderly care). The main purpose of the initiative is to strengthen the innovation capacity in the health care sector and the competitiveness of related companies.

The purpose of this report has been to describe any national strategies relating to test beds in health care and to describe interesting examples of test beds. The following definition has been used:

A test bed is a physical or virtual environment where companies in cooperation with stakeholders in health care can test, develop and introduce new products, services, processes, organizational solutions and business models.

The time available to produce this report has been short which has limited the scope. Considering that there are many test bed initiatives for health care in the U.S. and Canada, it would be of interest to perform a more comprehensive mapping of these in the future. Concerning Japan, no test beds adhering to the above definition have been found during the project. However, questions concerning innovation for elderly care are clearly in focus in the country and a number of initiatives exist.

The report has been produced by Sofie Björling at the Growth Analysis office in Washington D.C., Setsuko Hashimoto at the Growth Analysis office in Tokyo and Martin Wikström (project leader) at the Growth Analysis office in Stockholm.

Stockholm, November 2011

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Summary

National strategies for promoting the creation of test beds in health care have not been found neither in Canada nor the United States, and the term is not commonly used. However, test beds with the definition used for this study; *A test bed is a physical or virtual environment where companies in cooperation with stakeholders in health care can test, develop and introduce new products, services, processes, organizational solutions and business models,* exist in both countries and are often supported by national or federal funding programs. Clearly, academia plays central roles in most of the initiatives found.

In the United Stated, the Agency for Healthcare Research and Quality (AHRQ) as well as the National Institutes of Health (NIH) are important for test beds, in particular through their funding programs. In the case of NIH, which consists of 27 individual institutes and centers, the National Center for Research Resources (NCRR) is of particular importance through its funding of grants and infrastructure to support clinical and translational research. Furthermore, the newly formed National Center for Advancing Translational Sciences (NCATS) will most likely play a central role in the future. However, it is not only the biomedically and health care oriented agencies that are important for test beds in health care. One important example is the *i6 Challenge Competition* led by the Department of Commerce (DOC) and its Economic Development Administration (EDA). The *i6 Challenge* was designed to stimulate innovative new ideas that will accelerate technology commercialization in the United States.

In Canada, Industry Canada (IC-the commerce department), as well as agencies such as the Canadian Institute of Health Research (CIHR), the Canadian Agency for Drugs and Technologies in Health (CADTH) and some other research councils play central roles in supporting test beds. A number of funding schemes are available that could be used by test bed initiatives.

The study has identified a number of different types of test beds of which most are non-profit organizations while others are more commercially oriented. In Canada, all examples described are non-profit organizations that to various degrees are federally funded. In the United States, more diverse examples were found. It should, however, be kept in mind while reading this report that the available time for the project has not allowed a thorough mapping of all existing initiatives.

Interestingly, all but one of the test beds in this report have academic components no matter if they are motivated by commercial or research interests. Furthermore, all the studied initiatives are in some way discipline- or purpose-oriented. While some are directed towards the testing of physical infrastructure, others involve services for the elderly, advanced medical technologies, hospital/care services or biotherapeutics. For many of the test beds, a connection to a hospital is considered to be crucial for operations.

In the more academically motivated cases, the business models are often somewhat unclear and research interests are frequently mentioned as a driver of the activities. Even in cases where companies or other organizations are charged for services the test beds depend on public funds. In addition, the test beds are often not interested in pursuing the intellectual property (IP). The more commercially oriented examples have more clearly defined business models. In the case of the Pfizer/Academic Medical Centers (AMC) test bed, the major driving force is to commercialize research results from the AMCs and to accelerate

the development pipeline. At Kaiser Permanente´s Garfield Health Care Innovation Center real-world scenarios and activities are used to innovate and examine many aspects of delivering health care.

During this short project, we have not been able to find any test bed initiatives for health care in Japan adhering to the definition used. However, innovation for the elderly is clearly important in the country which has one of the largest proportions of elderly citizens in the world. Although test beds have not been found, there are a number of different initiatives relating to health care including the building of communities for the elderly and various research programs. Life Science research and innovation including translation of research results to the clinic is in focus in Japan. Clinical trials take a very long time in Japan and are costly. Therefore efforts are underway to remedy the situation.

For the development of a future Swedish test bed system, the above initiatives are of interest as examples of how various types of test beds may function and be funded. Three identified success factors appear to be; the proximity to a hospital and/or other care providers, the formation of academic-private partnerships and that each test bed focuses on a specific service or type of service, often within a technological or therapeutic area. However, a more comprehensive mapping of test beds in the United States and Canada would be of interest as well as an in-depth study of the effects of test beds on its “customers”.

1 USA

1.1 Federal Initiatives

The United States is currently going through an economic crisis and is, in comparison to several countries falling behind in many aspects, such as education, innovation and competitiveness. In the President´s innovation strategy from 2009[1] encouragement of high-growth and innovation-based entrepreneurship, as well as public sector innovation, are areas of high priority. The President also urges the American people to out-educate, out-innovate and out-build the rest of the world and the private and public part of the society to form partnerships. Test beds are examples of such public-private partnerships. ***There are several examples of test beds in or for health services that open up and give companies access to health care, in order to test, develop and implement new products and/or services in the United States.*** However, as with many things in the United States there does not seem to be a national strategy for creating them. As stated by Kei Koizumi, Assistant Director, Federal Research and Development at OSTP, the Office of Science and Technology at the White House:

"As far as we at OSTP can tell, these test beds are operated and planned independently and there is not a national strategy for coordinating these separate environments. They appear to form as bottom-up responses to the technical needs of specific policy areas."

Even though there is no federal strategy for test beds in health care, there are a lot of discussions on how to spur innovations in the United States in order to create the jobs that are needed to bring the country out of the economic crisis. Most research funding agencies in the United States support translational research, i. e. research that will take an idea all the way to a prototype or market and back to the laboratory. There are several programs that encourage this type of research, including the formation of test beds and a few are described below.

The objective of this short study has been to investigate strategies and give examples of different types of test beds in the health care sector, from truly academic to industry-driven. The choice of the examples described herein has also been partly affected by the response and the willingness of the test bed representatives to answer questions on short notice.

Below can be found short descriptions of some important federal agencies involved in promoting test beds, some examples of specific programs supporting the initiatives and four case studies of different test beds.

1.1.1 Agency for Healthcare Research and Quality

The Agency for Healthcare Research and Quality (AHRQ) is a federal agency under the auspices of the Department of Health and Human Services (HHS) with the mission to improve the quality, safety, efficiency and effectiveness of health care of all Americans. AHRQ supports research that helps people make more informed decisions and improves the quality of health care services. Dr. Michael I. Harrison, Organizations & Systems, Center for Delivery, Organization, and Markets at AHRQ, explains that many of AHRQ´s practice-based and demonstration research projects seek to provide a proof of concept.

[1] *http://www.whitehouse.gov/administration/eop/nec/StrategyforAmericanInnovation/*

These studies also often examine contextual and other factors affecting how and whether an innovation works. In some cases, AHRQ has been able to go from small preliminary studies to more comprehensive large-scale studies and even to national or regional roll outs.

1.1.2 National Institutes of Health

The National Institutes of Health (NIH) is the federal medical research council with a budget of approximately $32 billion per year. NIH comprises 27 institutes and centers, each with a different focus and often its own budget allocated by Congress. A new center is currently in its start-up phase - the National Center for Advancing Translational Sciences (NCATS). The mission of NCATS will be to catalyze the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. It is expected that NCATS will include versions of test beds.

National Center for Research Resources (NCRR)

NCRR is a Center at NIH that provides grants to fund the infrastructure required for translational research projects. Examples of such grants are the Clinical and Translational Science Awards (CTSA) and the **Biomedical Technology Research Centers** (BTRCs). The CTSAs are expected to become incorporated into NCATS. The BTRCs are aimed at creating unique technology and methods, and applying them to a broad range of basic, translational, and clinical research. This is accomplished through interactions between persons with technical and biomedical expertise, both within the Centers and through collaborations with other laboratories.

According to the NIH: "BTRCs serve a unique purpose in the broad context of NIH-funded research. They represent a critical mass of technological and intellectual resources with a strong focus on service and training for outside investigators, as well as dissemination of technologies, methods, and software. Their goal is to promote the widespread and routine application of the cutting-edge technologies they develop across the full spectrum from bench to bedside[2]." An example of a BTRC, the National Center for Image Guided Therapy in Boston, is described in detail below.

1.1.3 i6 Challenge

The i6 Challenge is an innovation competition led by the U.S. Department of Commerce (DOC) and its Economic Development Administration (EDA), which has received a considerable amount of recognition from President Obama´s Administration. The DOC and EDA coordinate the i6 Challenge with NIH, the National Science Foundation (NSF), and the U.S. Patent and Trademark Office (USPTO). The i6 Challenge is designed to "encourage and reward innovative, ground-breaking ideas that will accelerate technology commercialization and new venture formation across the United States, for the ultimate purpose of helping to drive economic growth and job creation. Projects include efforts to drive innovative technologies in the medical and bioscience industries to market more quickly by bringing experts in science and academia together with public and private sector businesses and entrepreneurs[3]." $12 million was awarded in 2010 to six projects, primarily within life science and health care, in six different regions of the country. One of

[2] *http://www.ncrr.nih.gov/biomedical_technology/biomedical_technology_research_centers/*
[3] *http://www.grants.gov/search/search.do?mode=VIEW&oppId=54209*

the winners of the i6 Challenge, the Global Center for Medical Innovation in Atlanta, will be described in detail below.

1.2 Examples of test beds in the United States

1.2.1 The "Operating Room of the Future"-the National Center for Image-Guided Therapy

The National Center for Image Guided Therapy (NCIGT) at Brigham and Women's Hospital and Harvard Medical School in Boston, Massachusetts, is a Biomedical Technology Resource Center funded by NIH via NCRR and the National Institute of Biomedical Imaging and Bioengineering (NIBIB), another NIH institute. NCIGT is the only environment in this study that actually calls itself a test bed, stating: "NCIGT serves as a test bed for new imaging technologies and their application in the operating room, where they can assist surgeons in delivering safer and more effective treatments"[4]. NCIGT is a national resource for all aspects of research into medical procedures that are enhanced by imaging, with the goal to provide more effective patient care. The center is focused on the multidisciplinary development of innovative image-guided intervention technologies. The goal is to enable effective, less invasive clinical treatments that are not only more economical, but also produce better results for patients. NCIGT serves as a testing ground for some of the next generation of medical therapies.

Tina Kapur, Executive Director of NCIGT, explains in an interview that since NCIGT is a non-profit organization that to a large extent is federally funded they are not accustomed to dedicating the Center to specific owners. By regulations, however, the owner of the equipment is Harvard Medical School and the leaders are two researchers at the university. An external review board, with experts from across the country, is part of NCIGT´s governance. Most customers are researchers from other parts of the country as well as abroad. Hospital administrators and industry representatives are frequent customers as well. The personnel at the test bed spend a lot of time doing outreach, i. e. giving workshops and seminars to inform about their work and the possibilities that the test bed offers.

The revenue mostly comes from grants. The hospital will charge for clinical trials, as most hospitals do. NCIGT receives $3 million/year over a period of ten years from NIH, as well as several smaller grants from other funding agencies. Brigham and Women's Hospital in Boston is supporting the Center as are several companies, both in giving discounts on equipment as well as paying for certain services. $25 million was spent in order to construct the facilities, funds received from the NIH and Brigham and Women's Hospital, among others.

NCIGT is called the Operating Room of the Future and includes several research laboratories that mimic real operating and examination rooms, such as the Advanced Multimodality Image Guided Operating (AMIGO) Suite, the Surgical Planning Laboratory, the Focused Ultrasound Laboratory, the Neurosurgery Laboratory and the CIMIT Image Guidance Laboratory (IGT)[5]. Using the laboratories are staff working on numerous research projects of which there are Principal Investigators (PIs) responsible. Currently projects include Structural and Functional Mapping for Neurosurgery, MRT

[4] *http://www.ncrr.nih.gov/ncrr_reporter/summer2008/critical_resources.asp#technology*
[5] *http://www.ncigt.org/*

Data Mining, Slicer Engineering, Blood Brain Barrier Disruption via Focused Ultrasounds, Prostate Focused Ultrasound, Prostate Imaging, Advances Focused Ultrasound Surgery Treatment Planning, Real-Time Imaging Platform for MR Monitoring During Focused Ultrasound Treatments, Real-Time Imaging Platform for MR Guidance of Prostate Biopsy, EPI Distortion Correction, Toolbox to Support Enhanced MR Imaging in Image-Guided Therapy, Improving Spatial Localization in MR Spectroscopic Imaging with PFS-Choice and K-Space Energy Spectrum Analysis for Echo-Planar Imaging[6]. The projects normally receive funding from different funding agencies to do research on their specific topics.

Any scientist or company may contact any of the PIs to discuss a new idea, project or product. If the PI is interested in the project proposed he/she will assist in writing a proposal for a project to be conducted in one of the facilities. The proposal will be evaluated by the internal review board of NCIGT. If the review board approves the project, an agreement between the researcher or company and NCIGT will be signed. The agreement will include writings about Intellectual Property (IP) regulations as well as a project plan.

NCIGT will not make prototypes, but will test existing prototypes of medical devices and conduct clinical trials. Researchers, hospital administrators and industry will come to NCIGT to test products on real patients. There are usually 10-20 companies in the laboratories every day performing development and testing. Most innovations that are tested have already been approved by the Federal Drug Administration (FDA) or are very late into the clinical testing process. NCIGT performes a lot of testing for new applications of existing medical devices that were originally intended and approved for other purposes.

Dr Kapur emphasizes that the Center is still young, but so far a focused ultrasound has been commercialized, as well as a completely new use of a cardiac catheter. She also stresses that a key element to the success of a test bed like NCIGT is its proximity to a hospital.

1.2.2 The Global Center for Medical Innovation

The Global Center for Medical Innovation (GCMI) in Atlanta, Georgia, is a newly formed partnership between the Georgia Institute of Technology, Saint Joseph's Translational Research Institute (SJTRI), Piedmont Hospital and the public-private Georgia Research Alliance (GRA). The Center is planning to bring together the core members of the medical device community including universities, research centers, clinicians, established drug and device companies, investors and early-stage companies.

The goal of the center is to accelerate the development and commercialization of next-generation medical devices and technology. GCMI will help new product teams shorten time to market, enhance their product development, achieve significant cost savings and create new jobs and economic activity. The center includes both a prototyping design and development facility and an initiative to create new approaches for identifying, developing and moving technology from university laboratories, hospitals, companies and other organizations into the marketplace. The EDA expects the center to generate $72 million in new investments and to create or save 161 jobs[7].

[6] *http://www.ncigt.org/pages/Research_Projects*
[7] *http://innovate.gatech.edu/healthcare/medical-innovation-device-prototyping-design-development-center-wins-26-million-funding/*

Wayne Hodges, the Executive Director of GCMI, explains in an interview that the approximately 1200-square-meter facilities will be finished by the end of 2011 and the Center will be open for business in late March 2012.

The above mentioned owners and members of GCMI are non-profits organizations. Georgia Institute of Technology in Atlanta, Georgia, is ranked as one of the top ten public universities in the nation. SJTRI has animal facilities and a new 18-bed, hospital-based facility for phase one and "first in human" testing, focusing on industry and government translational projects. Piedmont Hospital is, as the name reveals, a hospital and GRA is a public-private organization that supports the development of technology industry in Georgia.

GCMI is a non-profit organization (which also means that it is exempt from certain federal taxes) with a board of directors that includes representatives from each member. GCMI has received federal grants of $2.3 million so far, of which $1.3 million was awarded in order to build the facilities as part of the i6 challenge described above. This federal grant was matched by a grant by GRA of $1.3 million. Another $1 million was awarded by the EDA to cover operating costs for two years. Each member will pay $100 000 annually. GCMI is expecting to have approximately ten to twelve members in the future. Each company and individual that is not a member will be charged for the services that are desired while members will be charged a discounted fee for GCMI´s services. If the individual is a researcher with grant money those funds will be used to pay for the services of the Center.

GCMI will provide a continuum of service of all types of ideas, a "one-stop-shop" to companies, researchers and physicians. It will have an infrastructure in order to build a prototype of a device. The facility will include design, material and mechanical engineering resources, and will offer rapid and functional prototyping equipment which may produce a wide range of medical devices for development, pre-clinical testing and clinical studies. A device may be tested in a preclinical setting and in laboratory animals if needed via the collaboration with SJTRI. Clinical testing will be conducted in the hospital setting. A company which needs help to build prototypes or to modify prototypes may stay in the Center for several weeks to work with GCMI´s experts.

The Center may support a company with advice regarding regulatory issues and IP rights and will house IP experts. GCMI has no interest in acquiring the IP rights of participating companies and will sign a contract with the company which includes a release form in order for the company to keep the IP rights to its invention. If GCMI will create a joint venture with a company it might take equity in it. However that will be rare, according to Wayne Hodges. GCMI will be in close collaboration with for-profit organizations to take the collaboration further, if needed.

The process of how the activities will be steered and performed was not all planned out at the time of the interview. The decisions on which company or individual that the Center will work with, will primarily depend on GCMIs own abilities and capabilities at the time. All those interested will have access to the test bed if they pay the fee. Wayne Hodges believes that the customers will be the members as well as companies of all sizes and levels of development (large, small, start-ups etc.) as well as individual researchers. The processes available for companies to join or use the test bed are not all worked out yet, but Wayne Hodges envisions that the Center will be contacted by the party that is interested in using GCMIs services. Representatives from GCMI and the company or researcher will discuss the project to come up with a collaborative agreement that will include milestones.

GCMI will focus on medical devices in the areas of cardiology, orthopedics and pediatrics, as well as the IT solutions of the devices, where they will test how the devices are able to communicate with each other. GCMI could make an artificial knee or elbow, a micro needle array, a stent that could be implanted into an artery, a spine implant that could help to hold discs in place, and GCMI will be able to fabricate, package and sterilize so that the devices could be used in animal or human trials.

There will be no patients directly involved in the activities of the Center, but many companies, clinicians and researchers.

The awardees of the i6 Challenge meet once a year to discuss challenges and give advice to each other on the environments that have been created.

1.2.3 Centers for Therapeutic Innovation

At the end of 2010 the University of California at San Francisco (UCSF) published the following press release: "*UCSF and Pfizer, Inc. formed a new partnership to accelerate the translation of biomedical research into effective new medications and therapies for patients. For UCSF, this expansive agreement represents up to $85 million in research support and milestone payments over the next five years if the partnership leads to the development of significant new therapies for diseases with high unmet medical need. The collaboration is designed to substantially reduce the time required to translate promising biomedical research into new medications and therapies – a process now estimated to take more than 15 years and $1 billion per drug. The partnership, which could advance up to 10 projects at a time, breaks from traditional public-private partnerships by creating an open network of researchers, called the Center for Therapeutic Innovation (CTI). Unlike traditional public-private partnerships, the CTI will foster broad collaboration and exchange between UCSF and Pfizer scientists to help identify promising experimental molecules and quickly move them into proof-of-concept studies and clinical trials*[8]*."* Since 2010, four other laboratories within the CTI have been formed with 19 collaborating partners, of which eight are in the New York City region. According to Alex Fayne, chief operating officer for CTI at Pfizer, the plan is to expand and establish even more CTI laboratories and partnerships, possibly even abroad, in the future. However, during 2012 the model will be evaluated. Collaborations with SMEs could also be possible in the future.

The Centers for Therapeutic Innovation (CTI) are owned by the pharmaceutical company Pfizer Inc. Pfizer is a private company that in order to form CTI has established a global partnership with Academic Medical Centers (AMCs)[9] in different parts of the United States. CTI will perform research on biotherapeutic modalities (antibodies, peptides, and proteins) across all therapeutic areas. The goal of this collaboration is that it will lead to discoveries and development of biologic therapeutic candidates from early research through Proof-of-Mechanism in humans[10].

CTI is funded by Pfizer Inc. which will form partnerships with PIs from the AMCs. CTI will provide AMC PIs with funding (e g, postdoctoral support), technical support (e g, dedicated Pfizer personnel with expertise in protein sciences and development) and

[8] *http://www.pfizer.com/files/news/press_releases/2010/ucsf_press_release_111610.pdf*
[9] *AMCs are university hospitals that include medical students and researchers.*
[10] *Proof-of-Mechanism studies in humans are small, investigator-led clinical trials that typically involve 10 to 30 human subjects and have defined mechanistic or therapeutic endpoints.*

infrastructure (e g, laboratory space, libraries, robots). Alex Fayne explains in an interview that with the creation of CTI, Pfizer has found that it embarks on more developed projects than before, since preliminary research on many projects already has been performed by the academic partners. Pfizer expects to invest $12-15 million per project in making it through Proof-of-Mechanism in humans, which could end up being cheaper than conventional Pfizer projects. Pfizer will fund up to two postdocs per project for two to three years, which will cover most expenses and costs, and include access to the CTI laboratory space. Pfizer may support a certain amount of preclinical and clinical activities. PIs and AMCs may seek external funding in addition to any funding provided by Pfizer as long as such arrangements are consistent with the parties' agreements and do not negatively impact the overall objectives of the project. Alex Fayne expects each CTI to have a capacity of running eight to ten projects per year with a turnover of two to three projects per year.

CTI will contain jointly staffed laboratories located on or near an AMC campus, each with a Pfizer employee in charge. Each laboratory will include Pfizer employees plus prominent basic and translational science investigators and doctoral candidates from the AMCs. The postdoctoral fellows sponsored will provide the core technical expertise for the projects in the laboratory. Pfizer colleagues assigned to CTI laboratories might include: antibody engineers, assay biologists/cellular immunologists, protein scientists and project managers. Pfizer may provide access to company scientists that are not affiliated with the CTI if they have specific expertise that may be of use to a project. Alex Fayne envisions that each CTI will have approximately 25 Pfizer employees and 15 academic collaborators. The Pfizer employees will stay during the life of the CTI while the academic collaborators will differ depending on the projects that are accepted at the CTI.

Governing the partnership is a Joint Steering Committee (JSC), which includes members from Pfizer and the AMC. By sharing equally in the decision-making process, the partners emphasize a true commitment. The JSC will select high-quality projects, monitor timelines and milestone achievements, oversee management of potential conflicts of interest and ensure that leading PIs are involved in the program.

A project will begin with a PI from the AMC or Pfizer submitting a proposal to the JSC which will select projects for funding by the CTI laboratory. A PI from a non-affiliated organization will not be able to submit a proposal, says Suzanne Harnett, Investor Relations at Pfizer in an interview. Alex Fayne explains that CTI has received a lot of attention and interests for collaborations since its start and tries to do matchmaking when approached with proposals from non-affiliated scientists, i e tries to connect the scientists with Pfizer researchers.

Following the JSC approval of a proposal, the PI and lead Pfizer scientist will submit a description of the research plan that includes critical milestones. PIs, postdocs, and scientists will have the possibility to work jointly on research projects within the CTI laboratory and in the PIs laboratories at the AMC. The JSC will review study findings and make go/no-go decisions at each critical milestone. The JSC will review the data to determine if the project should progress to preclinical development once a project has progressed to the stage of a candidate therapeutic protein. The project will gain access to a broad pool of flexible funds to pay for "critical-path" activities if endorsed by the JSC. Prior to the initiation of human clinical trials, the JSC will review the project results. If endorsed by the JSC, the CTI will grant the project additional funds to execute first-in-human studies with a goal of demonstrating Proof-of-Mechanism in humans.

According to Suzanne Harnett, there are very equitable arrangements in the contracts signed by the AMC and Pfizer with milestone payments to collaborators. UCSF wrote in its press-release that "Pfizer is offering liberal intellectual property and ownership rights to support continued experimentation and exploration, as well as broad rights to publication – often a sticking point in traditional academic-industry relationships[11]." Alex Hayne explains that the way Pfizer treats the IP in CTI is quite "radical" and enlightened. He describes three possible IP scenarios:

- If the academic collaborator brings IP into the collaboration it will keep the IP ownership but Pfizer may license it.
- If Pfizer brings IP into the collaboration it will keep the IP ownership.
- If the IP arises from results Pfizer and AMC have created together it is jointly owned to the same degree.

According to Alex Hayne this is a very new way for Pfizer of dealing with IP, and changes the mindset of how the academic partners look at the partnership.

There have been no products commercialized stemming from this collaboration yet. As stated earlier, this process normally takes more than 15 years. The hope is that, with the creation of CTI, it will be shorter.

1.2.4 Kaiser Permanente´s Garfield Health Care Innovation Center

In the United States, a health maintenance organization (HMO) is a type of managed care organization that provides a form of health care coverage, fulfilled through hospitals, doctors, and other providers with which the HMO has a contract. Kaiser Permanente (KP)[12] is one of the largest not-for-profit HMOs in the United States, serving more than 8.6 million members. Most of these (6.5 million) live in California, Oregon and Washington State while the rest are scattered in a few other states. The organization comprises Kaiser Foundation Health Plan which is the insurance part of the organization, Kaiser Foundation with subsidiaries including its hospitals, and the Permanente Medical Groups which includes KPs medical staff. KP has 35 hospitals, 454 medical offices, 15 129 physicians and over 164 000 employees. HMOs seem more prone to doing work in preventive care than regular insurance companies, which do not appear to see any financial benefit of such activities. KP runs many preventive care activities[13] and resembles Swedish health care in many ways. It has patients of all ages and both genders that are somewhat geographically spread-out and takes responsibility for all of the patients care, including preventive care.

The Garfield Innovation Center is part of KP and opened in June 2006. It is located in San Leandro, California. The Center is jointly funded by Kaiser Permanente's National Facilities Services (NFS), Information Technology (KP-IT), and National Patient Care Services (PCS) groups and is created as a resource for all of KP and its regions.

The Garfield Innovation Center is a living laboratory where ideas are tested and solutions developed in a hands-on, mocked-up clinical environment. Real-world scenarios and activities including simulations, technology testing, prototyping, product evaluations and training are used to innovate and examine many aspects of delivering health care.

[11] *http://www.pfizer.com/files/news/press_releases/2010/ucsf_press_release_111610.pdf*
[12] *https://members.kaiserpermanente.org/kpweb/aboutus.do*
[13] *https://www.kaiserpermanente.org/*

Initiatives found successful after initial testing at the Garfield Center may undergo additional testing in live patient environments at various KP medical centers, medical offices, and clinics across the nation.

Care providers, patients, and designers collaborate to test, improve or innovate physical spaces, technologies or clinical operations. Participants physically enact their ideas to see and feel how they work in the Garfield Center's four innovation zones: home, clinic, hospital and prototyping. The center contains mock setups of a Labor Delivery Room, an Operating Room, an Emergency Treatment Room, an Inpatient Unit Core, Outpatient Settings and a Home Environment, among others.

According to Jennifer Liebermann, Garfield Center Director "The most exciting aspect of the Garfield Center is that it connects the groups who need to work collaboratively to develop technologies and facilities. It is always a challenge in health care to break out of our silos and the Garfield Center provides an exciting physical space that energizes our staff to work collaboratively on innovations which will provide our members with the best care[14]."

Information Technology, medical equipment, supplies and processes are tested at the Garfield Center. Teams of engineers, architects, designers, technologists, doctors, nurses, clinical support staff and patients (called members at KP) join forces to innovate at the Garfield Center. KP stresses that they design for the members and care providers - the people who actually are involved and/or are receivers of health care services and experiences.

Jennifer Liebermann explains that all the tests performed at the Center are initiated by Kaiser and also stresses that it is not a general place for entrepreneurs to test products. Connected to the Center are different specialty groups responsible for testing technology, devices, clinical technology, design and care delivery environment. There are two ways that products and processes can be accepted for testing. Either an employee or medical group anywhere within the KP system applies to an internal fund in order to test an idea, or one of the specialty groups applies to do testing.

The Governance Group comprised of the heads of the different specialty groups and the Director prioritizes among the suggestions submitted and decides on the Center´s activities. The Innovation and Advanced Technology group has the task of deciding which future innovative technologies and processes that KP will look into. Each year it will pick three topics for the coming year on which the Center will focus its activities. An example of this is "the Patient Room in the Future".

When a specific area to test has been decided upon, the Center will offer approximately 20 vendors with products in that specific area the possibility to demonstrate and test their products at one of the mock settings at the Center, for example the Labor Delivery Room. Partaking in the testing will also be decision makers from KP, who eventually will be making the decisions on which products to be used in the future. Jennifer Liebermann explains that the Center is not involved in the decision process of which products to buy.

KP does not reveal how much funding the Center requires each year. Between 300 and 600 events are staged every year at the Center, which often means that there are three to four concurrent tests per day. Some tests take one day and others last for a longer period.

[14] *http://xnet.kp.org/innovationcenter/about/index.htm*

Vendors that want to test and show their products at the Center are provided with contact information on the Center´s website[15]. It is only if the product fits into the Center´s objectives that the company is invited to partake in an event. Most products or ideas are already commercialized when they are tested at the Center and it is quite rare that the Center will get involved in co-development with an entrepreneur. If co-development does happen the entrepreneur will keep the IP. However, according to Jennifer Liebermann KP is working on a different approach to IP for the future.

1.3 Conclusions

The two, mainly federally funded, examples described herein are non-profit organizations integrated in a university and research setting, often with close ties to one or more hospital(s) in the close vicinity. The National Center for Image-Guided Therapy in Boston is truly an academic research initiative, and it has not been possible to find a clear specific business model or processes rigidly in place. It is open to all and will, as most other test beds investigated, charge companies for using its facilities and collaborate on projects. This academic environment also has the goal of publishing its research findings in expert journals. The Global Center for Medical Innovation in Atlanta is slightly more commercially oriented, with long-term goals of creating jobs and economic activity in the region. It is a partnership between several organizations which will pay for the services of the Center as members and also external users will. It is now specifying plans for its governance and its processes concerning how to take an idea to market.

Coordination activities for the test beds on a national level have not been found. Each agency that grants funding for programs will usually gather its recipients once or a few times per year to learn about their progress as well as to discuss challenges and opportunities.

In addition to the federally funded test beds described above, two privately owned examples are also included in this study - the Centers for Therapeutic Innovation and Kaiser Permanente´s Garfield Health Care Innovation Center. The first is run by the large international pharmaceutical company Pfizer Inc. and focuses on getting products to clinical trials. There are detailed directions and instructions on Pfizer´s website about the business models and governance of the CTI, and how projects should be run. The test beds are only open to partners, which at this point are the Academic Medical Centers across the country. It demonstrates a novel approach to public-private partnerships and the treatment of IP, which should be of interest to Swedish stakeholders. Kaiser Permanente´s Garfield Health Care Innovation Center is completely privately owned and will test and develop ideas and solutions that KP has a need for in a hands-on, mocked-up clinical environment.

This study has been performed during a short time, and not enough time has been available to perform deep analysis. However, some issues for Swedish stakeholders to consider are:

- There are many interesting examples of test beds in the health care sector in the United States, of which only a few have been described herein. The i6 Challenge seems to be an interesting form of support as well as the public-private partnership of CTI.
- Swedish stakeholders should consider a more detailed study of specific test beds including site-visits.

[15] *http://xnet.kp.org/innovationcenter/about/vendors.htm*

- A key element to the success of a test bed in the health care sector seems to be to locate it in close proximity to a hospital. This was stated in the interview with NCIGT, but is also obvious since Pfizer is setting up many laboratories close or on campus of AMCs across the country. Kaiser Permanente´s Garfield Health Care Innovation Center has close ties to Kaiser Permanente´s regular operations, which include hospitals and health care practices.
- Bringing Swedish and international test bed initiatives together for joint meetings could be valuable for sharing experiences and best-practices.

2 Canada

2.1 Federal Initiatives

Canada has a wealth of natural resources, and its oil, gas, metals and timber have created a rich country, but also an industry that has not have had to depend on advanced research to be profitable. This has led to a relatively weak innovation system that often fails to commercialize its innovations. The Canadian government has ambitions to change this in the future. A newly published report commissioned by the government critically discusses the structure of the Canadian research and innovation system. The report was named the Jenkins-report, and suggests several changes in the structures currently in place in order to stimulate industry-research as well as collaborations between academia and the private sector[16].

There are federal and regional initiatives in place to support translational research, i. e. research that will take an idea all the way to a prototype or market. Most funding agencies support this kind of research and collaborate in many such programs in order to also promote multi-disciplinary research. ***There are several examples of test beds in the health care sector in Canada that open up and give companies access to health care, in order to test, develop and implement new products and/or services.***

It has not been possible to find a national strategy for the formation of test beds. There are however several programs that encourage collaborations between industry and academia, of which some are described below. The objective of this short study has been to investigate strategies and give examples of different types of test beds in the health care sector. The choice of the examples described herein has also been partly affected by the response and the willingness of the test bed representatives to answer questions in a very short time span.

Below can be found short descriptions of relevant federal agencies as well as examples of specific programs supporting test bed initiatives.

2.1.1 Industry Canada

Industry Canada (IC) is a department of the Canadian federal government. Under its auspices are the major federal research funding organizations, except the medical research council - the Canadian Institutes of Health Research (CIHR). ICs mission is to foster a growing, competitive, knowledge-based Canadian economy[17]. The department is involved, jointly with its agencies, in most federal initiatives that are aimed at promoting innovation and commercialization.

2.1.2 The Canadian Agency for Drugs and Technologies in Health

The Canadian Agency for Drugs and Technologies in Health (CADTH)[18] provides decision-makers with the evidence, analysis, advice, and recommendations they require to make informed decisions regarding health care. Funded by Canada's federal, provincial, and territorial governments, CADTH is an independent, not-for-profit agency that delivers timely, evidence-based information to health care leaders about the effectiveness and

[16] *http://rd-review.ca/eic/site/033.nsf/eng/h_00287.html*
[17] *http://www.ic.gc.ca/eic/site/ic1.nsf/eng/h_00018.html*
[18] *http://www.cadth.ca/en/cadth*

efficiency of health technologies and conducts efficacy/technology assessments of new health products. CADTH responds to requests from federal, provincial, and territorial health ministries, health authorities, hospitals and national and regional health care programs on many different issues. Examples include 1) rigorous review of the cost-effectiveness of a drug, 2) comprehensive, evidence-based analysis of a health technology or technologies, 3) information and decisions about health policy, purchasing, service management, and 4) clinical practice and projects designed to encourage the optimal use of a health technology or technologies by health care providers, policy-makers and consumers.

2.1.3 Networks of Centres of Excellence

In order to foster research partnerships between academia, industry, government, and not-for-profit organizations, Networks of Centres of Excellence programs were initiated in 1989 to "turn Canadian research and entrepreneurial talent into economic and social benefits for all Canadians[19]." The Networks of Centres of Excellence is a joint program of the Natural Sciences and Engineering Research Council of Canada (NSERC), the Social Sciences and Humanities Research Council of Canada (SSHRC), CIHR and IC[20]. There exist four types of NCEs: Networks of Centres of Excellence (NCE); Centres of Excellence for Commercialization and Research (CECR); Business-Led Networks of Centres of Excellence (BL-NCE); and Industrial Research and Development Internships (IRDI)[21]. In 2007, the Government of Canada invested CAD[22] 285 million over five years to create the CECR program. CECR aims to create Centers that advance research and facilitate commercialization of technologies, products and services within the four priority areas identified in the federal Science and Technology (S&T) Strategy. The four areas are: Environment; Natural Resources and Energy; Health and Life Sciences; and Information and Communications Technologies[23]. An example of a CERC, the Center for Drug Research and Development in British Columbia is described in detail below.

2.1.4 College and Community Innovation Program - Innovation Enhancement Grants

The College and Community Innovation Program is a collaborative initiative between NSERC, SSHRC and CIHR in order to enable colleges to develop or expand research transfer activities in their communities through partnerships with local companies, particularly small and medium-sized enterprises (SMEs). The objective of the grants is to increase innovation at the community level by enabling Canadian colleges to increase their capacity to work with local companies. Applied research and collaborations that facilitate commercialization are supported, as well as technology transfer, adaptation and adoption of new technologies[24]. An example of a College and Community Innovation Program, Sheridan Elder Research Centre (SERC), will be described in detail below.

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[19] http://www.nce-rce.gc.ca/About-APropos/Index_eng.asp

[20] http://www.nce-rce.gc.ca/About-APropos/GrantingAgencies-OrganismesSubventionnaires_eng.asp

[21] http://www.nce-rce.gc.ca/About-APropos/Index_eng.asp

[22] 1 Canadian dollar = 6.60032 Swedish krona, on November19, 2011, http://www.x-rates.com/d/CAD/table.html

[23] http://www.nce-rce.gc.ca/NCESecretariatPrograms-ProgrammesSecretariatRCE/CECR-CECR/Index_eng.asp

[24] http://www.nserc-crsng.gc.ca/Professors-Professeurs/RPP-PP/CCI-ICC_eng.asp

2.1.5 NRC Industrial Research Assistance Program

The National Research Council (NRC) is a federal organization under IC that primarily supports intramural research at more than 20 institutes located in all provinces of Canada in order to stimulate community-based innovation. It also supports national programs, spanning a wide variety of disciplines[25]. The previously mentioned Jenkins report on the structure of the Canadian research and innovation system suggests large changes in the organization of NRC, as well as the formation of a new entity outside of NRC that will house the Industrial Research Assistance Program (IRAP)[26].

The NRC is in charge of IRAP, which provides technology assistance to SMEs at all stages of the innovation process in order to build their innovation capacity. The goal of IRAP is to help SMEs understand the technology issues and opportunities and provides linkages to the best expertise in Canada[27]. An example of a test bed that is used by IRAP grantees, the Living Lab in British Columbia, is described in detail below.

2.2 Examples of Canadian test beds

2.2.1 Center for Drug Research and Development

The Centre for Drug Research and Development (CDRD) in British Columbia is a Canadian not-for-profit research center that was formed in order to bridge the commercialization gap between drug discovery and private investment. CDRD creates partnerships between academia, industry and government and collaborates with a network of over 1,200 Principal Investigators (PIs) from 20+ affiliated research institutions. CDRD has supported close to 100 research projects since it started 2006. It claims that it provides state-of-the-art drug development facilities, specialized scientific and business expertise, and professional project management needed to advance the technologies to a stage where they are sufficiently de-risked for private sector consideration.

CDRD has a commercial arm, CDRD Ventures Inc. (CVI), which is at the interface between CDRD and industry. CVI in-licenses selected intellectual property generated from CDRD projects directly from the affiliated institution or inventor. CVI also forms partnerships with pharmaceutical and biotech companies to further develop and commercialize technologies. Profits from CVI are invested back into CDRD in order to support further ongoing drug-development projects[28].

Natalie E Dakers, CEO of CDRD, explains in an interview that the owners of CDRD are the members and directors, with a board consisting of representatives from affiliated institutions, industry, and the life sciences research and development community. The board oversees and provides direction to the mission and objectives of CDRD. The setup of having both a non-profit and a for-profit part of this type of organization is very unusual, according to Natalie Dakers.

The customers are primarily CRDR-affiliated universities and organizations, including the University of British Columbia, Simon Fraser University, University of Victoria, University of Northern British Columbia, Children's and Women's Health Centre, British Columbia Cancer Agency, Providence Health Care, Vancouver Coastal Health, and the

[25] *http://www.nrc-cnrc.gc.ca/eng/about/index.html*
[26] *http://rd-review.ca/eic/site/033.nsf/eng/h_00287.html*
[27] *http://www.nrc-cnrc.gc.ca/eng/ibp/irap/about/mandate.html*
[28] *http://www.cdrd.ca/*

British Columbia Provincial Health Services Authority, and also non-affiliated research institutions and companies. Natalie Dakers says that CDRD have had discussions about a possible collaboration with Karolinska Institutet.

CDRD became a CECR in 2007 and has received CAD 15 million for the years 2008-13 from the program. CDRD also receives funding from the Canada Foundation for Innovation, the Canadian Institute for Health Research, the Province of British Columbia as well as from affiliated universities, organizations and companies. CDRD, or affiliated researchers, might also apply for funding from the regular funding agencies for specific projects.

A university or company will usually approach CDRD to discuss a project. CDRD has certain criteria that need to be fulfilled in order to take on or continue to work on a project when it has commenced. The criteria are described in detail on CDRDs website. A Project Development Committee (PDC) determines which projects that are selected for development within CDRD and oversees the progress of all projects. The PDCs membership includes the CDRD executives (CEO and Scientific Director), division chairs, strategic advisors and independent experts.[29]

The facilities and expertise of CDRD includes target validation, drug screening, medicinal chemistry, drug delivery, pharmacology and toxicology, as well as biologics[30]. If a project is approved by PDC, experts from both the university or company and CDRD will work on the project. CDRD assigns a Project Champion to each project and a project plan is created for the project team to adhere to. Project Champions have over 10 years of experience in drug development combined with project management skills from the biotech and pharmaceutical industries. Their job is to help PIs advance projects from discovery to the preclinical proof-of-concept stage. CDRD projects work in cycles of six to nine months with well-defined project milestones that include "Go"/"No Go" points. A typical project will need to proceed through between two and four cycles before being considered ready for commercialization. A comprehensive technology dossier is prepared on final project completion, summarizing all data and information generated for each project[31]. CDRD has internal and external review teams to evaluate the project as it develops. CDRD runs approximately 20 concurrent projects.

CDRD signs agreements with the universities they are affiliated with as well as for individual projects with other collaborators. For each project CDRD is engaged in, project agreements, stating if Intellectual Property (IP) will be shared, as well as milestones and other specifics about the project, are formulated. According to CDRD[32]:

- The principal investigator and his or her affiliated institution maintain control of all pre-existing IP.
- Any new intellectual property created by the principal investigator remains the property of the principal investigator and his or her affiliated institution in accordance with the institution's IP policy.
- The principal investigator retains the right to publish all results.

[29] *http://www.cdrd.ca/working-cdrd*
[30] *http://www.cdrd.ca/target-validation-0*
[31] *http://www.cdrd.ca/working-cdrd*
[32] *http://www.cdrd.ca/faq*

- CDRD works together with the principal investigator and the technology transfer offices at affiliated institutions to determine the best course for each technology on a case-by-case basis.
- In return for the contributions made by CDRD, CVI, the commercial arm of CDRD, has only a first right to negotiate on terms for a license to technology arising from CDRD projects. CVI is allowed 90 days in which to make a decision as to whether it would like to license the technology or not. During these 90 days the technology transfer office cannot out-license the technology. If after 90 days CVI does not want or cannot come to an agreement, the licensing option is terminated.
- CDRD also considers technologies for in-licensing as well as opportunities for strategic partnerships with pharmaceutical and biotech companies to attract funding and advance promising technologies through development. Programs will eventually be out-licensed to pharmaceutical or biotech partners or spun off as life science companies. Profits from CVI flow back to CDRD to continue to support ongoing drug-development projects, operations, facility improvements, and equipment renewals. CVI will help CDRD become self-sustaining.

Researchers are encouraged to become members of CDRD on the Center´s website and will be supported in applying for grants, both CDRD´s own collaborative grants with Pfizer and Genome British Columbia, as well as from other granting agencies. There is no fee to become a member researcher. Companies are also welcome to approach CDRD with project ideas.

Work at CDRD has led to commercialization of a new delivery mechanism for a cancer drug as well as preclinical trials for a peptide to be used against cystic fibrosis. A project involving liposomes is also promising, according to Natalie Dakers.

The different CECRs interact with each other. The leaders meet once a year to inform about their work and discuss challenges. Sometimes they also run joint projects.

2.2.2 Sheridan Elder Research Centre

"From Lab to Life®"

The Sheridan Elder Research Centre (SERC) in Ontario, opened in September 2003. At SERC applied research into areas of practical concern and immediate relevance to older Canadians is conducted. The goal of SERC is to identify, develop, test and support implementation of innovative strategies that improve the quality of life for older adults and their families. The approach to the research builds on the personal strengths of older adults and seeks to empower them, their families and their communities. SERC continually seeks collaborative research, practice and education partnerships with SMEs, the community and academic leaders. SERC's research interests include: Creative and Performing Arts, Learning in Retirement, Civic Engagement, The Built Environment, Aging in Place and Product Design[33].

Pat Spadafora, SERC´s Director, explains in an interview that SERC was founded as part of Sheridan College and as such is a non-profit organization. SERC has several external partners that vary over the years depending on which projects the organization is working

[33] *http://www.sheridancollege.ca/Services/Sheridan%20Research/Centres/SERC.aspx*

on. Companies and academic researchers will do testing, mostly of different services and processes, at the Center.

SERC is funded through government grants as well as contributions from industry collaborators. The industry collaborators mostly participate with in-kind contributions, such as their time, software etc. SERC is solely dependent on grants and the grants received constitute the budget the Center has to work within. The Center will be staffed according to the funding situation. In 2010 it was granted a five year grant within the College and Community Innovation Program of a total of CAD 2.3 million. The project is titled "Aging in Place: Optimizing Health Outcomes through Technology, Design and Social Innovation" and focuses on enhancing the quality of life of older Canadians and their families. SERC has also received grants from CIHR.

Any company or academic researcher is welcome to contact SERC´s Director in order to discuss collaborations with the Center. SERC is now in the process of setting up a service on its website in order to make contacts easy. If the area of the project is in the realm of SERCs interests and mandate of its grants, Pat Spadafora will meet and discuss the project with the company representatives. SERC has an Advisory Board that meets three times a year to discuss the objectives and progress of the Center. Pat Spadafora will sometimes discuss potential projects with the Advisory Board and always with colleagues at SERC or the Sheridan College. She will decide on which projects the Center will be working on.

When a project has been approved, SERC will assemble a team of experts and students in order to develop it. Sometimes the experts will include elderly people, since they are the target group of the projects. Sheridan College is comprised of many different experts that often work on projects at SERC. Student involvement is very important to the college. A contract will be written between SERC and the company, where the IP rights are given to the company. If any results are commercialized, SERC´s only demand is that they may be used for educational purposes at Sheridan College. Milestones are set up during the course of the project, in order to make sure it is on the right track.

One unique aspect of the Center is the extensive interaction with the community and involvement of its elderly in testing the different projects that the Center works on. SERC mostly focuses on creating and performing arts and technology that will make elderly stay healthy, but might work on other projects as well. As an example of the latter is a project that SERC is currently working on that involves testing of food-blends for elderly patients in nursing homes.

Companies that SERC has worked with have commercialized software interfaces to make it easier for elderly to use applications such as Facebook, as well as translations of interfaces into other languages to make it easier for older immigrants. Many of the activities of SERC are in the areas of creative and performing arts and there are few examples of commercialization in those areas. Pat Spadafora is speculating that the development of a dance protocol, for example, could potentially be transformed into a course that could be commercialized in the future.

The different colleges that have received a College and Community Innovation Program grant have a group that convenes via teleconference several times per year to discuss best practices among other practical things. Pat Spadafora highly values being part of such group.

2.2.3 Dr. Tong Louie Living Laboratory

Named after the late Dr. Tong Louie, the Living Lab in British Columbia is a joint venture between British Columbia's Institute of Technology (BCIT) and Simon Fraser University. The facility's primary mandate is to conduct research and training activities that make the daily living and working environments of people work better. This is done by studying the interaction of people with devices, assistive technology, other products and environmental features.

Christine Flegal, Research Program Head, Technology and Product Evaluation Group at BCIT and the Living lab, explains in an interview that the Living Lab is a non-profit educational organization where researchers from BCIT and private companies will evaluate their projects. The Lab has two full-time employees and approximately 50 affiliated researchers that are active in different research groups at BCIT.

The Lab occupies approximately 140 square meters and contains a large open space (the Experimental Studio) resembling a movie set that allows researchers to simulate any built environment. The space can for example be transformed into a simulated home, a workplace or other environments. A viewing theatre allows observers to monitor activities in the Living Lab without intrusion or distraction of the research activities or participants, since it is constructed with one-way glass.

The Living Lab has a data acquisition and analysis center equipped with a sophisticated motion analysis system. Researchers are able to record and quantify the interactions of the occupants of the Living Lab and the environment or product being studied within it, using this system. The complete system allows two-way communication throughout the Lab's spaces, which makes it a tool for behavioral observation, ergonomic analysis and physiological monitoring.

Research at the Living Lab entails evaluation of new or existing products, technologies or processes, for example through product feasibility studies, market and focus group research, product design, prototype fabrication, human factors testing with target users, clinical trials, and behavioral observations. At the Lab simulation and ergonomic/biomechanical analysis of tasks or procedures as well as simulation and analysis of training procedures are also performed. Another example of research at the Lab is environmental design research, for example when the most effective bathroom or kitchen design for older adults and/or persons with disabilities is studied.

Researchers at the Living Lab have many skills, including; product evaluation, human kinetics, prosthetics and orthotics, gerontology, assistive technology, urban studies and planning, biomechanical engineering and disability research[34].

The Living Lab is funded to 40 percent by British Columbia government funds, the Public Health Agency of Canada and the IRAP program. The laboratory space is donated by BCIT. The rest of the funding, 60 percent is received through grants from government and industry, which are constantly being applied for in order to support the research projects at the Lab.

The Living Lab advertises its services and markets its Lab through their researchers. Christine Flegal also attends meetings and conferences that sometimes have match-making sessions between companies and test beds like the Living Lab.

[34] *http://www.bcit.ca/appliedresearch/tc/facilities/livinglab.shtml*

The research at the Technology Center at BCIT, to which the Living Lab is a facility, is organized in four research groups: The Group for Advanced Information Technology, Natural Health and Food Products Research Group, Products and Process Applied Research Team and Technology and Product Evaluation Group. All these groups have access to the Living Lab, as well as other specialized laboratories at BCIT. Any entrepreneur or company may contact any of the research groups with a suggestion of a joint project. If it is decided after a few meetings with the leaders of a specific research group, as well as with Christine Flegal, that the Living Lab is required for the work, a proposal is written by the entrepreneur. The BCIT will evaluate the proposal and if accepted a contract between the entrepreneur or his/her company and BCIT will be signed. The contract will contain an IP policy. BCIT is generally not interested in pursuing the IP rights of a product or process that has been tested in its laboratories. The project will include several milestones during its course.

The most commonly tested innovations in the Living Lab are medical devices and different technologies and processes. Christine Flegal describes that they have converted the Lab into mimicking a bus stop, a bath room and a restaurant, in order to test different products or processes. The community is often involved in testing like these, and they specifically target seniors and disabled persons. Companies they have worked with have commercialized a walk-in bathtub for seniors and have improved the design of catheters. In the latter case users, in this case nurses and medical professionals, where brought in to test the catheter. Company representatives could then see, through the one-way glass in the viewing theatre, that the catheters were not used in the way they were intended. After this experiment the company could adjust the instructions of the catheter in order to commercialize it.

2.2.4 Canada Health Infoway

Canada Health Infoway (Infoway) is an independent not-for-profit organization funded by the federal government. It was founded in 2001 with the mission to foster and accelerate the development and adoption of electronic health record (EHR) systems with compatible standards and communications technologies in Canada.

Infoway collaborates with health care providers and technology solution providers. It runs programs that promote the active engagement of clinical practitioners, physicians, nurses, pharmacists and other health care providers in the implementation of electronic health information systems across Canada. Infoway enables best practices and successful projects in one region of Canada to be shared and replicated in other regions[35].

Infoway plays two key roles in the development of Canada's EHR: It collaborates with Canada's provinces and territories to select and fund EHR projects across the country and it has also developed the EHRs Blueprint for Canada in collaboration with the provinces and territories. This Blueprint serves as the model, standard and vision for connecting Health-IT (e-health) systems in Canada[36].

Shelagh Maloney, Executive Director, External Liaison, Consumer Health and Innovation, Canada Health Infoway, explains in an interview that Canada´s Deputy Ministers of Health own Canada Health Infoway. It is an independent non-profit organization with 50 Board of

[35] *https://www.infoway-inforoute.ca/lang-en/working-with-ehr/health-care-providers*
[36] *https://www.infoway-inforoute.ca/working-with-ehr/solution-providers*

Directors from the public and private sectors. The customers are the health care providers of the ten provinces and three territories that comprise Canada.

Infoway has received CAD 2.1 billion since 2001, when it was founded. All funding comes from the federal government but it is not allocated every year. In 2010 Infoway received CAD 500 million, from which CAD 350 million was allocated for the development and adoption of EHR systems. Infoway pays 75 percent of the cost of the infrastructure and the province pays the rest. Since operating costs are also incurred, the cost-sharing will usually end up equal between Infoway and the province in question. Infoway pays the funds to the provinces after milestones have been achieved in the installment and use of the product, usually during 24-48 months.

Infoway does not develop electronic health information systems, but tests that the systems fulfill the set Blueprints for Canada. It also has a mandate to encourage Canadian regions to adopt such systems. This usually involves changing the management system of the region which is a big challenge, according to Shelagh Maloney. Infoway has a lot of knowledge of the different solutions that are on the market, as well as contacts with different vendors, and can therefore recommend solutions to the province in question. Since Infoway also has developed the standards for connecting different health information systems in Canada, the solutions it will recommend will adhere to these standards. Infoway will give free advice to vendors of such systems, in order for them to understand the needs of the Canadian market. The different regions are responsible for testing the systems and adopting them to their specific needs, if necessary.

The activities of Infoway are governed by the five senior Vice Presidents (VP), each one responsible for a different part of Canada. One of the VPs is approached by representatives of the health care system in their region of responsibility, when they have a need for a new health information solution. The VPs evaluate the request, with the help of expert groups comprised of nurses, clinicians, pharmacists and other health care professionals. If the province in question is prepared to change its management system to adapt it to an electronic health information system and if the product fulfills the standards set by Infoway, the VP will bring it to the CEO for prioritization. Normally Infoway uses the first-come-first-serve approach when it is approached by the provinces, i. e. the province that submits the first request will receive the help it asks for (as long as there is money left). According the Shelagh Maloney this is not always how funds for the different Canadian provinces are allocated; the more populated provinces usually get precedence.

Infoway does not normally become involved with contracts and agreements as the provinces and the vendors are responsible for the formal arrangements. If Infoway pays for any customization of a system, the vendor of that product is forced to provide the system for free to the rest of Canada. Infoway will not try to secure part of the IP of the product in that case.

Any company may contact Infoway if it has developed a Health-IT solution. On the organizations website, companies are encouraged to contact the organization to demonstrate their products[37].

The health care providers in the provinces are very much involved in choosing the appropriate vendor for the IT solutions required. Shelagh Maloney stresses, however, that in terms of innovating new products, Infoway is not that much involved. It mostly engages

[37] *https://www.infoway-inforoute.ca/working-with-ehr/solution-providers*

in effort to make the provinces change their management systems and adopt Health-IT solutions.

One, if not the most successful EHR solution adopted to date, has been Alberta´s Netcare EHR Portal. The portal´s technology makes patient information such as test results, prescription history, allergies and relevant demographic information available immediately to providers at the point of care[38].

2.3 Conclusions

The four examples described herein are all federally funded to different extents. They are all non-profit organizations, two of them, the Sheridan Elder Research Center in Ontario and the Living Lab in British Columbia are closely integrated with its collaborating university. Sheridan Elder Research Center, being connected to a College, heavily involves students in its activities, and uses its findings in its classrooms. At the college the community is heavily involved as well, which seems to be a fruitful collaboration. As is common with academic environments, the business processes do not appear explicitly defined and do not seem to follow specific and detailed protocols. The Centre for Drug Research and Development in British Columbia is run in a very different way, with the governance and the development of projects planned and described in detail. It is obvious that this Center is geared towards commercialization. Its arrangement with a non-profit and a for-profit part of its organization is a very interesting arrangement that seems to be working effectively.

The last environment studied in this inquiry is Infoway, which is a very different type of organization compared to the previous. Infoway ensures that different Health-IT solutions adhere to the standards for Canada that Infoway has decided upon. It also promotes Health-IT to the different Canadian regions and gives advice on which Health-IT solutions that would be the most suitable for the specific need of that region.

Activities to coordinate these test beds on a national level have not been found. Each agency that grants funding for a program will usually gather its recipients once or a few times per year to learn about their progress as well as to discuss challenges and share opportunities of the initiatives.

This study has been performed during a short time, which has made deep analysis impossible. However, a Swedish stakeholder may consider that:

- There are many interesting examples of test beds in the health care sector, of which only a few have been described herein. The Center for Commercialization and Research as well as the College and Community Innovation Program in particular, seem to be interesting forms of support.
- The CDRD has an interesting arrangement, in which CVI, the for-profit arm of the non-profit CDRD, will help CDRD to become self-sufficient. This will be needed at the time when the CECR grant expires.
- Swedish stakeholders should consider a more detailed study of specific test beds including site-visits.

[38] *https://www2.infoway-inforoute.ca/Documents/ar/Annual_Report_2010-2011_en.pdf*

- In several of the examples described herein, involvement of the community of the test bed is an important factor, and should be considered in potential Swedish initiatives.
- Bringing Swedish and international test bed initiatives together for joint meetings should be valuable for sharing experiences and best-practice.

3 Japan

3.1 National Strategies of Green and Life Innovation

Japan has seen its relative global competiveness gradually decline. Still, Japan remains the third largest economy in the world, with some of the worlds' leading and most innovative companies. From a governmental policy level, there have been a number of initiatives and growth strategies put into place, however often by individual ministries and with a lack of coordination. Following the historical change of government in 2009, the new government set out to develop a comprehensive growth strategy and the Council for the Formulation of a Growth Strategy was chaired by the Prime Minister. On June 18, 2010, the 10 Year perspective New Growth Strategy: Blueprint for Revitalizing Japan was released and "Green Innovation" and "Life Innovation" were the two main pillars for growth. Following the Great East Japan Earthquake in 2011 government promoted efforts to reinforce growth capacity to overcome the challenges, with the concept of "Open Reconstruction". The 4th Basic Science and Technology (S&T) Plan, with a five year perspective, originally to be released by April 1, 2011, but delayed until Aug. 19, is in line with the Growth Strategy and aims at letting S&T promote the three above mentioned pillars (Green Innovation, Life Innovation, Open Reconstruction). A basic shift of stance in the 4th Basic Plan compared to earlier plans is a shift from discipline-oriented funding to issue-driven science and innovation - that is to identify clearer societal areas where S&T could accelerate progress and to design cross-disciplinary programs.

The targets for Life Innovation are to foster industry growth to meet the demands for medical, nursing care and other health-related services, as well to create jobs. This involves roughly 50 trillion Japanese Yen[39] in new markets and 2.84 million new jobs. The rapidly ageing society in Japan poses an opportunity for the development of new manufacturing and service industries by "Life Innovation" (innovation in the medical and nursing care sectors).

In order to accomplish this, the government has set out to further promote research and development of highly safe, superior, and innovative pharmaceuticals and medical and nursing care technologies. Unified approaches among industry, government and academia are encouraged to foster drug development ventures and to promote research, development and application in a number of fields. These include new drugs, regenerative medicine and other state-of-the-art medical technologies, remote medical treatment systems making full use of information and communications technologies, the use of manufacturing technologies to improve personal mobility for the elderly, and medical and nursing care robotics.

Although the growth strategy and the 4th Basic Plan declares a unified approach by industry, academia and government, this has so far in practice not been found to work well in business development in the life sciences. In spite of heavy investment in life sciences both by the government and industry, industrialization is lagging behind that of the United States and Europe. One example is when the Ministry of Education, Culture, Sports Science and Technology (MEXT) set up a target to establish 1,000 spin-off companies from academia in year 2000 and organized supporting grants. The number of newly started companies has reached the target and approximately 30 percent of these companies are in

[39] *1 Japanese YEN = 0.09SEK*

the area of life sciences. However, only a few new products have reached the market and most of the companies are in red figures. Main reasons for this gap include the strict regulations and complex drug approval procedures. Approval of new drugs and medical devices is the responsibility of the Ministry of Health, Labour and Welfare (MHLW). MHLW takes a very conservative approach when it comes to the approval of innovative drugs or therapies. It has been pointed out that many of the problems could result from the fact that ministries act independently without coordinated policies in place.

3.2 Agencies and organizations of importance

3.2.1 Council for Science and Technology Policy (CSTP)

CSTP is established within the Cabinet Office and is responsible for Japan's integrated efforts to advance science and technology. It is basically the "control tower" with the mission to coordinate activities and policies between ministries and agencies. CSTP is responsible for the formulation and execution of the S&T Basic Plan. Currently the 3rd S&T Basic Plan (FY 2006 –FY2011) is in effect. In accordance with the Basic Plan, a funding program called the special fund to promote science and technology was formed through the Japan Science and Technology Agency (JST). The fund is unique in that it operates in a flexible way and accepts the participation of industry. It also performs strict evaluations of project outcomes. A detailed example is described in section 3.4. The 4th S&T Basic Plan is now being finalized to start from FY 2012. Major points include 1) promoting health technology assessment and 2) regulatory science. One may expect more test bed type initiatives and funding programs to be implemented in the 4th Basic Plan.

3.2.2 Ministry of Education, Culture, Sports Science and Technology (MEXT)

MEXT plays a central role in the funding of basic and applied research in the life sciences. The total amount of research funding has increased during the last 10 years, with funding for basic research as a priority. As a consequence of the heavy investments, we now see many publications in top life science journals by Japanese researchers. However, innovation from basic research is far from what is expected. MEXT has realized the problems and started to fund programs which include industry partners, largely through JST. JST is also collaborating with VINNOVA and The Swedish Foundation for Strategic Research (SSF). One of the largest funding programs for translational research (and potentially test beds) is described in 3.3.1.

3.2.3 Ministry of Health, Labour and Welfare (MHLW)

MHLW is responsible for drug/medical device approval and the health care reimbursement system in Japan. The ministry has been taking a conservative approach to the approval of new drugs. The problems of drug and device lag have been pointed out earlier in the text and are by many considered to be a great hindrance to innovation. There is an average of 4-5 year time lag for the approval of drugs, and much longer for medical devices when compared to their first approval in some other countries. The fact that many foreign pharmaceutical companies have closed their research institutes in Japan and re-opened them in China has furthermore been a big shock to the Japanese government. The total number of newly approved drugs and clinical trials in Japan has been declining over the years. After reports from various governmental agencies that have highlighted the problems, changes have been implemented such as an increase in the number of reviewers

at the Pharmaceuticals and Medical Devices Agency (PMDA), the implementation of a pre-consultation system as well as a fast track system in the drug approval procedures. A five year project to activate clinical trials in Japan has been implemented, which will be described in detail in chapter 3.3.2.

3.2.4 Ministry of Economy, Trade and Industry (METI)

A funding agency within METI, the New Energy and Industrial Technology Development Organization (NEDO), has been organizing a number of projects by combining industry, government and academia in various scientific areas. Eight percent of the funds of NEDO are spent within the life sciences. Life science/health care is the area primarily covered by MHLW. However, METI also takes proactive leads in developing new business in the areas of the human genome, regenerative medicine, microdose clinical trials and medical devices. Most of the NEDO projects have academic researchers as project leaders which are joined by invited industry members as well as governmental institutes such as the Advanced Institute of Science and Technology (AIST). Projects are fully funded by NEDO and industry will be funded for the project activities. Very time-consuming administrative procedures and unfavorable IP-policies clearly reduce the attractiveness of the projects for industry. For test bed type projects, the approval of the resulting products/services is outside METI's responsibility. It is not straight forward for the industry members to bring the outcome from the projects to the market.

3.3 Effort to improve translational research

3.3.1 Coordination, Support and Training Program for Translational Research

This is a project organized by MEXT with a total budget of 25 billion JPY, which is administrated by JST. The project is aimed at supporting translational research of seed technologies in academia. MEXT invited applications in 2007 and selected eight organizations, including, the University of Tokyo, Kyoto University, Osaka University and one supporting organization as grantees. The project lasts for five years and every university receives 300 million JPY and the supporting organization 50 million JPY. Universities organize the infrastructure among the project members and are running about ten programs, many of them in the clinical trial phases. Interestingly many of them are related to regenerative medicine.

The goal of the program is to bring the research seed into clinical phases and the expectation is that industry sponsors will be attracted to take over the late phases of development, that are very costly. After an interim review after two years, six universities remained in the project. The outputs of the projects are reviewed by a third party committee which could result in less well performing projects being terminated or that budgets are reduced. The supporting organization play a role in educating the academic researchers about what is needed in order to enter the clinical phases and to convey the results to industry. Some of the clinical trials were conducted in hospitals funded by the below mentioned five year project (see 3.3.2).

3.3.2 Five year project to activate clinical trials

MHLW has been supporting a project on clinical trials since 2003 – starting with a four year program (2003-2006), followed by a five year program (2007- 2011). The objectives of the projects are 1) to establish hospital networks, 2) to educate the personnel, 3) to

promote clinical trials to the public, 4) to improve the efficiency of administrative procedures by the use of IT. The project aims to speed up the processes of clinical trials and reduce the costs to the level of those of the United States. Another aim is to increase the number of clinical trials. In the projects ten core hospitals and 30 base hospitals will be assigned and 3000 new Clinical Research Coordinators will be educated.

MHLW funds all costs and two billion JPY was allocated for the project. The project will establish the infrastructure related for clinical trials but not directly support the individual product development projects. MHLW and MEXT are now planning for the next five year project to start in FY 2012.

3.3.3 Adaptable and Seamless Technology Transfer Program through Target-driven R&D (A-STEP)

A–STEP, run by the JST, is a funding program to support technology transfer from academia to industry. There are six types of A-STEP programs depending on the seed technologies. Each type consists of two stages, a feasibility study stage and a research and development stage. Researchers in academia and industry or innovation support organizations have to apply jointly. The duration of the programs varies between two and seven years.

3.3.4 Research Institute of Science and Technology for Society (RISTEX)

Prof. Hiroko Akiyama, Research Institute of Science and Technology for Society (RISTEX) at the University of Tokyo is organizing a consortium and invites major Japanese companies with different fields of expertise to discuss and try ideas concerning how to cope with the ageing society[40]. The project is called “Redesigning Communities for Aged Society”.

Prof. Akiyama pointed out two important issues; to extend the number of years of being independent and to create an environment for ageing in place. She currently conducts a social experiment to redesign a community for 2030 in Kashiwa City. Stakeholders in the experiment are universities, municipal governments, industries and citizens. In 2009 a research group was established in cooperation with the authorities of Kashiwa City and the Urban Renaissance Agency (UR), with the Toyoshikidai housing complex community in Kashiwa City being designated as the research field. The research group’s mission is to study urban development for a long-lived society. The two main themes for the research are: “Development and spreading home-based medical care, nursing and care systems,” and “Developing an urban environment that will create jobs and motivation for middle- to old-aged residents.” The aim of the research is to create urban areas that are capable of realizing the “Aging in Place” goal of allowing the elderly to live their lives with ease and peace of mind.

Industry members include Ajinomoto, the American Family Life Assurance Company, Daikin Industry, Daiwa House Industry, Dentsu Misui Real Estate and others.

Industry members pay member fees to join the consortium and academia received grants of 75 million JPY for the project.

[40] *http://www.ristex.jp/EN/examin/korei/index.html*

3.4 A Case Study: Cell Sheet Tissue Engineering Center (CSTEC)

Prof. Teruo Okano, Institute of Advanced BioMedical Engineering and Science (ABMES), Tokyo Women's Medical University, has developed unique technologies to grow cells in a sheet format which can be used for regenerative therapies. Prof. Okano is determined to help patients globally who cannot be treated with conventional therapies. However, it was not easy ten years ago to try the technologies in clinical environments. Mime Egami, Visiting Professor at ABMES who is responsible for external collaborations, explained how ABMES managed to receive funding and organize a large project team. In 2006 CSTP started the program "Realization of Innovation Center for Fusion of Advanced Technology" using funding from the MEXT special fund to promote science and technology. Prof. Okano applied and was awarded the grant along with eight other themes. The grant is relatively unique in that it includes industry with matching funds and is lasting for 10 years, which may give enough time for the project to develop into the clinical phases. Prof. Okano invited Hitachi, Dai Nippon Printing, Olympus and Cellseed, a venture company spin-out from Prof. Okano's inventions, to become the industry partners. This formation was very favorable for the development of several different core technologies that enable therapies. Nine projects were stringently reviewed after three years and only three projects survived. Prof. Okano's project survived the interim review and received a good evaluation. ABMES is now aiming at expanding its applications globally.

Furthermore – the Winner Takes it All: In 2009, in a program where funding was decided and allocated directly by CSTP, Prof. Okano won a large scale grant to support commercial development using advanced technologies developed by academia. The grant is called "Funding Program for World-Leading Innovative R&D on Science and Technology" - FIRST. In FIRST, 30 top groups in Japan were awarded three billion JPY each to be used over five years. Prof. Okano expanded a project to develop instruments to culture cells automatically to form 3D sheets. The project members formed a special type of company organization to which all IP belong and they can enjoy tax reductions during the development period. Once the business takes off, this organization can be converted to the ordinary corporate form to share the profit. This is currently one of the most successful projects in Japan. The project team, a mixture of basic researchers, medical doctors, engineers and industry researchers is highly motivated with a clear objective. It should, however, be noted that they had difficulties in starting clinical trials in Japan and had to do this outside the country. Prof. Okano is now collaborating with Karolinska Institutet and the very first clinical trials will soon be started. MEXT invested a large amount of money in the project, but it is not in Japan that the test beds were provided first. Instead Prof. Okano is collaborating with Lyon City Hospital and the Karolinska University Hospital.

3.5 Conclusions

There is a general national strategy to be driven under the name of "Life Innovation" to foster industry growth to meet the demands for medical, nursing care and other health-related services and to create jobs. However, there is no national strategy for test beds in health care, and no well-defined strategies or systems could be found for the innovation of services in health care including elderly care. It is however likely that this will change in the future.

Three major ministries, MEXT, MHLW and METI, are funding many projects to bring academia, industry and government sectors together to develop the life science industry. Each program is conducted independently and according to their own administrative routines. Unfortunately good potential seed technologies and results are sometimes struggling to move forward in Japan and there appears to be a lack of coordination between ministries. The Center for Research and Development Strategy - CRDS of JST issued a report already in 2008 arguing that a Headquarter of Life Innovation with a strong leadership to coordinate across the ministries is missing in the Japanese system. A number of initiatives to improve translation of results and clinical trials are underway.

4 Discussion

Sweden is currently considering the introduction of test beds in health care to strengthen innovation in the health care sector and the competitiveness of companies active in the area. To do this it is of interest to analyze initiatives that already are in place in other countries. We have in this short report studied a number of test beds and funding mechanisms in the United States, Canada and Japan. In the United States and Canada several test beds exist although these have different aims and profiles. The term "test bed" is rarely used. The number of test beds seems to be significantly higher in North America compared to Japan where we have not, so far, identified any that agree with the definition used here. It is, however, possible that some examples exist, for example inside the major corporations. It is also quite possible that some will appear as a result of the implementation of the 4th Science & Technology plan from 2012. For Japan we have therefore focused on the efforts relating to clinical trials and technology transfer in this report. It should be emphasized that the time available for this project has not made a thorough mapping and in-depth analysis possible.

Some of the test beds studied are non-profit organizations and are more oriented towards research than business. However, it may also in such cases be possible for companies to gain access to the facilities, either through an academic collaboration or by purchasing services. Such test beds will rarely pursue IP rights. Other test beds are much more commercially oriented but may sometimes not be available for non-members.

From this report it is clear many of the initiatives are academically coupled and also that a large number of them collaborate with hospitals. This, in fact is an important success factor for many of them. Another common theme for all the test beds described is that each focuses its activities on a specific area whether it is in services, infrastructure, hospital/care settings, a technology or biotherapeutics.

What is the relevance of this study for the coming Swedish initiative? In our view it is important to learn from models and initiatives used by others. Our study suggests that test beds organized in conjunction with academy and private organizations are of interest and that a clear focus area for each individual test bed may be desirable. Furthermore, it seems clear that it is advantageous if experts from the test bed or personnel from member organizations in the test bed are able to work with personnel from customers during an extended period.

A number of different business scenarios, from open non-profit academic-oriented models to focused among-members innovation models are possible but it is obviously important to explicitly define how IP rights as well as publication rights shall be handled in each case. A substantial funding is also most likely critical for a successful test bed, in particular during the start-up phase. For service development within the elderly care sector, it would also be of interest to directly involve elderly citizens and some organizations dealing with elderly care. Furthermore, collaborations with hospitals and other health care providers are often important for the testing of solutions.

www.growthanalysis.se

The Swedish Agency for Growth Policy Analysis (Growth Analysis) is a cross-border organisation with 60 employees. The main office is located in Östersund, Sweden, but activities are also conducted in Stockholm, Brasilia, Brussels, New Delhi, Beijing, Tokyo and Washington, D.C.

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