MedTechLabs

Strategic plan 2021-2026

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1 Executive Summary

At MedTechLabs, advanced medical technology research and education is conducted close to the patient care flow. The healthcare environment requires a patient-safe laboratory environment which also includes expertise in the management of medical devices. The lab environment will enable different research groups in the Stockholm region to carry out health-related research in the medical technology field. The first Research Programme to be launched is Imaging and minimally invasive techniques. Two subsequent Research Programmes, that was launched in January 2020, are AI in Healthcare and Bioelectronic Medicine.

These interdisciplinary collaborations in technology and medicine aim to increase survival and improve quality of life. This is achieved by, among other things, strengthening process-orientated healthcare. Organisations have the potential to bring about significant production and cost-efficiency improvements in healthcare, and centres similar to MedTechLabs in other parts of the world (e.g. Mayo Clinic, Stanford, Johns Hopkins) have shown that this is a winning concept as it offers a unique opportunity to clinically evaluate world-leading research in a patient-safe manner.

MedTechLabs directs its recruitment effort at young faculty, at both KTH and KI, in the form of a number of assistant professors (biträdande lektor) where collaboration in technology and clinical research creates the conditions for research results that can be quickly implemented into the care of the patient. MedTechLabs also aims to increase its use as an environment for the training of healthcare professionals in the method and implementation of research results, as well as for validation of the proof-of-concept for new medical technology products. In 2020-2022, MedTechLabs aims to become an important arena for symposia and seminars. The centre will also act as a facilitator to foster combined research and clinical studies.

2 Introduction

2.1 Background

MedTechLabs was founded in 2018 as a joint strategic initiative by the Stockholm Region, Karolinska Institutet and KTH. The centre acts a facilitator for medical technology development. Implementation will take place through the clinical activities where studies and research are conducted.

MedTechLabs will conduct advanced and healthcare-related medical technology research in a patient-safe lab environment. The clinical activities control the needs and the type of studies to be conducted. The main tasks are to generate new knowledge in medical technology and to convey and implement this knowledge.

The interdisciplinary collaboration in technology and clinical research creates the conditions for research results to be quickly implemented in healthcare for the benefit of the patient.

The lab environment will benefit various research groups in the Stockholm region and means a strengthening of a process-oriented healthcare. The centre's research results not only bring significant socio-economic gains, but can also contribute to production and cost efficiencies in healthcare. It offers a unique opportunity to clinically evaluate world-leading research in a patient-safe way.

The establishment of MedTechLabs also means a renewal of faculty within KTH and KI.

The center will be used as an environment for the training of health and medical staff in the method and implementation of research results, as well as for the validation of new medical technology products. MedTechLabs will be an arena for symposia and seminars.

2.2 Status Analysis

In the 2019 -2020 two-year period, the centre was directly financed by all three parties. Of the total budget, Region Stockholm contributed 4/6 (four-sixths) and the universities contributed 1/6 (one-sixth) each, ramping up from totally 12 mnsek (2019) to 15 mnsek (2020). Funding was principally used for lump-sums to Scientific Directors (e.g. for salaries, equipment and training-related expenses within the Research Programmes), plus administrative running costs for the centre Programmes are each funded on a five-year basis.

Research Programme *Spectral-CT imaging and endovascular techniques* funded by 7 mnsek per year started in 2019 . By now three Assistant professors, one post-doc and two PhD students are recruited for this research program.. Faciltites within the BioClinicum are being re-built during 2020, for the CT lab. The lab will be in operations by Q1 in 2021. Research Programme *Breast cancer imaging powered by AI diagnostics* funded by 4 mnsek per years started in 2020 as well as the Research Programme *Bioelectronic medicine* funded by 3 mnsek per year.

2.3 Outlook and continued relevance

No benchmarking surveys has been executed lately. It would be nice with updates for evolving initatives for benchmarking for Europe (Eindhoven, Alsace) but also in Asia. The survey that was ececuted by MedTechlLabs in 2017 searching for international top environments in the field could also be updated . The outlook was focused on USA and below is some of the findings three years back:

During the last decade, a number of interdisciplinary collaborations have been initiated as a means of improving different aspects of health care delivery. Innovation centers established within hospitals seek to provide solutions to identified clinical challenges, while partnerships between universities and hospitals promote translational research.

When Mayo Clinic's Center for Innovation (CFI) was established in 2008, it was the first innovation center to be integrated into a medical practice setting. The central location at the heart of Rochester hospital campus enabled patient interactions at the very moment of health care delivery. While the innovative environment has contributed to numerous advancements within the design aspect of health care, most projects at CFI are still limited to a period of six months or less. The short-term scope has presented a challenge of moving beyond incremental innovation, which in turn jeopardizes commitment from the best innovators.

Embracing interdisciplinarity, a range of new innovation centers has emerged during the last years. University of Pennsylvania Health System established the Center for Health Care Innovation in 2012 to test new models of care and build evidence of their effectiveness. Johns Hopkins Medicine founded the Technology Innovation Center (TIC) in 2014 to build and deploy innovative clinical information systems across the hospital.

Advancing multidisciplinary research, Stanford University is renowned for its collaborations between engineers and clinicians. In October 2013, the Stanford Predictives and Diagnostics Accelerator (SPADA) was established to stimulate innovation and encourage interdisciplinary work within clinical and translational research (CTR). SPADA offers grants to projects with the objective of translating discoveries into novel predictives and diagnostics products that address unmet clinical needs.

Other renowned American universities have a long tradition of collaborating with hospitals to foster interdisciplinary research and education. For more than 40 years, Massachusetts Institute of Technology (MIT), Harvard Medical School (HMS), Harvard University, and Boston area teaching hospitals have been engaged in The Harvard-MIT Program in Health Sciences and Technology, where all education programs promote innovative research at the intersection of science, engineering, and medicine.

While innovation centers offer the opportunity to identify and develop solutions to current clinical needs, the challenge remains to reach beyond incremental innovation. At the same time, interdisciplinary research collaborations between universities (and hospitals) could often benefit from producing stronger clinical evidence of research developments. Combining interdisciplinary research teams with a patient-centred infrastructure thus provides great opportunities to transform entire care pathways.

At Johns Hopkins University, these insights have resulted in a unique resource for research, education, and translation in imaging and image-guided interventions. Located in the heart of Johns Hopkins Hospital, the Carnegie Center for Surgical Innovation provides a synergistic co-location of expertise to identify major clinical needs, drive development of new technology, translate advances to clinical use, and cultivate the next generation of engineers and clinicians.

3 Idea with MedTechLabs

3.1 Vision

To increase patient survival and improve quality of life in cardiovascular diseases and oncology. We create new conditions for healthcare to offer patients a much safer diagnosis and better treatment at a lower cost.

3.2 Mission

To generate needs-motivated, clinically-based research and education in medical tecnology

3.3 Goals

- To become among the top 10 interdisciplinary centres globally for medical technology research where we develop instruments and methods that will benefit large patient groups, measured through quality and number of journal and conference papers, scientific awards, invited keynotes, and individual research grants
- To provide a stimulating environment and seed funding for creating new interdisciplinary research projects attracting significant external financial support from national and European funding agencies and partners
- To establish MedTechLabs as a facilitator combining research and medical technology trials, by providing a holistic process for how clinical studies can be conducted attracting both researchers and international companies.
- To enable high-impact technology transfer for implementation in healthcare, demonstrated through start-up companies, patents, industrial collaborations, events, and on-line education.

4 Strategic Research areas

MedTechLabs today comprises three Strategic Research areas; Imaging and minimally invasive techniques, Artificial intelligence in healthcare, Bioelectronic medicine. The research areas have been carefully chosen from needs pointed out by healthcare decision-makers in dialogue with KTH and KI faculty.

Calls for programmes are announced within the respective Research Areas. An Evaluation Panel consisting of national and international experts in the field is appointed by the MedTechLabs Board. Funds within each programme are made available to the Scientific Directors (who are also the research leaders) on the basis of the approved Research Programme.

4.1 Imaging and minimally invasive techniques [Mats Danielsson, Staffan Holmin]

Imaging

Description

Combinations of medical imaging and minimally invasive interventions is becoming increasingly popular for treatment of a range of diseases, with acute stroke care as a highly successful example. The combination of x-ray CT for diagnosing incoming patients and minimally invasive removal of blood clots from patients found likely to benefit from this based on the CT scan had shown good outcomes for patient groups previously considered untreatable. Selecting the right treatment for each individual patient requires highly accurate diagnostic imaging techniques, and a principal aim of this program is to develop a new imaging technology, photon-counting spectral CT, which has the potential to provide images with drastically improved diagnostic quality, to the point where it can be widely adopted in the clinic for imaging of acute stroke and other diseases. Specifically, the new technology promises lower image noise, higher spatial resolution and more reliable characterization of the atomic composition of tissues.

Needs

In the management of acute stroke, there is a need for better differentiation between grey and white matter, and better brain perfusion imaging to measure blood flow in the brain and understand which regions contain salvageable tissue. Oncological needs include better visualization of small tumours and accurate measurements of the uptake of iodinated contrast media. There is also a demand for higher spatial resolution for imaging bone fractures in trauma imaging and detecting and characterizing small lung nodules. Higher spatial resolution in combination with accurate separation of iodine and calcium is also highly desirable in order to better characterize atherosclerotic plaques, e.g. in the coronary or carotid arteries, and identify vulnerable plaques that risk causing stroke or myocardial infarction.

Challenges

Although the new photon-counting detector technology has shown promising results in phantom imaging studies and an early prototype has been used for imaging human volunteers with promising results, there is a need to test the prototype on a larger number of study participants and for a range of applications. This will allow evaluating the performance of the new technology in a realistic imaging setting and identifying strengths and weaknesses with the current implementation. This in turn can give important feedback for further development of the system.

As any new medical imaging technique, the introduction of photon-counting CT hardware needs to be complemented by the development of new data processing methods and algorithms to reach its full potential in terms of image quality. This requires developing accurate calibration methods, careful mathematical models of the image acquisition and fast algorithms to produce the final image within a time frame consistent with the clinical workflow.

Plan

A photon-counting CT prototype will be installed at Karolinska University Hospital and will be used for imaging human volunteers, for a range of imaging tasks in head, neck, chest and abdomen imaging. In parallel with this evaluation, the new detector hardware will be further developed with the purpose of further improving image quality in the future. Furthermore, new data-processing and reconstruction algorithms will be developed based on careful physics modelling and deep-learning reconstruction methods.

Minimally invasive techniques

Description

When Sven-Ivar Seldinger introduced his world-famous technique of percutaneously inserting catheters into arteries at Karolinska in 1952, it came to revolutionize the field of endovascular procedures and led to ground-breaking minimal-invasive procedures such as balloon angioplasty, modern angiography, coiling and mechanical thrombectomy that have saved millions of lives. Five years ago, Prof. Staffan Holmin and his team developed and patented the “inverted Seldinger technique” which allows to safely exit the arterial or venous space at an arbitrary location to reach directly into organs such as brain, pancreas, heart and others that are difficult or risky to access by other methods. This trans-vessel wall technique is also called the “Extroducer” technique in contrast to “Introducer” that was the result of Seldinger’s work for gaining access to the interior of the vascular tree. A key element to the safe implementation of this technique is the small transarterial or transvenous perforation from the inside to the outside of the vascular tree, typically in the order of 100 µm, necessary to avoid hemorrhage. Hence, any intervention into these hard-to-reach organs via the Extroducer needs to be very small. Profs. Göran Stemme, Niclas Roxhed and Wouter van deer Wijngaart, also scientific leaders of MedTechLabs, are specialized on minimal invasive microelectromechanical systems (MEMS) where they, for example, developed ultraminiaturized electromechanical pressure sensors for the coronary arteries with a size of only 100 µm (today PressureWire™, a world-success product within Abbott/St.Jude Medical). A minimally invasive and safe miniaturized working channel to “hard to reach organs” could have major implication for new treatment regimens both for regenerative treatment strategies and in oncology. In addition to trans-vessel wall technique and intra-luminal devices, these catheter techniques can potentially be used for new methods and devices for taking samples from e.g. the heart and lungs for analysis with gene-expression analysis techniques such as micro-array and RNA-transcriptomics, or with proteomics.

Needs

To be able to develop these methods, we need access to long-term employed qualified personnel, lasers, micro-machining tools and MEMS techniques and the possibility to test the devices in translational animal model labs including 3D angio suite, surgical theatres, MR, PET and CT for evaluation of safety and efficacy. Furthermore, when testing and implementing this in the clinical setting, an infrastructure and supportive know-how functions for performing the required regulatory studies and clinical trials is needed. This would require access to clinical labs accessible both for health care personnel and engineers, yet with access to the hospital patient safety infrastructure. A clear legal pathway for clinical research and regulatory studies needs to be established in view of the new laws for clinical research as well as the transition of MDD to MDR.

Challenges

Specific challenges for the ultra-small catheter techniques includes friction between materials and also bending forces with preserved flexibility and navigability. In broader terms for the med tech field, the transition from MDD to MDR creates uncertainty both for inventors, investors, start-ups and regulatory personnel. There is a lack of capacity of notified bodies trained and certified for MDR. On top of this, the constantly increasing demands on documentation and different interpretations of laws regulating clinical trials in Sweden, creates an environment that is hard to navigate in. In fact, it has become difficult to do the right things in all aspects when performing clinical research and regulatory studies. When collaborating with companies based in the US, the GDPR law and its interpretation, creates a lot of friction and lengthy negotiations.

Plan

This part of the program aims at utilizing the trans-vessel wall- or, inverted Seldinger technique, as well as related techniques, in combination with MEMS to achieve advanced localized drug/cell therapy to any "hard-to-reach" organ. Moreover, the development of such techniques can allow for miniaturized tissue sampling of e.g. the heart, lung and brain tissue for metabolic disease diagnostics, differential diagnosis, profiling and monitoring. A separate part of the project is aimed at developing methods for ultra-small tissue sample handling and protocol for gene-expression analysis of such samples. Although, "omics" techniques have demonstrated excellent results in cultured cells and tissues, significant work remains to be able to use these very promising analysis methods also on small clinical samples from "real" tissues.

4.2 Artificial intelligence in healthcare [Johan Hartman, Kevin Smith]

Description

Decision support systems based on AI have an enormous potential to contribute to improved quality in modern healthcare across a multitude of domains. Recent advances in an area of AI referred to as *deep learning* have enabled development of novel and more powerful solutions, especially in the domains of image analysis and image classification. These new solutions outperform image classification systems that were state-of-the-art just a few years ago. To enable competitive AI research in the healthcare domain, the process for seeking and gaining access to healthcare data that underpins these research activities need to be well-defined, transparent, predictable and expedient. In this program, our goal is to develop AI algorithms for breast cancer diagnostics based on radiological and pathological images. We are aiming to implement part of our research results into a clinical study starting 2021.

Challenges experienced

- Long processing times for data requests (often many months) cause severe delays in the research programmes and reduce national and international competitiveness - even when applying to extract data from same legal entity (e.g., K) at which the researcher are working and where the head of department already before approved the ethical application
- One researcher in the group experienced previously more than 12 months' time to extract radiological images required for the AI training

- In many cases, there is a perceived unwillingness from the Region to facilitate research despite the regulatory and legal requirements being fulfilled.
- According to KI/KTH interpretation of GDPR currently MTA or similar agreements need to be approved before collaborations (data transfer) can be initiated. This is a major hurdle for the whole Medtechlabs consortium as it severely delays collaboration.

Needs identified

- Improved quality in administration and decision-making of biobank applications
- Improved efficiency in mechanisms for data-access/retrieval
- Legal support to simplify collaboration, data access and management across KI-KTH borders
- Additional support in terms of access to compute and storage resources

Plan

Medtech labs should promptly address the major challenges described above. We would like to see a legal decision function centralized, possibly to Center for Health Data, which would both assess applications and also actively help researchers with the entire process to obtain approval for data extraction, including biobank access and extraction of electronic medical records including digital radiology and pathology images. Such a function should have an explicit time limit, e.g. 1-2 weeks, from receiving an application to a final decision (which may include modifications of the original application that were required to follow rules and regulations). After this, there would also be a need to handle the data extraction process expediently.

4.3 Bioelectronic medicine [Peder Olofsson, Henrik Hult]

Description

Bioelectronic Medicine is the use of technology to target molecular mechanisms for treatment of disease. The field bridges neuroscience, immunology, engineering, and computer science and builds on the discovery of neural reflexes regulate inflammation.

Development of new therapies relies on detailed understanding of the molecular mechanisms of disease. Pharmaceutical drugs are optimized to target defined molecular mechanisms, but often lack anatomical and cellular specificity, which inevitably causes toxicity from off-target effects. Drugs are not inherently designed to adapt to individual treatment, so both under- and overdosing are common, resulting in therapy failure or unwanted side effects. Advances in bioelectronic medicine hold promise to address some of these challenges and provide personalized treatment of disease.

The discipline bioelectronic medicine arose from groundbreaking discoveries of mechanisms for neural control of biological processes that underlie disease, and the development of devices to modulate these specific neural circuits as therapy using electrons instead of drugs. Recent clinical trials indicate that it is feasible to target specific neural reflex circuits in humans for treatment of inflammatory diseases such as rheumatoid arthritis and inflammatory bowel disease.

The Strategic Research Area Bioelectronic Medicine focuses on

1) Development of a device-based tool for monitoring of inflammation aiming to improve personalized disease treatment in patients with chronic inflammation.
2) Functional mapping of neural reflexes that regulate inflammation in experimental models aiming for automated detection of inflammatory events by analysis of electric neural activity.

Needs:

The project needs to collect and mathematically model data from patients suffering from inflammatory diseases from patients in cross-sectional and longitudinal studies. Increased inclusion of patients from multiple clinics will facilitate this work.

Analyis of biological samples requires a dedicated lab for cell- and molecular biology and close collaboration with basic researchers in immunology and neuroscience. A dedicated facility for animal neurophysiology experiments would considerably facilitate progress.

An improved mechanism for recruitment of excellent PhD students, post-docs, and junior faculty would be of value.

Challenges:

Improving the pipeline for effective collection, storage, and analysis of longitudinal patient data in a secure and fully compliant environment.

Inclusion of sufficient numbers of patients, particularly during the current pandemic.

Production of the required experimental support to propagate discoveries to Phase I trials.

Plan:

Establish common facilities in Bioelectronic Medicine for KI, KTH and Stockholm Region employees at Bioclinicum.

Expand subject inclusion to hospitalized individuals from multiple clinics and establish a streamlined and fully compliant pipeline for data analysis.

Synergize with the program area minimally invasive techniques to generate neural reflex mapping data and more funding, and with the program area AI in health care on the compliant data analysis pipeline.

Strengthen the transatlantic collaboration with the New York Center for Bioelectronic Medicine and Northwell health.

5 Medical Technology trials

The new European regulatory framework for clinical trials will start in 2021. MedtTechLabs shall be act as facilitator for a holistic perspective for the entire process how to conduct the medical technology trials that will gain researchers and industry. Together with Karolinska Trial Alliance and other expert departments within Region Stockholm and Swedish MedTech, that offer courses and documentation in this field, MedTechLabs will work actively together with the organizations mentioned above to set the whole process for Medical Technology trials and communicate it. The goal is to increase the amount of clinical studies executed in the clinical departments.

5.1 Physical location and Infrastructures

MedTechLabs is physically located in administrative premises and the laboratory environment at BioClinicum, Karolinska University hospital. The local infrastructure is one of the first research buildings in the country to be built with the potential to be used as an integral part of the patient care flow. MedTechLabs facilities are designed for high utilisation by several research projects. The premises comprise a general infrastructure provided through Medtechlab's general funds. The respective Heads of the hospital have the ultimate responsibility for patients when on BioClinicum premises. There are also laboratories at KTH and at KI campus that are part of the MedTechLabs infrastructure network.

6 Strategic Implementation

6.1 Research Programmes

Research Programmes within each Research Area are sought through competition and it is possible for several programmes to exist within one Research Area. Leadership is shared within each Research Programme between researchers from KI and KTH. Region Stockholm employees should also participate in the Research Programmes where possible. Research Programmes run for five years and shall report activity annually.

Each granted programme will contain at least one project. Scienctific directors are expected to seek additional research funding through external means. Collaboration agreements with external actors, such as companies, are concluded at project level.

In 2020, each Research Area is represented by a Research Programme and within each programme there may be one or more individual projects: Spectral CT-imaging and endovascular techniques, Breast cancer imaging powered by artificial intelligence diagnostics (BCAIND) and Program for Bioelectronics medicine

Spectral-CT imaging and endovascular techniques [Mats Danielsson, Staffan Holmin]

A photon-counting CT prototype will be installed at the premises of MedTechLabs and the resulting image quality will be evaluated for imaging human volunteers who have had a previous CT examination, and the image quality obtained with the new prototype will be compared to the previous images. Imaging tasks in this evaluation include detection and characterization of lung nodules, characterization of plaques in the carotid and coronary arteries, visualizing of low iodine contrast concentrations in tumors, diagnosis of brain infarcts, imaging of metal implants and visualization of bone fractures.

In addition to the evaluation of photon-counting CT prototype, research is being done on next-generation silicon-strip detector designs, with a potential for drastically improved spatial resolution as well as improved contrast-to-noise ratio and energy resolution compared to the current prototype. Furthermore, new reconstruction algorithms are being developed to utilize the data optimally and attain the best image quality achievable. To realize the required accuracy, low noise and fast image generation, these new algorithms will be based on deep neural networks, which have been demonstrated impressive performance for conventional CT reconstructions. One potential application of this line of research is to develop highly accurate CT measurement methods for data-driven research. Other advanced applications include ultra-low dose imaging for paediatric applications and screening, motion correction for accurate cardiovascular imaging, integration with fluid dynamics models for blood flow measurement, and improved radiation therapy planning.

Incoming patients with a diagnosis of acute or subacute stroke undergo CT scanning under the guidance of a hospital engineer and clinician and are then transported to surgery or back to the care department. The research team develops hardware and software that, among other things, results in ever-higher image resolution and material decomposition, which is of great value for clinics to perform safer therapies, and to achieve better diagnostics and treatment for bleeding-induced stroke, for improved diagnosis of different lung diseases and for more reliable determination of stenosis grade in atherosclerotic arteries of the heart and brain New software and upgrading of the CT technology are continuously being done. The lab environment is also used for education where it becomes part of the care chain for the diagnosis and treatment of acute and subacute stroke. Furthermore, the first care programme will include the development of minimally invasive endovascular techniques to be able to take small tissue samples from organs that are difficult to reach by conventional methods. This technique, combined with the evolution of gene expression analysis in small samples, provides potentially great patient benefit in both cancer and cardiovascular disease. There will be several interesting synergies within the research programmes. The routines and infrastructure built by the pilot in a patient-safe radiation-protected lab environment will benefit a variety of research projects within MedTechLabs with various imaging techniques including x-ray, angiography (special x-ray imaging of blood vessels and heart), MRI (magnetic resonance imaging), DT/CT , X-ray) and PET (positron emission tomography) or combination of these, so-called multimodal imaging.

Breast cancer imaging powered by artificial intelligence diagnostics (BCAIND) [Johan Hartman, Kevin Smith]

BCAIND will develop innovative multidisciplinary AI models, trained on millions of images, aimed at increasing breast cancer survival through a quantum leap in diagnostic precision compared to the benchmark performance of human expert pathologists and radiologists.

Our healthcare is facing huge challenges to cope with an increasing number of cancer patients. Improvements across several components of clinical cancer care are required to make substantial improvements with respect to patient outcomes, ranging from early detection, to diagnosis and therapeutic interventions. In this Research Programme we develop and validate Artificial intelligence (AI)-based solutions to improve early detection of clinically relevant breast cancer (mammography screening, radiology) and to improve breast cancer diagnosis (histopathological assessment). The most promising area for applied artificial intelligence currently in healthcare is for medical image analysis applications.

Image-based diagnoses are the central part of both clinical radiology and pathology. BCAIND will develop and employ AI-models throughout the course of the disease; from the initial mammography while still healthy, to the pathology analysis of pre- and postoperative breast cancer tissue to predict the optimal oncological systemic therapy. Finally, we aim to integrate the radiology and pathology AI-models into even stronger methods. Although the project and expertise lies within breast cancer, the Programme should serve as a role-model to be applied into other cancer types.

The Programme’s aims are the following:

1. To develop and validate AI-based models for radiological image analysis.
    a. Decision support models for risk-stratified screening to improve early detection
    b. Stand-alone computer-aided tumor detection for increased resource efficiency
2. To develop and validate AI-based models for histopathology image analysis.
    a. Decision support for histological grading

   b. Improved prognostic models
   c. Novel treatment predictive models
3. To develop joint models from multiple data modalities, combining radiology and histopathology data with routine clinical assessments to improve patient risk stratification and optimize oncological therapy.
4. To perform pilot studies across radiology and pathology for prospective validation of the developed models.

Research Programme for Bioelectronic medicine [Peder Olofsson, Henrik Hult]

Inflammation is a major contributor to development of common and debilitating diseases, e.g. cardiovascular disease, rheumatoid arthritis and inflammatory bowel disease, but available therapeutic options to monitor and control inflammation, and promote resolution, are limited. Bioelectronic medicine is the convergence of molecular medicine, neuroscience, engineering, mathematics, and computing to develop devices to diagnose and treat diseases. This Research Programme will develop parallel clinical and experimental tracks, using available technology in ongoing clinical implementation to lay the foundation for smart devices that monitor inflammation, aid inpatient care and automate treatment optimization.

The Research Programme aims to develop:

1. A device-based tool for continuous monitoring of inflammation aiming to improve personalized disease treatment in patients with chronic inflammation
2. Artificial intelligence and inference algorithms for automated detection of inflammatory events by analysis of electrical neural activity
3. Highly biocompatible electrodes that minimize the foreign body response to maintain function and enable long-term studies and treatment

An added value is the strengthened collaboration between KI-KTH-Region Stockholm in medical technology research and education.

6.2 Clinical studies

To ensure clinical relevance in the projects, participation of voluntary patients and healthy test persons is a prerequisite. This is made possible within MedTechLabs through Region Stockholm’s participation. Projects within the centre must follow good clinical research practice (GCP), law on ethics review and other principles of health and research ethics. They must also be approved by the relevant authorities.

Next coming years MedTechLabs will support routines and infrastructure that will make it easier for researchers and companies to combine research projects with clinical studies.

Common policies needs to be in place that is aligned with the new MDR regulation with help from compliance officers, lawyers/ data protection representatives. This will help to get Clinical Managers in the hospital secure and willing to sign project agreements with researchers and companies. There is also a need for policy documents that are approved by the public health service and universities to "share data" with commercial actors, not least when it comes to imaging.

6.3 Faculty renewal - MedTechLabs fellows

MedTechLabs also involves an effort to recruit young researchers to KTH and KI in the position of assistant professors, that will strengthen appointed research areas. Recruitment aims to form new interdisciplinary teams. Collaboration in technology and clinical research creates the conditions for research results that can then be implemented in health care for the benefit of the patient.

6.4 Implementation in healthcare

MedTechLabs continuously communicates knowledge to the healthcare sector on results from its research as well as the advanced technology and method development conducted at the centre. This mediation entails, among other things, the use of image analysis matched to the needs of caregivers, especially when it comes to major public diseases such as cancer and cardiovascular diseases. This is done through continuously training healthcare professionals and presenting new findings via symposia, workshops and seminars. The researchers should more clearly describe, and be followed up as regards, the implementation process and education connected to the research programme.

6.5 Scientific networking and dissemination

Sabbaticals

MedTechLabs shall open up for sabbaticals, spending half a year in the team, connected to some of the ongoing research programmes.

Seminar series

A set of frequent seminar series will help to position the center as a stimulating international research hub with a clinical focus. The MedTechLabs Seminar series will have the theme combining medical technology research with clinical impact. It will feature a mix of international key-notes and senior researchers closely connected to MedTechLabs to disseminate state-of-the art research problems, approaches, and results to the MedTechLabs community but also to highlight MedTechLabs Fellows.

Participation on annual events like Digitalize in Stockholm

To tighten interactions between academia, industry, and society, MedTechLabs will actively take part in events like Digitalize in Stockholm -- an annual conference and meeting place for global thought leaders and rising stars engaged in digital transformation. MedTechLabs shall offer to be engaged by in-kind contribution in the program committee for the event on behalf of Region Stockholm. www.digitalizeinstockholm2020.se

Co-arrangement activities with SciLifeLab

MedTechLabs shall postion itself as a partner to SciLifeLab contributing as a fascilitator for medical technology trials.

7 Funding

After start-up, Scientific Directors (and associated PIs) are expected to apply for external grants. The ambition is that the total scope of the centre in Years 7-8 (2024-25), including external research grants, will amount to around SEK 50 million per year.

The MedTechLabs Executive Director shall work close together with Development Offices at KI and KTH, to foster external funding by developing offers for funding. Focus shall be to strengthen existing research areas by renewal of faculty through recruiting of MedTechLabs fellows – assistant professors with well funded start-up packages, but can also be project specific funding like PhD´s and PostDoc projects. how that using the platform with affiliated MedTehLabs researchers close to clinic´s benefit that results will reach patients faster.

8 Governance

MedTechLabs is set up as a research centre at KTH.

Board

The centre is governed by a Board responsible for announcing Research areas, appointing external assessment groups, establishing strategic plan and yearly activity plan including budget, and monitoring the activities. The Board is represented by four (4) members from Region Stockholm, two (2) from KI and two (2) from KTH. A Chairperson is appointed who shall be from Region Stockholm.

Reference Group

A Reference Group (RG) will be established in 2021 to be called by an annual basis. This group will consist of patient organizations, industry organizations in medical technology and companies.

Planning group for CT lab

A planning group (PG) will be established in 2020 reporting to the Board. The task will be to plan logistics and occupancy rate together with budget for the CT lab. Relevant Operations Manager (verksamhetsansvarig) at the Karolinska University hospital (K) is responsible for compliance with current laws and regulations and that patient management is conducted correctly. The Executive Director will lead the group.

Management

The management team consist of Director, Vice-Director, Executive Director, Senior Advisors from Region Stockholm and KI, Communication Officer and Scientific Directors.

- Director and Vice-Director is in charge of establishing international collaborations.
- Executive Director is responsible for operations and administration of the centre.
- Senior Advisors from Region Stockholm and KI will support the Executive Director for short- and longterm operations.
- Communication officer is responsible for the Communication plan.
- Scientific Directors. Each Research Programme is led by two Scientific Directors, one from KTH and one from KI. Scientific Directors also act as mentors to assistant professors, postdocs and other young researchers by, for example, transferring knowledge to young faculty about interdisciplinary working methods

9 Appendices

9.1 Key Perfomance Indicator´s, KPI´s for annual follow up

We define seven central performance dimensions for MedTechLabs as an interdisciplinary, research centre in Stockholm. The performance dimensions are meant as strategic impact directions towards various stakeholders of MedTechLabs. MedTechLabs will have to demonstrate along these dimensions the impact it created over a five- and ten-year period.

Scientific excellence

– Measures of scientific excellence: Publications, Research awards, Distinguished grants, International network, Invited talks.

Clinical studies

Clinical studies executed in MedTechLabs Research programs
Clinical studies executed at Karolinska Universitetssjukhuset
Clinical studies executed at Danderyds sjukhus
Clinical studies executed in Stockholm region

Infrastructures and facilities

Occupancy rate for the CT lab in BioClinicum
Interdisciplinary meetings/workshops/seminars in BioClinicum

Industrial transfer

– Measures for industrial transfer: Industrial transfer grants of third parties (for instance VINNOVA, EU funding, direct company funding), patents, start-ups, jobs created, industrial-academic mobility, adjunct professors.

Societal outreach

–Measures for societal outreach: Appearance in public/political discourse, public lectures, consulting to decision makers, media presence, social networks presence.

Education/ Clinical Implementation

– Measures for education: Courses, seminars, lectures, # participants from hospital in seminars

(Strategic) Renewal

– Measures for renewal: New hiring, scouting, new fields, promotion & leadership change.

9.2 Terms and conditions for funded Research programmes/projects

See attached document

9.3 Communication strategy 2020-2026

9.4 Activity and Communication plan 2021

See attached document

9.5 Budget 2021

See attached document