Aus der Abteilung INKA-Application Driven Research[1]

der Medizinischen Fakultät

der Otto-von-Guericke-Universität Magdeburg

Biodesign and Entrepreneurship for Biomedical Engineering

Design of a university based innovation laboratory for technical translation from bench to bedside

Dissertation

Zur Erlangung des Doktorgrades

Dr. rer. medic.

(doctor rerum medicarum)

an der Medizinischen Fakultät

der Otto-von-Guericke-Universität Magdeburg

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From Magdeburg, Germany

Magdeburg, 28. February 2022

[1] Forschungsgruppe INKA (Intelligente Katheter)
Innovationslabor für bildgeführte Therapien- Innolab IGT

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„Probleme kann man niemals mit derselben Denkweise lösen,

durch die sie entstanden sind.“

Albert Einstein

Dokumentationsblatt

Die wachsende Anzahl klinischer Versorgungslücken, hohe Regulierungs- und Zertifizierungsstandards aufgrund der neu eingeführten MDR EU 2017/745 und steigenden Kosten für Forschung und Entwicklung erschweren den Innovations- und Technologietransfer. Die Nachfrage nach schneller Innovation mittels Techniktransfer und einem qualifizierten unternehmerischen Verständnis innerhalb des Gesundheitswesens steigt, insbesondere nach innovativen Ausbildungsprogrammen, die vermitteln, wie man diesen Herausforderungen begegnet und Medizintechnik gemeinsam mit allen beteiligten Akteuren (weiter-) entwickelt.
Die frühzeitige Integration von Innovationsmanagement und unternehmerischen Denken in der akademischen Ausbildung von Studierenden der Biomedizintechnik ist unerlässlich. Der Lehransatz „Identifizieren, Entwickeln und Implementieren gemeinsam mit Ingenieuren, Medizinern und Ökonomen“, eine Kombination aus dem Stanford Biodesign und dem Design-Thinking Ansatz, lehrt Studierenden, Innovationsprozesse zu leiten, klinische Abläufe zu verstehen, technische Entwicklungen zum Nutzer zu transferieren und Gründungsabsichten umzusetzen.
Die Motivation dieser Arbeit ist es, kliniknah ein innovatives Forschungslabor für Medizintechnik aufzubauen und Unternehmensgründungen aus Universitätsprojekten, durch ein kreatives und motivierendes Umfeld, zu generieren. Das Innovationslabor für bildgeführte Therapien bildet ein Netzwerk zwischen akademischer Ingenieurausbildung, Medizin, Forschung und Wirtschaft. Die Schaffung eines Innovationsökosystems mit Zugang zu allen wichtigen Ressourcen wird den Erfolg von Innovationen erhöhen und Biomediziningenieure mit den entsprechenden Fähigkeiten für die Herausforderungen des 21. Jahrhunderts ausbilden.

Schlüsselwörter: Stanford Biodesign, Design Thinking, Innovationsgenerierung, Innovationsökosystem, biomedizintechnische Ausbildung, Start-Up, Unternehmertum, Technologietransfer, medizinisches Forschungslabor, ungedeckter klinischer Bedarf

Abstract

Today's challenges in healthcare with a large number of unmet clinical needs, high regulatory and certification standards due to the new MDR EU 2017/745 and increasing costs for Research and Development make innovation and technology transfer difficult. The demand for faster innovations through technical translation and entrepreneurial understanding of the healthcare sector is increasing, especially for innovative training programs that teach how to tackle these challenges and develop with stakeholders.

Early integration of innovation management and entrepreneurship in the academic education of biomedical engineering students is essential. The teaching approach “Identify, Invent, Implement together with Engineers, Medical Users and Economists”, a combination of Stanford Biodesign and the Design Thinking approach, teaches students to lead innovation processes, understand the everyday clinical practice, transfer technology to the user, and stimulate and implement startup intentions.

The motivation of this thesis is to build an innovative research laboratory for medical technology and generate business startups from university projects through a creative and motivating environment close to the clinic, with a network of various stakeholders from medicine and industry. The Innovation Laboratory for Image Guided Therapies, a laboratory for innovation, research, and entrepreneurship form a network between academic engineering training, medicine, research, and economics. Creating an innovation ecosystem with essential resources within reach will increase the success and adaptation of innovations and train biomedical engineers with the appropriate skills to face the challenges of the 21st century.

Keywords: Stanford Biodesign, Design Thinking, Innovation Generation, Innovation Ecosystem, Biomedical Engineering Education, Start-Up, Entrepreneurship, Technology Transfer, Medical Research Laboratory, Unmet Clinical Needs

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List of Abbreviations

AIA	dt. Autonomie im Alter/ Forschungscampus
ABINEP	International Graduate School on Analysis, Imaging and Modelling of Neuronal and Inflammatory Processes
cf.	compare
DRG	Diagnosis Related Groups
e.g.	for example
ERDF	European Regional Development Fund
EMBS	Engineering in Medicine and Biology Society
FEIT	Faculty of Electronic and Information Technology
FDM	Fused Depositioning Molding
FME	Faculty of Medicine
I³ EME	Identify, Invent, Implement together with Engineer, Medical User and Economists
i.e.	that is
Innolab IGT	Innovation Laboratory for Image Guided Therapy
IEEE	Institute of Electrical and Electronics Engineers
MedTech	Medical Technology
MDR	Medical Device Regulation
OVGU	Otto-von-Guericke-University, Magdeburg
RF	Radio Frequency
SR	Surgical Room
SLA	Stereolithography
T²I²	Graduate School for Technology Innovation in Therapy and Imaging
VDI	dt. Verein Deutscher Ingenieure

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Preamble, List of Publications

The present dissertation refers to the publications listed below.

It corresponds with the implementation provisions of the doctoral regulations for doctor rerum medicarum (Dr. rer. medic.) of the Medical Faculty at Otto-von-Guericke-University Magdeburg for a cumulative dissertation in the version dated May 14, 2018.

Publication 1

INNOLAB - Image guided surgery and therapy lab - Run by engineers at a university hospital for interdisciplinary and useful innovation with clinicians.

Fritzsche, H.; Boese, A.; and Friebe, M.

Current Directions in Biomedical Engineering, 3(2): 235–237. September 2017.

DOI: 10.1515/cdbme-2017-0049

Publication 2

How do we need to adapt Biomedical Engineering Education for the Health 4.0 challenges?

Fritzsche, H.; Boese, A.; and Friebe, M.

Current Directions in Biomedical Engineering, 6(3). November 2020.

DOI: 10.1515/cdbme-2020-3154

Publication 3

A structured pathway towards Disruption: a novel Entrepreneurship Design Thinking Curriculum for Health Innovation

Fritzsche, H.; Barbazzeni, B.; Mahmeen, M.; Haider, S.; and Friebe, M.

Frontiers in Public Health, section Health Economics. Volume 9, September 2021.

DOI: 10.3389/fpubh.2021.715768

Publication 4

State-of-the-Art: Biodesign based Innovation Ecosystems in Europe

Fritzsche, H.; Mahbub, E.; Boese, A.; and Friebe, M.

Current Directions in Biomedical Engineering, 7(2). Dec. 2021, pp. 231-234.

DOI: 10.1515/cdbme-2021-2059

Publication 5

From 'bench to bedside and back': Rethinking MedTec innovation and technology transfer through a dedicated Makerlab.

<u>**Fritzsche, H**</u>.; Boese, A.; and Friebe, M.

The Journal of Health Design, 6(2). July 2021.

DOI: 10.21853/JHD.2021.13 3

1. Introduction

Medical technology as a lead market with future potential [1] is highly technical and an engine of innovation and growth in the German economy. In 2018, this industry employed 350.000 people (including suppliers and service providers in the value chain) in more than 1.352 companies [2], generating a turnover of 30,3 billion euros [3], and is the most substantial market within the European Union [4].

The market is mainly characterized by small and medium-sized companies [5]. 94% of German medical technology companies have less than 250 employees and only 1% more than 1000 employees [6].

The MedTech industry is innovative and has very short product cycles. German medical technology manufacturers generate around a third of their sales with products not older than three years. On average, the research-based MedTech companies invest around 9 percent of their turnover in research and development [2]. Therefore, the MedTech sector is well above the industry average.

In order to further strengthen and expand this innovation performance, medical technology is part of the federal government's high-tech strategy. With the research and funding strategy of the Federal Ministry of Education and Research, the Federal Ministry for Economic Affairs and Energy and the Federal Ministry of Health, the national strategy process "Innovations in Medical Technology" was initiated to speed up the transfer of innovative approaches from research into application [7].

Additionally, current challenges like long and cost-intensive development cycles and complex cost structures for reimbursement in the healthcare sector, ethical approvals, new certification rules, and the impact of the new medical device regulatory guidelines, can hinder innovation and pose significant challenges for R&D and the transfer from bench to bedside.

1.1 The impact of new EU Medical Device Regulation on innovation

On May 26th, 2021, the new EU Medical Device Regulation (MDR) was intended to make medical devices even safer in Europe. For this purpose, medical devices must be re-certified as well as the notified bodies (state-authorized bodies that - depending on the risk class of the medical devices - carry out tests and assessments as part of the conformity assessment to be carried out by the manufacturer and certify their correctness according to uniform assessment standards).

Furthermore, the new MDR calls even more for Clinical Evidence, Clinical Performance and Clinical Benefit (Article 2, No. 52-54) [8, 9]. Thus, for the clinical need evaluation jointly with the user, the clinician has an essential role in the medical product development and should be integrated into a structured innovation process [10]. Here, clinical need evaluation includes not only the description of a deficit. Additionally, information about application, workflow, technical equipment, usability, case numbers and clinical relevance or risk is necessary. New requirements are [2, 11]:

- New classification rules, some are associated with higher classifications/ integration of a notified body
- Introduction of an additional evaluation procedure/consultation by a panel of experts for class III products
- More stringent requirements for clinical evaluation and the creation of clinical data
- Higher demands on the risk and quality management system as well as the technical documentation
- New regulation of monitoring after medical products have been placed on the market.
- The introduction of a European traceability system (UDI) with registration procedures (EUDAMED).

- Manufacturers must appoint a person responsible for compliance with the regulatory provisions (VPR) in their company.
- Notified bodies have to go through a notification process with more stringent requirements that is complex and time-consuming.

These high regulatory requirements will significantly impact the innovative strength, not only for the small and medium-sized companies that have to deal with this in terms of human and financial resources but also for the transfer of university research [12]. Many of the existing medical devices will not make it into the MDR in time. By 2024, when the transition period for legacy devices runs out, there is a bottleneck of access to notified bodies, innovation backlogs and distortion of competition [13]. And in the future, time to market and costs for innovation will be significantly extended and these cost will be added to the products and the healthcare system.

1.2 Innovation process and entrepreneurship activities

Innovation is defined as introducing new or improved products, services, or processes to increase a specific value [14] and advance successfully on the market, remain competitive, or differentiate oneself from the market [15]. Therefore, the term innovation includes a certain novelty and diffusion in the market [16] and is inseparable from entrepreneurial understanding and activities like spin-off and business generation [17].

In healthcare, innovation can cover several fields such as novel surgical technology, new tools, imaging methods, services, or nursing processes that aim to improve compared to previous methods [18]. In the health sector, the introduction of new products is regulated by many regulations and standards to ensure the safety of patients at all times [19]. This limits the freedom of innovation compared to other sectors than healthcare.

Using the example of "Open Innovation", the innovation process shaped by Henry Chesbrough starts with the idea generation as a creative process, followed by the concept screening and technical development of a solution, the validation and the market launch *(Figure 1)*. Especially in the healthcare system with patient benefits and the generation of added value for the doctor, the process is extended due to the high regulatory requirements and the complex market structure. Considering healthcare needs at an early stage would accelerate this process and provide a higher guarantee that the ideas will be examined and successfully implemented.

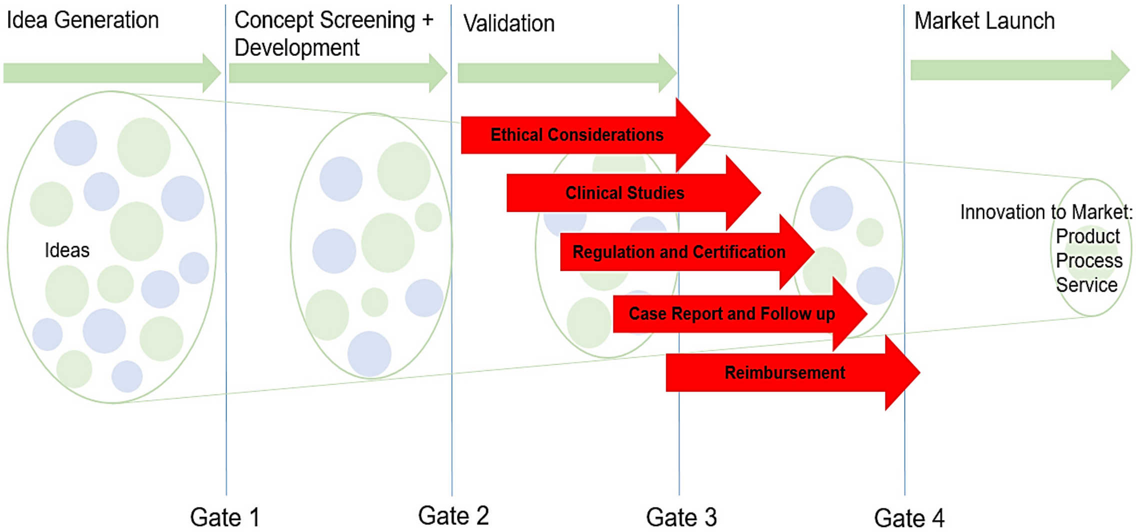

Figure 1: The innovation process (here using the example of open innovation) is extended in medical technology by considerable regulatory requirements with the associated ethical considerations, study designs, case reports and reimbursement.

Transformative and disruptive innovation in medical technologies is changing the delivery of care [20]. Disruptive innovations aim to replace the successful series of an already existing technology, an existing product or an existing service or to displace them entirely from the market and make the investments of the previously dominant market participants obsolete. Not only to develop new market models and the integration of exponential technologies but additionally to master the challenges of the 21st century with digitization, demographic change, a shortage of skilled workers, rising costs, overregulation and certification, pandemic and climatic conditions [21, 22, 23]. These are significant challenges but also opportunities to develop new technical solutions and open up new markets. Furthermore, exponential technologies, miniaturization and dematerialization also offer approaches that democratize healthcare delivery and will allow the affordability of technologies and services in different countries and economic statuses.

1.3 Obstacles in current academic training

Many initiative training programs try to meet the need for interdisciplinary training at the academic level [24] to face these regulatory- social- and political issues. However, universities have not adequately addressed these conditions and the adaptation of academic training concerning the interdisciplinary generation of innovation in the cooperation of medical professionals, biomedical engineers, scientists and economists. Thinking, acting and educating is still present at the faculty level instead of application-driven research and need-based education for this sector [25].

Techniques and methods for innovation and entrepreneurship at the interdisciplinary level should be learned early in undergraduate and graduate education. As a key developer at the interface between medicine and engineering, the biomedical engineer must be equipped with the appropriate tools to transform the current supply for medical technologies in modern healthcare.

Current problems in training are a lack of competencies in the 21st-century skill set for the interdisciplinary exchange like problem-solving, communication, stakeholder empathy, curiosity stimulation [26, 27, 28]; a lack of start-up generation, entrepreneurship for understanding health economics and reimbursement within healthcare [29] and the integration according to the regulations required by the MDR [30].

These are essential factors for innovation [31], but the aim should be teaching within a dedicated environment with applied Innovation and Entrepreneurship rather than about Innovation and Entrepreneurship [32]. Therefore, it needs application-oriented hands-on trainings within an innovation ecosystem with solid innovation culture and creative stimulus.

2. Methods

This chapter describes how a university-based innovation laboratory can meet this need for medical technology innovation and entrepreneurship on the academic side for teaching, research, and transfer. The laboratory structure, innovation methods, operations, and network activities as a concept for rapid ideation, development, and market exploration from the idea to prototype are presented.

2.1. ego.-INKUBATOR Innolab IGT

The establishment and expansion of an innovation laboratory were carried out as part of the ego.-INKUBATOREN funding from Saxony-Anhalt with ERDF funds to set up a maker lab, i.e., a prototype and a start-up workshop at the OVGU in Magdeburg. The promotion of incubators is intended to develop entrepreneurial thinking in universities, research new solutions, and promote academic business start-ups [33], which exactly fits the innovation process's transfer concept.

In 2016-2021, the Innolab IGT was set up as an innovation hub between academic training, medical technology research, clinical application and industrial marketing. For this purpose, the FEIT and the FME cooperated in establishing this technical development laboratory directly on the medical campus to guarantee clinical access, involvement of all stakeholders and fast communication structures.

2.2. Methodology – structured innovation process

To approach a structured innovation process, the Innolab IGT follows a combination of the innovation methodologies of Tim Brown's "Design Thinking" from IDEO and Paul Yock's "Biodesign" program from Stanford.

These agile and disruptive innovation methodologies, encompassing all stakeholders, are intended to generate growth through innovation. It is based on high-frequency, low-cost tests and iterative improvements that promote flexibility and quick reactions to validated feedback from all stakeholders involved.

2.2.1 Biodesign

The Biodesign methodology developed at Stanford University in 2001 is based on the concept that innovations in healthcare can be reproduced, taught and learned in a closed-loop [34]. The process consists of three phases: identify, invent, implement [35]. They are identifying unmet clinical needs in a clinical area of a hospital, brainstorming and inventing a solution to those needs, and implementing them through a solid business model aimed at developing a medical device or technology.

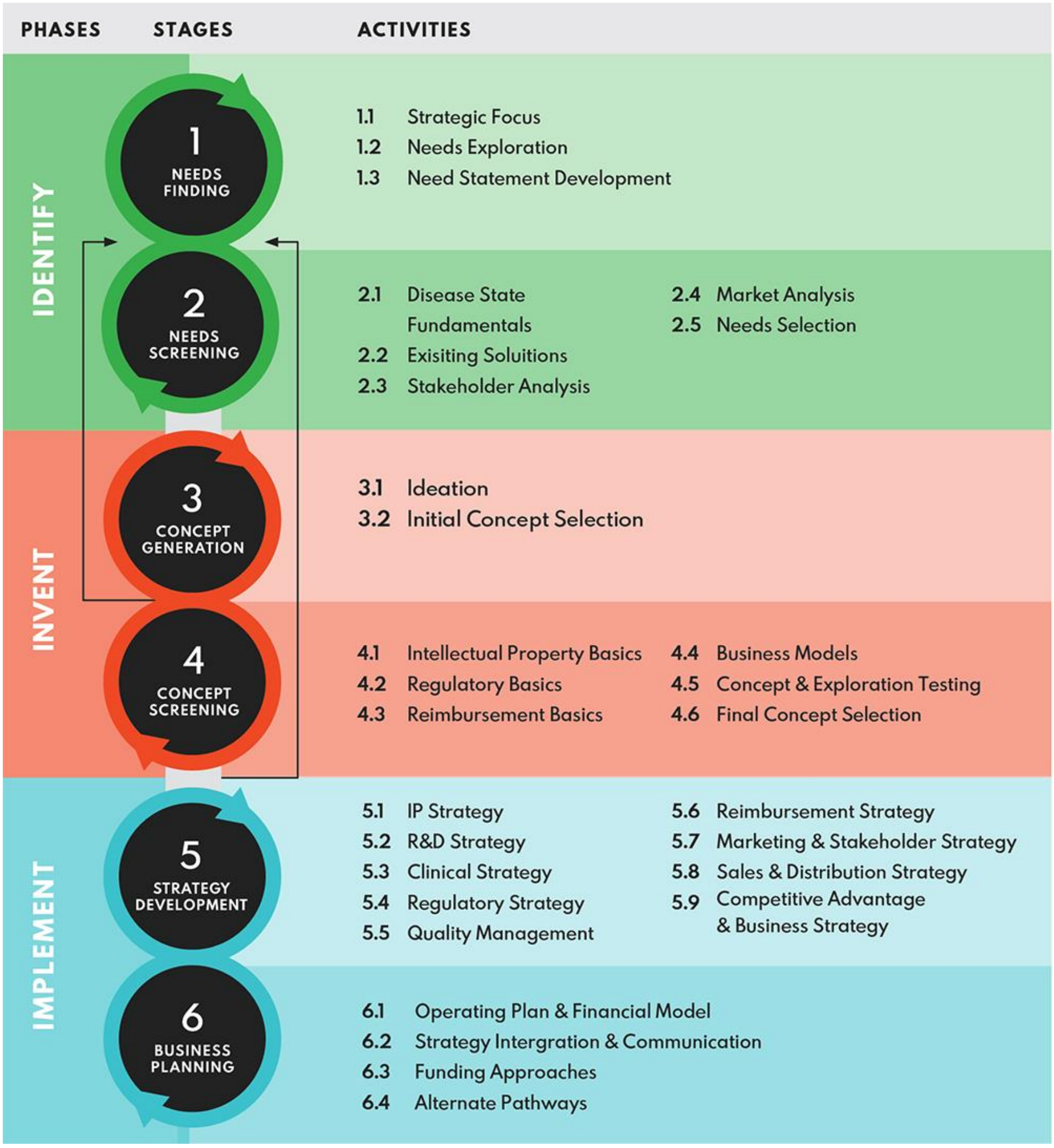

Figure 2: Biodesign, the Process of Innovating Medical Technologies split into the phases Identify, Invent, Implement and the associated stages and activities. [35, 36]

2.2.2 Design Thinking

Design Thinking as an innovation methodology creating innovations and new business ideas that are closely oriented towards the user and his needs. It is primarily about a deep understanding of the problem and user empathy (in the healthcare sector, the patient, the doctor or the nursing staff). This agile innovation process is divided into six iterative steps [37]:

1. Empathize
2. Define
3. Ideate
4. Prototype
5. Test
6. Implement

It is about experimenting quickly and gathering new knowledge to focus on the user and his needs.

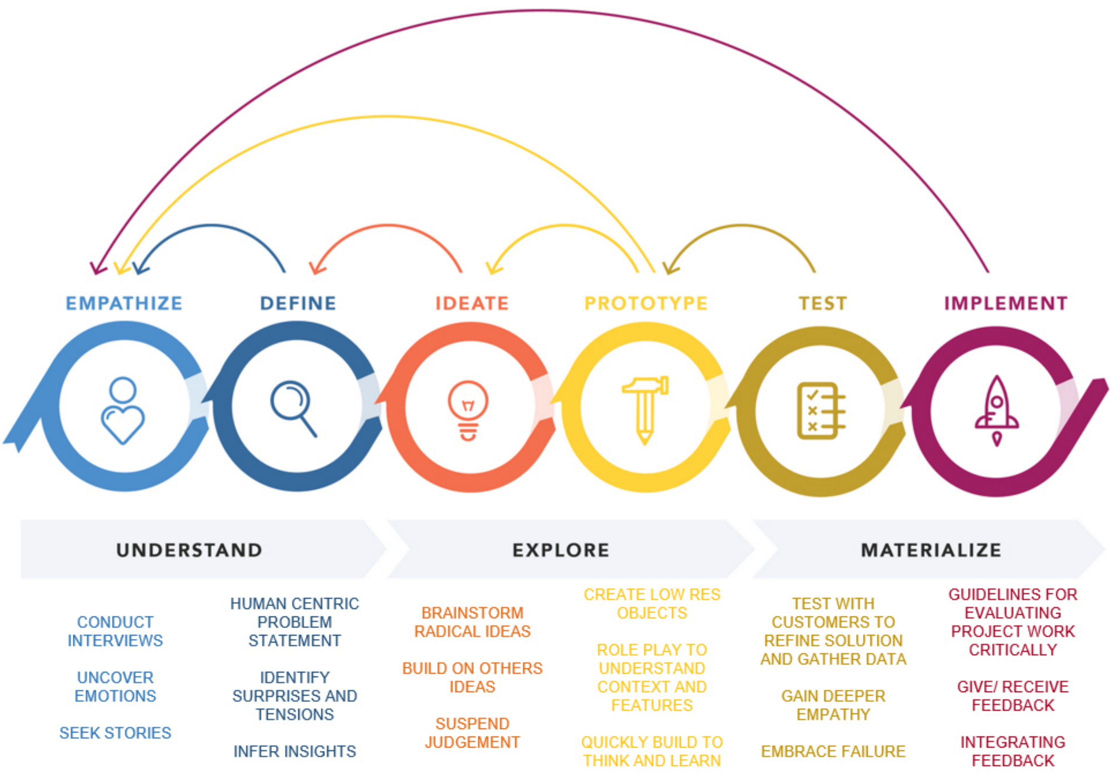

Figure 3: The six iterative steps of the Design Thinking approach and the corresponding tasks must be solved within the individual steps [37, 38].

2.2.3 Innovation methodology merge: I³ EME

Experience from both innovation methodologies show that

- Innovation can be learned and carried out in a structured manner and is necessary, especially in medical technology.
- Interdisciplinary teams improve the innovation process and are the basis for successful developments in medical technology.
- Medical technology is a combination of various technologies.
- Understand the working methods and problems of the customer (medical professionals and patients).
- Teamwork, presentation techniques, communication and other soft skills are taught.

Therefore, the essential core points of both innovation methodologies were fused and taught under the innovation concept I³ EME by Prof. Michael Friebe within the student training of the Innolab IGT [39]. The combination of the Biodesign process (iterative interaction between Identify an Unmet Clinical Need - Invent a potential solution - Implement a verified solution in a product = I³) and the interdisciplinary exchange of competencies and the cooperation between the Engineer, the Medical User and the Economist *(Figure 4)*.

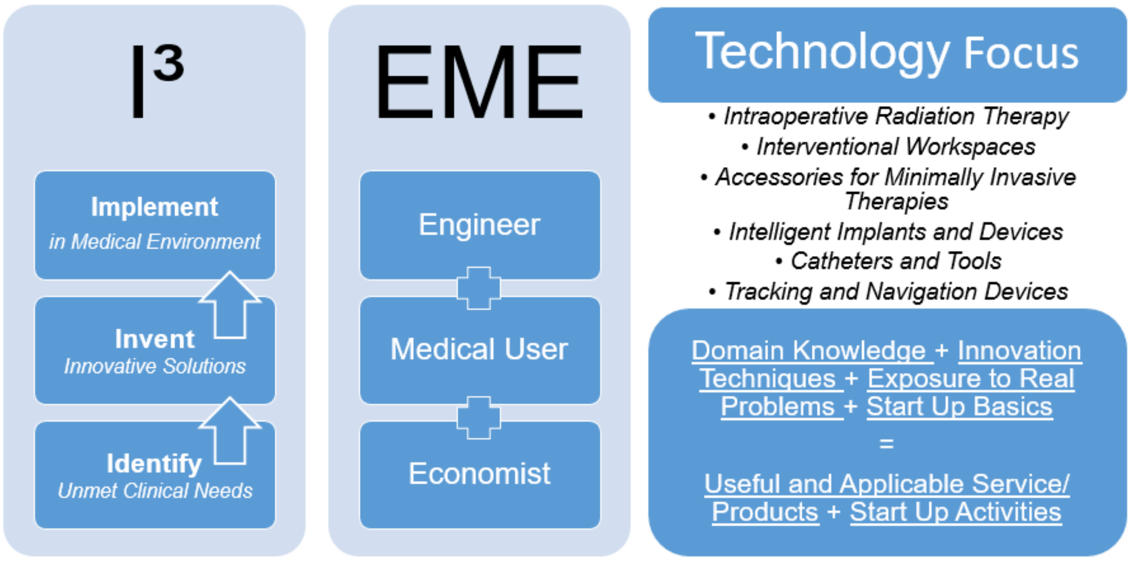

Figure 4: The innovation concept I³-EME by Michael Friebe for medical products and services of the former chair for catheter technologies @ OVGU Magdeburg (I³ - Identify, Invent, Implement + interdisciplinary exchange between the engineer, medical user and economist)

2.3. Organization and design of the Innolab IGT

According to the innovation methodologies presented, a creative and adapted workspace is required to process individual steps accordingly. The main aim here is to create an open and creative environment that stimulates and promotes innovative work with adjustment to the teaching concept of Michael Friebe and the professional orientation of the research group. Furthermore, it must offer the possibility of building prototypes and corresponding test options under clinical conditions. Therefore, the lab is divided into three workspaces: a creative workspace, a prototyping workshop and a simulation OR.

2.3.1 Creative workspace

The creative area is intended as an open, bright and colorful workspace for brainstorming, concept studies and meetings. Here one will find individual and group workplaces in a flexibly furnished area. Several whiteboards, a smartboard, a cozy couch corner, desks and group spaces offer a variety of options always to meet group requirements and offer enough opportunities to find, discuss, and develop ideas.

Figure 5: View into the creative workspace of the Innolab IGT

2.2.2 Prototyping workshop

After the creative and ideation phase, the concepts can be technically implemented in the connected prototype workshop. First, the developed product ideas are checked for technical feasibility and built directly as prototypes. For this purpose, the prototyping workshop is equipped with various 3D printers (3 FDM printers, 1 SLA printer), milling and turning tools for processing the finished parts, workplaces with a soldering station to implement electronic components, and many precision tools are available. In addition to building prototypes, there are various options for building test and measuring stands, producing gelatin phantoms and using a static-material-testing machine.

2.2.3 Simulation SR

A simulation surgical room was set up to test, demonstrate and evaluate the manufactured prototypes under simulated clinical conditions. Here one finds a minimally invasive operation setup with patient table, ENT and urology-capable endoscopy tower with RF generator and irrigation system, ultrasound and ultrasound tomography systems, navigation and tracking devices, a vacuum pump, two fully programmable robotic arms, surgical equipment and other clinical consumables.

Figure 6: View into the Innolab IGT, the open creative space (above) with simulated surgical room (bottom left) and one of the prototype workshops for hardware development and electronics production (bottom right) [cf. Publication 5].

2.3. Innovation training

In addition to the physical infrastructure, the innovation ecosystem includes the appropriate people who implement creative ideas with their skills and mindset. The focus is on the aforementioned agile innovation methods, 21st-century skills and future-oriented thinking.

2.3.1 Student education

The lecture series *Innovation Generation and Entrepreneurship in the Healthcare Domain*, *Image Guided Surgeries*, *Translational Technology Entrepreneurship* and *Health Tec Innovation Design (Figure 7)* was offered as a training basis for the students, mainly in the master's seminars. Above all, students with interdisciplinary approaches from the respective master's degree courses participated (especially integrated design engineering, medical systems engineering, mechanical engineering, electrical engineering, software engineering and medicine).

Interdisciplinary student teams (3 to 5 members) are formed here every semester to identify clinical needs when visiting live surgeries and develop many ideas for each problem. The ideas are then regularly passed back to the clinicians, who see and discuss the developed prototypes.

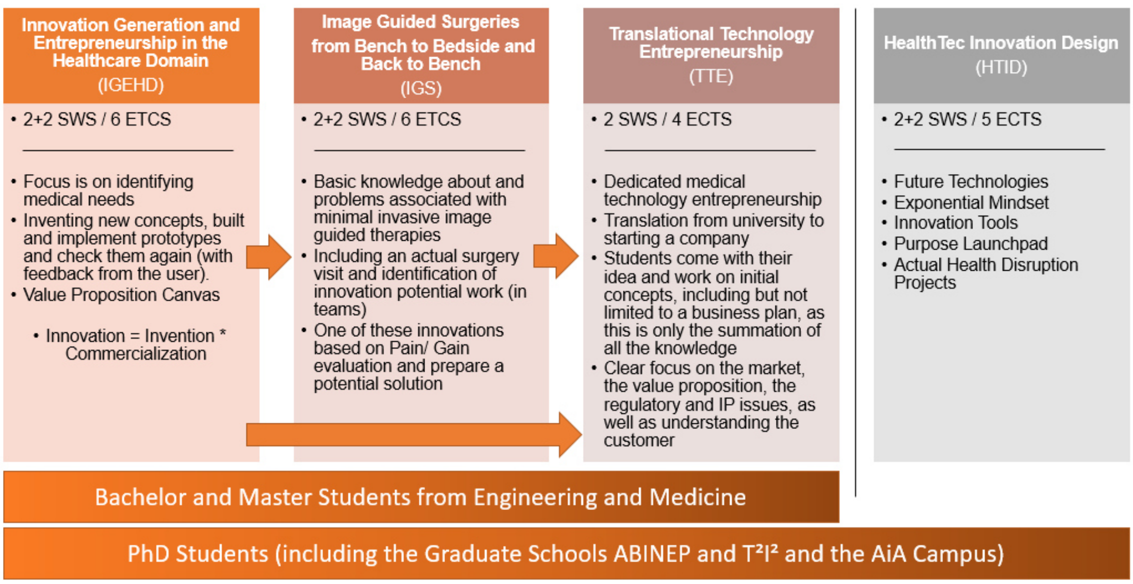

Figure 7: The series of lectures on innovation design and entrepreneurship conducted by Prof. Michael Friebe [40, 41]

2.3.2 Graduate school

In order to integrate and manifest innovative and creative thinking as an integral part of the development process, the project supervisors- primarily the Ph.D. Students must be trained in innovation methods, their technical skills and applied skills of the 21st century.

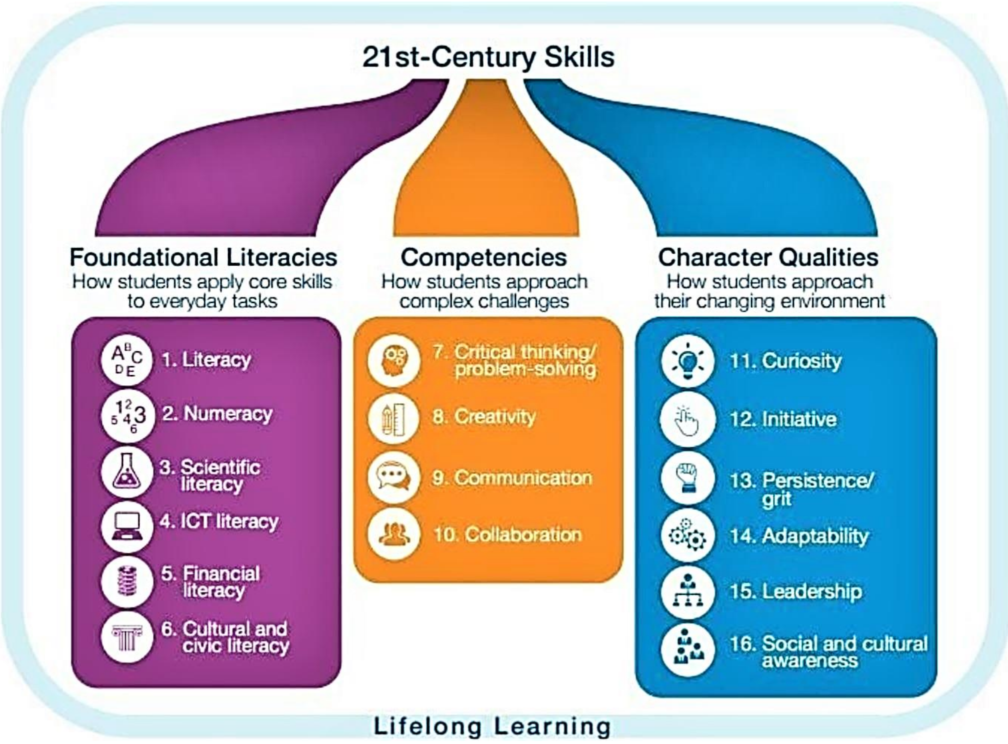

Figure 8: 21-st century skills for students; students require 16 skills for the 21st century [42]

For this purpose, the Innolab IGT acts as the central point of contact for the doctoral program of the graduate school "Technology Innovation in Therapy and Imaging – T^2I^2". It is a structured doctoral program focusing on innovation generation, technology transfer, and medical technologies' economic implementation. Thus, the training includes technical understanding in medical application and taking economic aspects into account.

The aim of postgraduate education is an intensive, research-oriented education in which the students acquire knowledge in the fields of natural or engineering sciences and medicine and deepen their knowledge in the field and expand technological innovations in therapy and imaging with the ability to maintain the practice, research and teaching-related fields of activity, as well as their soft skill development.

2.3.3 Innovation Think Tank Certification Program

The Siemens Healthineers Innovation Think Tank Program trains participants about the innovation management methodologies derived from the vast experience of establishing and running ITT Labs worldwide and driving numerous interdisciplinary projects between locations. In addition, the participants learn co-implementation approaches by working on real-life challenges of the healthcare systems. Students and staff are capable of taking part in this program to get an innovation mindset from the industrial side. Here the focus is on:

- Innovation Think Tank Methodology in practice, experiential learning, team building and task assignment
- Ideation and Development, teamwork, feedback sessions, elevator pitch preparation
- Outcome Exhibition and review of the results

If the participants are successful, they will receive a recognized Siemens Healthineers Innovation Think Tank certificate. Meaningful experiences and knowledge for the new development of a demand-oriented curriculum are to be collected here.

2.4 Internal innovation networks

The internal network is intended to offer exclusive access to various actors in the innovation process for medical-technical ideas and projects with the aim of:

- Accelerate internal information flows
- Securing internal information and its communication,
- Quick access and availability of all stakeholders,
- Simplify work by allowing all departments to access one another
- Organize and optimize operational processes,
- Provide a wealth of evaluation options for ideas, prototypes and clinical applications

2.4.1 Medical Advisory Board

Especially for medical technology development and the application of new ideas and prototypes, a network of clinical users with appropriate expertise is necessary to evaluate chances and possibilities for added value. With the establishment and quarterly medical advisory board meetings, the students can present their innovation projects and record needs from a clinical perspective. They also regard specific questions about study design, ethical issues, MDR and DRG.

Cooperating partners from FME for Innolab IGT are the ENT, urology, neuroradiology, radiology, nuclear medicine, dermatology, vascular surgery, nephrology, orthopedics departments, and the cardiac surgery represented by the leading professors or their deputies.

2.4.2 Industry Advisory Board

The industry advisory board with several small, medium-sized, and large companies from Saxony- Anhalt and other German locations was also established. The companies come from the most diverse branches of medical technologies and also follow different business models. Therefore, the board should be available as an advisor, especially for questions relating to market design, production, and medical technology certification. In total, the Innolab IGT has received support from 19 companies over the past five years.

2.4.3 Makerlabs

The above-mentioned ego.-INKUBATOR funding from the state of Saxony-Anhalt resulted in 12 makerlabs in a wide variety of specialist areas at the university.

Due to the wide range and the technical expertise of individual supervisors and the special equipment of these start-up laboratories, the Innolab IGT gets broad support, especially in electronics production, prototyping and design, and software development. The laboratory supervisors meet in a monthly brokerage meeting and exchange information regularly. They are supported and coordinated by the Transfer and Entrepreneur Center of the OVGU.

Table 1: Overview of all 12 Makerlabs run at the OVGU from the ego.-INKUBATOR program

Makerlab	Field of Use	Main Equipment
ADDITIV ego.-INKUBATOR	Additive manufacturing	SLM / LMF 3D printing, Vibratory grinding machine, Confocal microscope, Drag grinding system, X-ray diffractometer
AppLab ego.-INKUBATOR	Development of mobile apps, web services and graphical surface development	Database Software, Programming Software, Graphical surface/ user software
AWI-Lab ego.-INKUBATOR	Product, process and service solutions in the area of "Working World 4.0" with focus on lead markets "mechanical and plant engineering" and "health and care"	Assembly laboratory, Care laboratory Communication laboratory
FabLab ego.-INKUBATOR	Prototype construction and hardware design	3D printer, Maker carrel, Laser cutting, CNC portal milling machine, Conventional lathe, Conventional milling machine, Injection molding machine
FinTech ego.-INKUBATOR	Hardware and software solutions for cryptocurrencies and block chain technology	Solar modules, storage and Measuring systems, Sensor kit for Raspberry Pi and Arduino, Blockchain.prototype, python, latex
FLEXtronic ego.-INKUBATOR	Manufacture and design of electronic and mechanical parts	Laser structuring system, Galvanic through-hole plating system, Riveting press, 3D printer, Laser cutter, CNC milling machine, chemical circuit board structuring, Soldering and measuring technology
iGE innovative Gussteil-Entwicklung ego.-INKUBATOR	Casting production	Color laser scanner, RP machine, Molding printer
IGT INNOLAB ego.-INKUBATOR	Prototyping for Image Guided Therapies	Simulation OR with Medical Equipment (Endoscopic system, Ultrasound, Tracking system, robotic arms, RF-generator, patient table) / Prototype Workshop (3d Printer, electronic workshop, Soldering devices, fine tools)
inzell innovative zellulare Werkstoffe ego.-INKUBATOR	Manufacture of materials, components and coatings	Computed tomographic Scanner, Planet ball mill, software

IP-LogMo ego.-INKUBATOR	Prototypes for logistics and mobility	Aluminum, wood and steel processing, Motorized swivel bending machine
Performance Lab ego.-INKUBATOR	Development of diagnostic and training devices for sport, health, psychology, neurophysiology and medicine	Biofeedback / Neurofeedback, Eye tracking, Response time measurement, Motion capturing, Spiroergometry, functional screening, Inertial sensor, Balance measurement, Hand force dynamometer
PM Patientenindividuelle Medizinprodukte ego.-INKUBATOR	Prototype and phantom construction for medical applications	CAD construction, Computed Tomography, STL printer, 3D scanner for component measurement

2.5 External innovation networks

The external networks are associations and clubs with access to scientific conferences, various academic journals and specialist committees to standardize techniques, hardware and software. The platforms are intended to facilitate scientific exchange and the knowledge base for the newest achievements in the medical technology sector.

2.5.1 VDI AK Medical Technology (regional network)

The Medical Technology Working Group has existed since January 1st, 2017 and is one of the five specialist areas of the VDI Association Technologies of Life Sciences. It works with topics and new trends in medical technology, the importance of this industry for the business location of Magdeburg and the surrounding area, and the influence of medical technology developments on our modern life and society.

The working group will take up current research results and challenges from dynamically changing political guidelines and deepen them through lectures, exchange of ideas, discussions, and excursions. All areas of medical technology such as therapy and diagnostic procedures, rehabilitation measures, approvals of medical products, materials, surgical techniques and tools, implants and much more are addressed.

The Medical Technology Working Group of the Association of German Engineers is committed to transferring knowledge between engineers and doctors on the one hand and scientists and users on the other.

2.5.2 BMEidea EU (European network)

In 2013, the first Europe BMEidea (Biomedical Engineering- Innovation, Design and Entrepreneurship Alliance) meeting was held among programs there and is held annually. With the goal to [43]:

- Review the experiences of different university programs involved in innovation, design, technology transfer and entrepreneurship in biomedical engineering education.
- Discuss objectives, challenges, and opportunities for further development of these programs – including industry and academic perspectives.
- Explore the potential for sharing resources and creating community-wide tools (e.g., web portal, national design contest).

Create Toolboxes for innovation, design, technology transfer and entrepreneurship within Biomedical Engineering Education. In addition, there is the opportunity to present tools that have been developed to support need-led innovation education. Alumni will also have the opportunity to exchange knowledge with participants of other programs and learn from each other.

2.5.3 IEEE EMBS (international network)

The IEEE - EMBS is the world's largest international society for biomedical engineers. The IEEE EMBS establishment comprises members who are helping to transform the way healthcare is delivered by developing advanced computer models, tools, and wireless technologies that enable patients and doctors to communicate over long distances. Revolutionizing the face of healthcare is the goal.

The OVGU MedTech chapter helps medical and digital technology students with their current needs or future aspects. It promotes the IEEE and EMBS at various partner universities and organizations in Germany by offering seminars, lectures and educational, academic and social activities as part of the regular training. As the IEEE chapter, they invite renowned experts from all over the world to seminars for speakers and IEEE Distinguished Lectures to present topics from biomedical fields that are of interest to members and students and impart knowledge about the latest technological developments worldwide.

3. Results

With the approval of the ego.-INKUBATOR funding at the beginning of 2016, the former Chair for Intelligent Catheters (INKA) set up the Innolab IGT directly on clinic onsite and put it into operation. As a result, an innovation ecosystem was established, close to clinical facilities and partners, with prototyping infrastructure, simulation SR, internal and external networks, a broad offer of student courses and a structured Ph.D. Program (cf. Publication 1).

This chapter presents key performance indicators and achievements of the Innolab IGT in the period 2016 - 2021. Data and results of the papers listed in the list of publications have been summarized here and can be found in detail in the individual papers.

3.1 Training and education

In the section of training and education, the number of students (Bachelor/ BA, Master/ MA and Ph.D. Students/ Ph.D.) was set as a key performance indicator and the number of processed projects and international research engagements. In *Table 2,* one can see that in this five years, 125 students have taken the innovation and entrepreneurship training within the Innolab IGT framework, which has worked on 85 Projects and collaborated in 10 international research engagements.

Table 2: The Key Performance Indicators for Training and Education are split into Students that have taken the Innolab IGT Innovation and Entrepreneurship Training, processed Projects and International Research Engagements.

Training/Education	
Students (BA, MA, Ph.D.)	125
Projects	85
International Research Engagement	10

(cf. Publication 4, 5)

3.1.1 Graduate school

The graduate school T²I² (Technology Innovation in Therapy and Imaging) was officially recognized and supported in 2017 as a structured doctoral program by the graduate academy of the OVGU. Intending to set the innovation and entrepreneur mindset for the supervising Ph.D. students, mainly from Biomedical Engineering, 8 Ph.D. students follow the teaching program within the research group at Innolab IGT. Six Ph.D. students are in the final phase, and two have already completed the program.

Table 3: The Graduate School T²I²- Technology Innovation in Therapy and Imaging had an overall attendance of 8 participants, here 6 are currently working on their PhD Thesis and two are already finished.

Graduate Program	
PhD Students	6
PhD	2

(cf. Publication 1, 2)

3.1.2 Advanced innovation curriculum

With the learnings of the previous teaching programs, conferences, and certification programs, a novel study plan for Biomedical Engineering educational curriculum based on economy/business, medical/clinical/healthcare innovation and engineering study subjects, with corresponding credit points (CP), is proposed. A four-semester study plan with the interaction of medical faculty, engineering faculty and hospital structures (cf. Publication 3)

Table 4: The study plan articulates into four semesters covering economic/business with 50 CP (blue color), medical/clinical/healthcare innovation with 50 CP (purple) and the Innovation Lab in cooperation with the hospital with 10 CP (orange color).

1. Semester	2. Semester	3. Semester	4 Semester
Marketing for Healthcare 5CP	Value Based Technology and Innovation Management 5CP	Entrepreneurial Finance and Venture Capital 5CP	Master Thesis 20CP
Market Research and Business Modeling 5CP	Medical Innovation Needs 1 - Clinical Input (MI1) 5CP	Discover UNMET CLINICAL NEEDS in a clinical Innovation Lab - think Entrepreneurial (UCN) 10CP	
Innovation to Healthcare Democratization 5CP	Individual Healthcare International - application of Value Proposition Canvas and Biodesign Principles (IHI) 5CP		Health Economics and Reimbursement 5CP
Healthcare Technology Innovation - future developments with high impact and need for change (HTI) 5CP	Exponential Technologies and Designs for Extreme Affordability - Healthcare related (EXP) 5CP	Medical Innovation Needs 2 - Screening, Diagnosis, Therapy, Prevention, Inpatient versus Outpatient (MI2) 5CP	Healthcare related Regulatory issues + Medical Product Risk Analysis (REG) 5CP
20 CP	20 CP	20 CP	30 CP

3.1.3 European and international conference

From 11.- 13. June 2017, the 5th BME-IDEA EU conference took place in Germany for the first time. Ninety international participants came to Magdeburg for three days to discuss future trends and technologies in the healthcare sector. The program included scientific talks and lectures, panel discussions with clinical and technical experts from research, development and industry, and working sessions in which ideas were developed in small groups during the conferences. The conference proceedings and the summary of the European "Biomedical Engineering - Innovation, Design, and Entrepreneurship Alliance - BME-IDEA" are available with more than 50 articles on:

- healthcare vision and clinical innovation,
- healthcare digitization,
- exponential technologies,
- regional healthcare vision,
- and dedicated healthcare technologies,

by a very international and interdisciplinary group of people. Available as *ISBN 978-3-944722-59-7* or as *DOI: 10.24352 / UB.OVGU-2017-76.*

From November 22 to 24, 2019, the IEEE EMB International Student Conference 2019 followed directly on the clinic side with more than 150 students and guests from Biomedical Engineering, natural sciences and medicine. In addition, the topic of "Global Young Professionals Addressing Today's MedTec Challenges for a Healthier Tomorrow" was pursued in 8 keynotes by international specialists and business leaders, three working sessions and a poster award competition.

Here, it could be implemented successfully:

- an engaging platform for identifying current health problems,
- inventing possible solutions that are sustainable and scalable through breakout sessions,
- a range of networking opportunities with industries and startups,
- exposure to quality content,

- immersive experience through hands-on sessions, stimulating discussions and workshops,
- research opportunities and opportunities in the biomedical field,
- improving technical writing skills.

(cf. Publication 5)

3.2 Research activity

Other key performance indicators in the research activity section were Publications, Patents / Invention Disclosures and Clinical Studies / Preclinical Studies. More than 262 publications have been published by the Innolab IGT since 2016. Seventeen patents could be registered, and 37 invention reports were written. In addition, there are ten clinical studies / pre-clinical studies, mainly in the areas of data acquisition for tracking and ultrasound.

Table 5: The Key Performance Indicators of the Research Activity of the Innolab IGT are divided into publications, registered patents/ invention disclosures and clinical studies / preclinical studies carried out

Research Activity	
Publications	262
Patents/ Invention Disclosures	17/ 37
Clinical Studies/ Pre-clinical Studies	10

(cf. Publication 4, 5)

3.3 Transfer

In *Table five*, the key performance indicators for the transfer of the Innolab IGT are presented. Due to the clinical connection and the intensive integration of industry and networks, Innolab IGT completed three industry-driven projects (injection pump, thermographic imaging, and non-destructive testing). In addition, six startup projects have been generated thus far:

SURAG GmbH (Surgical Audio Guidance): auscultation system for sound-based tissue characterization (e.g., positioning of verres needles for laparoscopic interventions).

InLine GmbH: MRI-compatible surgical tools and assistance devices that help radiologists to perform safe, precise, and easy interventions.

EasyJector GmbH- a lightweight, inexpensive, easy-to-use (MRI-compatible) injection system for pharmaceuticals.

Rad print - Individual radioactive patches for treating superficial skin tumors.

SmartReha - a virtual reality-based training program for stroke rehabilitation for people with paralyzed limbs.

MEDICS GmbH - Medical innovation and certification services for supporting companies in regulatory and certification processes/quality and process management - especially in the context of new medical device regulations.

Table 6: The Key Performance Indicators for the Transfer Strategy of the Innolab IGT shown as transferred Projects, generated Revenue and foundet Start-ups.

Transfer	
Transfer Projects (ZIM/ IB)	3
Revenue Generated	€ 3.7 million
Startups	6

(cf. Publication 4, 5)

3.5 Differentiation from other Biodesign based EU programs

Under the established key performance indicators, the individual programs of the BMEidea network were checked in an EU comparison and as a statistical survey from the individual institutions. Through a qualitative survey, seven Biodesign-based programs in the EU were examined. The study contains information (from an academic perspective) covering:

- Resources (Employees, Network Partners)
- Activities (Training Batches, Participants)
- Academic Performance (Unmet Clinical Needs, Research Projects, Publications, Studies) and
- Transfer Performance (Patents, Transferred Unmet Clinical Needs, Start-Ups/ Spin-Offs).

Table 7: List of the results of surveyed institutions from the BMEidea EU network partners

	Resources		Activities		Academic Performance				Transfer Performance			
	Empl	**Net**	**Batch**	**Partic**	**UCN**	**RP**	**Pub**	**Studies**	**Patent**	**Trans**	**Startup**	**Spin-off**
Erlangen	150	170	reg	8000	500	50	N/A	0	500	N/A	5	20
Aarhus	6	25	1	16	600	1	0	0	0	1	2	0
Acibadem	16	20	4	40	N/A	N/A	15	4	3	14	1	0
London	2	N/A	6	40	100	40	20	40	10	0	8	0
Oxford	2,5	7	4	18	2000	4	1	N/A	2	0	4	4
Magdeburg	12	29	14	150	150	85	262	10	64	5	3	4
Munich	2	9	10	110	30	4	2	0	0	0	5	0
Stockholm	2	N/A	10	80	N/A	N/A	N/A	N/A	0	N/A	7	N/A
Delft	50	N/A	15	2000	N/A	N/A	N/A	N/A	N/A	N/A	25	N/A
Galway	4	26	10	108	5000	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Barcelona	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

(cf. Publication 4)

4. Discussion

The motivation of this thesis is to build an innovative research laboratory for medical technology and generate business start-ups from university projects through a creative and motivating environment, close to clinic, with a network of various stakeholders from medicine and industry. The aim is to involve students in real-life projects at an early stage in their academic training and to teach them innovation management and entrepreneurial thinking in order to enable technical transfer. The biomedical engineer gets a fundamental understanding of the problem through live medical intervention observation, good communication and an empathic understanding of the user (doctor, patient, nurse), which forms the basis for the innovation process within the Innolab IGT. Creative work produces a multitude of ideas and possibilities to solve the unmet clinical needs which are quickly checked and validated by the corresponding innovation concept I³-EME for their usability in terms of technical implementation, market launch, reimbursement and regulatory obstacles. The validated ideas can be quickly converted into a prototype with good laboratory equipment and broad support from network partners. Students receive hands-on training on real-life problems and applications while working on the project. As a result, all stakeholders involved benefit from scientific recognition of economic translation via patents and start-up generation, education and knowledge transfer, or economic stimulus.

4.1 The innovation laboratory concept (Publication 1)

In the Paper "INNOLAB - Image-guided surgery and therapy lab - Run by engineers at a university hospital for interdisciplinary and useful innovation with clinicians", the structure and the organization of the Innolab IGT are presented according to the innovation methodology of the Biodesign approach: identify, invent, implement.

Innovative and creative work is intended to encourage the rapid implementation of prototypes with a creative area, a prototype and electronics workshop and a simulation operating room. Furthermore, good communication and exchange structures are created to process projects quickly and efficiently due to clinical proximity. For this purpose, the interdisciplinary cooperation of the biomedical engineers with medical students and clinical staff is part of the teaching approach of the chair. Based on this approach, engineering students get access to the clinic and real-live surgeries, to observe unmet clinical needs, and to get a deep understanding of clinical processes and an empathic understanding of patients and doctors. For further project development, students have the opportunity to share their prototypes and project ideas with experts from the presented advisory boards, i.e., the clinical panel (later medical advisory board) and the industry advisory board.

4.2 Postgraduate innovation training (Publication 2)

The Paper "How do we need to adapt Biomedical Engineering Education for the Health 4.0 challenges?" shows challenges and requirements for Future Medical Technologies and reports on the setup of the Graduate School "Technology Innovation in Therapy and Imaging (T^2I^2)" to face these needs. The graduate school has implemented a structured post-graduate program and focuses on interdisciplinary and application-oriented innovation generation education within the Innolab IGT as a central contact point. The educational process starts with observing and identifying clinical needs and an in-depth understanding of the need. Subsequently, it covers all steps necessary to transfer prototypes into viable solutions and further into implementing valuable products to face challenges and requirements for Future Medical Technologies.

The graduate school will focus on healthcare's innovative and entrepreneurial aspects and teach students to make those innovations marketable. Four areas are defined here, which form as the basis for training the core competencies of the Ph.D. Students:

- For *Scientific literacy*, at least 3 Conference Contributions and 3 Journal Publication and over 300 h subject-specific further training are expected.
- *Clinical literacy* includes several OR observations, medical co-supervision and working in interdisciplinary groups.
- In *Entrepreneurship/ Business modeling*, active involvement in start-up projects, writing at least one invention disclosure/ patent application and cooperation through industry-driven projects is required.

- For *Management skills*, the students have to work on research proposals, take over master/ bachelor supervision, and a minimum of one conference/ summer school organization.

4.3 Applied innovation education (Publication 3)

The Paper, “A structured pathway towards Disruption: a novel Entrepreneurship Design Thinking Curriculum for Health Innovation”, describes the learnings from the Innovation Think Tank Certification Program, Health Tec Innovation Design Lecture and SciFi Hive- Future of Health Event to define a new curriculum. It is intended to face the need for educating students at the border of engineering and medicine to manage and streamline the innovation process, focusing on disruptive and exponential technologies with healthcare democratization as the aim. The presented master curriculum for Health Tec innovation design primarily aims at three interface areas for clinical innovation:

- *Healthcare economics*: Methods of health economic evaluation (benefit assessment, cost assessment, direct costs, indirect costs) play a significant role concerning healthcare democratization and require a deep understanding of economic processes and reimbursement for medical effectiveness and economic efficiency. Students are trained in a financial analysis perspective and can decide on broad expertise in various economic backgrounds for research and innovation projects.
- *Innovation Methodologies*: with various agile innovation methods in product development, students can quickly resolve any problem and be goal-oriented. In addition to the basics and the constant exchange in interdisciplinary groups, the students apply methods in real projects and deal with regulations and certifications.
- *Application-driven research*: Students cooperate with the Innovation Lab and clinical departments to apply economic knowledge and innovation methodologies to detect unmet clinical needs, solve them with the newest approaches, and change the whole process.

4.4 Innovation ecosystems (Publication 4)

The research and development of medical technologies and devices face long and capital-intensive product development cycles, complex regulatory procedures, slow market uptake requiring the support of key opinion leaders and intensive follow-up with early adopters. Not only the qualitative education of students plays a role, but also the access to essential resources within this innovation ecosystem. These resources include clinical and industrial partners, access to clinical units like surgery rooms, development structure, and transfer concepts.

In the Paper "State-of-the-Art: Biodesign based Innovation Ecosystems in Europe", 7 Biodesign based Innovation Programs from the BMEidea EU Network are analyzed to detect strengths and weaknesses and to learn for further improvement. Based on the key performance indicators of the Innolab IGT, here Information about Resources (Employees, Network Partners), Activities (Training Batches, Participants), Academic Performance (Unmet Clinical Needs, Research Projects, Publications, Studies) and Transfer Performance (Patents, Transferred Unmet Clinical Needs, Start-Ups/ Spin-Offs) are collected.

The data collection generally shows a strong innovation network with all the necessary factors for successful innovation and transfer, in which the Innolab IGT (Magdeburg) is widely represented. What is striking here is Siemens Healthineer's Innovation Think Tank Program (Erlangen), which is the only industry-driven innovation program to have consistently strong indicators. However, comparability is generally limited because all Biodesign programs have different start and run times, focus points, transfer strategies and application areas.

4.5 Realization and achievements (Publication 5)

The Paper "From 'bench to bedside and back': Rethinking MedTec innovation and technology transfer through a dedicated Makerlab." presents the setup, network environment, and the initial results and learnings from developing the Innolab IGT from 2016-2021.

It describes the learning environment with short distances between operating rooms and labs, quick, responsive communication structures and direct identification of clinical needs.

Key performance indicators for Innolab IGT are defined and presented: Training/Education (Students (BA, MA, Ph.D.); Projects International Research Engagement), Research Activity (Publications, Patents/Invention Disclosures, Clinical Studies/Preclinical Studies), Transfer (Transfer Projects, Revenue Generated, Startups).

125 students successfully participated in the teaching concepts for innovation and entrepreneurship for biomedical engineering within the Innolab IGT. In addition, students were able to deepen their knowledge of problem identification in the SR, needs analysis, prototype development and business modeling in interdisciplinary groups. Overall, 85 incubator projects were presented quarterly to the medical and industry advisory boards.

From the developed prototypes, test and measurement stands, data analysis, software applications, image reconstructions and fused imaging methods, 262 publications were published, 17 patents were registered, 37 invention disclosures were reported, and six startups were spun off. Which fully satisfies the set goals in education, research and transfer.

All partners of the Innolab IGT also benefited from whether for scientific recognition, economic translation (patents and startup generation), knowledge transfer, or economic stimulus.

Summary

This Thesis presents the setup, network environment and partners, the initial results and learnings from developing Innolab IGT, an innovation and entrepreneurship laboratory for medical technology at the university clinic in Magdeburg, Germany. From 2016-2021, a learning environment was created that had short distances between operating rooms and prototyping labs, quick, responsive communication and direct identification of clinical needs. Everyone involved in this Innolab IGT network benefits, whether for scientific recognition, economic translation (patents and startup generation), education and knowledge transfer, or economic stimulus.

The application-oriented hands-on training within this innovation ecosystem with solid innovation culture and creative stimulus forms the startup interest by students and educates tomorrow's biomedical engineers who are capable of facing the challenges of the 21st century for healthcare. Furthermore, within their innovation projects, biomedical engineers will have the necessary understanding of medical device regulations, reimbursement, business modeling and empathic understanding of the user and take this experience into the technical implementation.

The Innolab IGT established itself as a permanent partner within its networks: *Innovation Think Tank Program*, the *European BMEidea* and *international IEEE EMBS* through successful conference formats, lectures and courses.

The experiences and learnings from the curriculum offered by the former chair for catheter technologies were summarized in a new master curriculum (HealthTec Innovation Design) and implemented in the T²I² graduate school.

During the five years of Innolab IGT operation, 125 students (BA, MA, Ph.D.) were trained in innovation and entrepreneurship methodologies. The students processed eighty-five research projects (based on the identified unmet clinical needs); this resulted in over 265 publications, ten international research collaborations, 17 patents, 37 invention disclosures, ten clinical studies, three industry transfer projects and six startups.

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Appendix

Danksagung

In erster Linie möchte ich mich herzlichst bei Herrn Prof. Dr. rer. medic. Michael Friebe bedanken, für die Möglichkeit, an seinem Lehrstuhl INKA- Intelligente Katheter der Otto-von-Guericke-Universität in Magdeburg, zuarbeiten, für das Vertrauen, das Innovationslabor Innolab IGT am Universitätsklinikum aufzubauen und zu betreuen sowie für die Möglichkeiten, meinen persönlichen und wissenschaftlichen Horizont zu erweitern. Mein besonderer Dank gilt auch Herrn Dr. Ing. Axel Boese, für die enge Zusammenarbeit, tatkräftige Unterstützung aller Projekte und Vorhaben und seiner motivierenden Natur. Großer Dank gilt auch Herrn Prof. Dr. med. Hermann-Josef Rothkötter für sein Interesse und Engagement, das Innovationslabor als technische Einheit an der medizinischen Fakultät zu etablieren. Außerdem möchte ich mich bei allen Kollegen der INKA-Forschungsgruppe bedanken, für eine tolle Arbeitsatmosphäre mit kreativen Austausch und freundschaftlichem Umgang.

Zu guter Letzt möchte ich mich bei meinen Eltern Dr. med. Christina und Dipl.-Ing. Peter Fritzsche bedanken, die mich für die Medizin und das Ingenieurwesen zugleich begeistern konnten. Ohne ihre Unterstützung und Ermutigung wäre es mir nicht möglich gewesen, diese Arbeit zu schreiben.

Eidesstattliche Erklärung

Ich erkläre, dass ich die der Medizinischen Fakultät der Otto-von-Guericke-Universität zur Promotion eingereichte Dissertation mit dem Titel

Biodesign and Entrepreneurship for Biomedical Engineering

Design of a university based innovation laboratory for technical translation from bench to bedside

im Zentrum/Institut/Krankenhaus/in der Klinik

INKA-Application Driven Research

mit Unterstützung durch

Prof. Dr. rer. medic. Michael Friebe

Prof. Dr. med. Hermann-Josef Rothkötter

Dr. Ing. Axel Boese

ohne sonstige Hilfe durchgeführt und bei der Abfassung der Dissertation keine anderen als die dort aufgeführten Hilfsmittel benutzt habe.

Bei der Abfassung der Dissertation sind Rechte Dritter nicht verletzt worden.

Ich habe diese Dissertation bisher an keiner in- oder ausländischen Hochschule zur Promotion eingereicht. Ich übertrage der Medizinischen Fakultät das Recht, weitere Kopien meiner Dissertation herzustellen und zu vertreiben.

Magdeburg, den 28.02.2022

Unterschrift

Darstellung des Bildungsweges

Der Lebenslauf ist in der Version aus Datenschutzgründen nicht enthalten.

Originale der Publikation

Publication 1

INNOLAB - Image guided surgery and therapy lab - Run by engineers at a university hospital for interdisciplinary and useful innovation with clinicians.

Fritzsche, H.; Boese, A.; and Friebe, M.

Current Directions in Biomedical Engineering, 3(2): 235–237. September 2017.

DOI: 10.1515/cdbme-2017-0049

Holger Fritzsche*, Axel Boese and Michael Friebe

INNOLAB- image guided surgery and therapy lab

Run by engineers at a hospital for interdisciplinary and useful innovation with clinicians

Abstract: Incremental innovation, something better or cheaper or more effective, is the standard innovation process for medical product development. Disruptive innovation is often not recognized as disruptive, because it very often starts as a simple and easy alternative to existing products with much reduced features and bad performance. Innovation is the invention multiplied with a commercial use, or in other words something that eventually provides a value to a clinical user or patient. To create such innovation not a technology push (technology delivered from a technical need perspective) but rather a pull (by learning and working with the clinical users) is required. Medical technology students need to understand that only through proper observation, procedure know-how and subsequent analysis and evaluation, clinically relevant and affordable innovation can be generated and possibly subsequently used for entrepreneurial ventures. The dedicated laboratory for innovation, research and entrepreneurship- INNOLAB ego.-INKUBATOR IGT (Image Guided Therapies) is financed by the state of Sachsen-Anhalt as part of the European ego.-INKUBATOR program with (EFRE funds) at the university clinic operated by the technical chair for catheter technologies and image guided surgeries. It forms a network node between medicine, research and economics. It teaches students to lead innovation processes, technology transfer to the user and is designed to stimulate the start-up intentions.

Keywords: Innovation Generation, Start Up, Technology Transfer, Entrepreneurship, Medical Research Laboratory, Medical Technology, Medical Systems

https://doi.org/10.1515/cdbme-2017-0049

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1 Introduction

Compared to universities in the US or the UK, the potential for innovation generation and subsequent translation in start-up companies at German universities has not been a focus yet and the process is not part of the scientific education. The engineering courses are designed to impart knowledge from the natural sciences in the technical context. Innovation, creation and implementation are rarely part of the curriculum. However, there is a high potential for the cooperation between clinicians and engineers, especially in medical technology.

This collaboration in the development of product ideas is relatively new and has become an essential part of the medical systems engineering training in Magdeburg with an established clinical network with a focus on minimally invasive and image-guided procedures. From a series of lectures, a network of clinicians and engineers has been established in a short time. This network produces numerous inventor reports, patents, and publications- and collaborates also on joint research applications as well as cooperation with industry partners.

The interdisciplinary approach of the chair is based on the identification of clinical needs, the implementation of product ideas in collaboration with medical users, and the transfer to industrial partners. The focus is on image-guided minimally invasive diagnostic and therapeutic procedures and the necessary medical technology systems. [1]

The approach "innovation with and not only for the medical profession" is pursued both in research and development, but also in student training. Now, with the help of the EU funding (EFRE), a research and start-up lab is build up directly at the university hospital to expand this innovation program. In addition to the project processing, and as central point of entry for medical partners, it also serves as lecture room for the new dedicated graduate school "Technology Innovations in Therapy and Imaging- T^2I^2“.

2 INNOLAB ego.-INKUBATOR IGT (image guided therapies)

The INNOLAB IGT - Image Guided Therapies is a concept in which engineers and doctors work together on new product ideas for clinical application. (Prospective) engineers go to the clinic on site to identify unmet clinical and medical needs during normal operations or surgical procedures performed by the medical users. Based on the Stanford- Biodesign concept (identify, invent, implement), a large number of product and process ideas are developed and subsequently tested in short iterations (see **Figure 1**) on their benefits and general feasibility [2].

Figure 1: INKA work philosophy based on the Stanford University BIODESIGN principle

In addition to the technical implementation, the market potential of such products is of enormous importance. The team of the chair of catheter technologies uses this concept and innovation generation lab to stimulate and motivate engineering students and employees of the university to think about starting a company based on their own verified product ideas. This is especially important since healthcare is of global concern, but every country has a different healthcare system and also different healthcare needs. This opens huge opportunities for entrepreneurial activities [3].

An innovation network has already been established in Magdeburg with clinicians from various specialist disciplines, enabling the implementation of the initial student training and education strategy.

The new INNOLAB ego.-INKUBATOR IGT, located directly at the university clinic, will further intensify the collaboration between the medical doctors and the engineer. At the lab, it is now possible to check, verify, and improve the prototypes in a clinical development environment and with a direct and immediate participation of the clinicians. The basic idea is the concept "innovation with and not only for the medical profession" [3, 4].

The technical and clinical focus are minimally invasive and image guided therapies for vascular and oncological applications. The identification of clinical needs is the beginning of this structured process of innovation. In addition to a fast concept study for the technical implementation and short iterations together with the user, the focus is on the market and a possible business model. Innovation is defined by technical innovation multiplied with commercial feasibility.

2.1 Creative workshop

The lab encompasses a creative area for idea generation, concept studies and meetings with single and group workstations. A bright and colorful setup invites the creative work. The flexible furniture offers a variety of possibilities to always meet the group requirements. Cork walls, whiteboards and mobile projection beamers offer enough options to find, discuss and develop ideas (Fig. 2).

2.2 Prototyping Lab

The attached prototype laboratory is for invention and technical realization. Smaller and larger product ideas are tested for technical feasibility and are built directly as the first prototypes. Various 3D printers, CNC milling and injection molding machines are available for this purpose. A large number of fine tools are available for processing the finished parts and implementing electronic components (Fig. 2).

Figure 2: INNOLAB IGT Setup at the OVGU University Clinic

2.3 Simulations OR

The simulation OR is for implementation and verification of the developed prototypes. A minimal invasive surgery setup with patient table, 3D C-arm, Ultrasound tomography system, endoscopy tower with RF generator, ultrasound systems, navigation/tracking equipment and different phantoms give the opportunity to test in a simulated clinical environment with the user (Fig 2).

3 INNOLAB network

For the mentioned development approach identify, invent, implement, strong partners were found for practical and content support. A clinical and industrial panel was created. The medical and the electrical engineering faculties are currently involved in the innovation processes (identification, invention) and the economics faculty will most likely join soon. The industry board is helping to find and identify technology transfer options (implementation).

3.1 Clinical panel

Current clinical cooperating partners are the ENT, urology, neuroradiology, radiology, nuclear medicine, dermatology, vascular surgery, orthopedics departments as well as the cardiac surgery at the University Clinic Magdeburg. Interdisciplinary student teams of 3 to 5 members are formed every semester to identify the clinical needs while visiting the actual surgeries and come up with a large number of ideas per problem (Biodesign, Stanford). Ideas are then regularly fed back to the clinicians that come, see, and discuss the developed prototypes.

3.2 Graduate school T^2I^2

The INNOLAB IGT acts as the central contact point for the Ph.D. program of the Graduate School "Technology Innovations in Therapy and Imaging — T^2I^2“. Currently 13 Ph.D. students are in a structured doctoral program for innovation generation, technology transfer and business implementation of medical technologies. The training includes technical understanding in the context of the medical application and taking economic factors into account.

3.3 Industry board

An industry board with several small, medium sized and large companies from Sachsen-Anhalt, and other German locations was also established.

4 Outlook

The INNOLAB IGT makes it possible to create an innovation and idea generator where clinicians and engineers work closely together in a simulated clinical setup at the campus of the University clinic. The engineer gets an understanding of everyday procedures, as well as identify problems and deficiencies in the clinical workflow or technical products.
Another unique feature of the INNOLAB ego.-INKUBATOR IGT is the close collaboration between engineering students, doctors, scientists and business partners.
Solutions and innovative ideas are developed in constant consultation with the doctors and implemented, altered, or discarded. Test and evaluation by the clinical user, as well as wishes and suggestions from the business partners, are constantly being integrated into the individual development stages of new medical products and ensure a market-oriented product development

Acknowledgment: We would like to thank all of our clinical partners at the university clinic, our cooperation partners from the industry and especially for the support of the state Saxony Anhalt.

Author’s Statement
Research funding: The authors state no funding involved. Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent is not applicable. Ethical approval: The conducted research is not related to either human or animals use.

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Publication 2

How do we need to adapt Biomedical Engineering Education for the Health 4.0 challenges?

Fritzsche, H.; Boese, A.; and Friebe, M.

Current Directions in Biomedical Engineering, 6(3). November 2020.

DOI: 10.1515/cdbme-2020-3154

Holger Fritzsche*, Axel Boese, Michael Friebe

How do we need to adapt Biomedical Engineering Education for the Health 4.0 challenges?

Proposal for novel HealthTechnology teaching focused on applied Innovation Generation

Abstract: Novel challenges and developments require adaptations on skill set, content, and associated education. A biomedical engineer will require a broad range of skills — which to a large extent are currently not taught — in the coming years to meet the development needs of future healthcare: intensive interdisciplinary team work, advanced communication skills, team management and coaching capabilities, advanced project management, learn how to learn, visionary and forward looking thinking, understanding of health economics, entrepreneurship and leadership. But above all empathy towards the clinical user and patients is needed as well as a basic understanding of the current and future clinical workflows that can globally vary. An innovation process for a healthcare related product or service will likely only create value through the consideration and implementation of several of these points. Even though techniques for the development of innovation and enhancing creativity in individuals are widely discussed, there are relatively few reports on the practice of mainstreaming creativity in an organizational setting. We report on the setup of our Graduate School "Technology Innovation in Therapy and Imaging (T²I²)" that has implemented a structured post graduate program and focuses on interdisciplinary and application-oriented innovation generation education. The educational process starts with the observation and identification of clinical needs and an in-depth understanding of the problem and subsequently covers all steps necessary to transfer prototypes into viable solutions and further into implementing valuable products.

Keywords: Biomedical engineering education, Innovation generation, clinical translation, Biodesign, Healthcare challenges, 21st Century Skills,

https://doi.org/10.1515/cdbme-2020-3154

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1. Introduction

Modern Medicine is evolving fast. But the education lacks behind the new and needed developments. The following needs should be included in training innovation oriented biomedical engineers:

(1) Since technology is the driving force to improve diagnosis and therapy there is also a growing need for professionals that specialize in bridging the gap between traditional and a new technology driven medicine.

(2) This needs to be combined with effective tasks management within a customer focused and economic context.

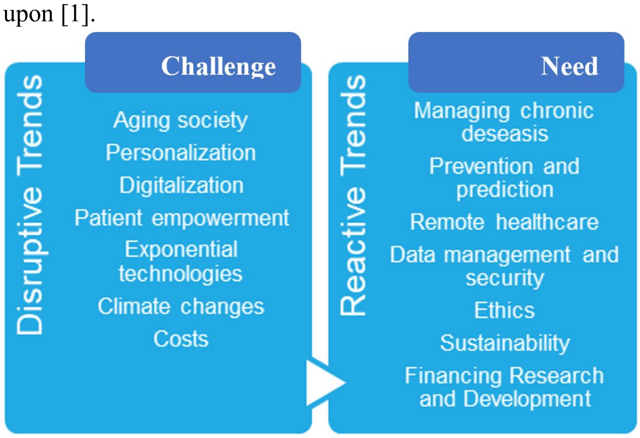
(3) Innovation generation and subsequent professional translation from bench to bedside should be introduced at German universities. While basic research is of course needed, applied - and possibly - disruptive development focusing on improving treatment quality and patient experience, while reducing delivery costs significantly will become more and more important.

The current medical technology engineering courses are designed to impart knowledge from the natural sciences in the technical context. Innovation, creation and implementation, including some economic understanding and entrepreneurial training are rarely part of the curriculum, nor are interdisciplinary or application focused approaches within a clinical setting. Structured innovation generation, translational concepts understanding local and regional needs, as well as knowledge of manufacturing and management processes are likely as important as technological depth for successful product and service implementation.

The important cooperation between clinical users, engineers, economists, and politicians is becoming increasingly difficult due to the fragmented value chains but the core of an innovation process solving unmet clinical needs and creating valuable products and services.

2. Challenges and requirements for Future Medical Technologies

European healthcare technologies are in worldwide demand and a very successful export. To keep technological leadership future healthcare related trends need to be understood and considered as important input for the development of meaningful and affordable products.
Understanding future needs means dealing with current scientific topics, market developments and needs, as well as upcoming social changes. For this, we differentiate between disruptive trends and reactive trends. Disruption comes and can be beneficial in reshaping healthcare. Reactive trends are emerging as a result of the disruptive trends and can be acted upon [1].



1. Disruptive trends as future challenge resulting in reactive trends- as need for educational focus [1 - 4]

Aging society

In the next 20 years, 2040, the German population of ages of 65-79 and 80+ is expected to have an increase up to 24% and 79%, respectively. Up to 30% of the population would be retired from the working life [5]. Especially, the increase of 80+ agers requires more healthcare resources which can be supported by daily life's diagnostic tools and devices. Early detection of health problems will be the most relevant impact factor of successful treatment. This will affect the entire care sector. There is a need for smart diagnostic devices and tools which are connected to a whole care network with local care services, hospitals, medical offices and pharmacies.

Personalization

Personalized medicine, uses diagnostic testing for selecting appropriate and optimal therapies based on the context of a patient's genetic content or other molecular or cellular analysis. Personalized medicine may provide better diagnoses with earlier intervention and more efficient drug development and therapies. As personalized medicine is practiced more widely, a number of challenges arise. The current approaches to intellectual property rights, reimbursement policies, patient privacy and confidentiality as well as regulatory oversight will have to be redefined and restructured to accommodate the changes personalized medicine will bring to healthcare. [3, 6] Genetic data obtained from next-generation sequencing requires computer-intensive data processing and adequate tools will be required to accelerate the adoption of personalized medicine to further fields of medicine, which requires the interdisciplinary cooperation of experts from specific fields of research, such as medicine, clinical oncology, biology, and artificial intelligence.

Digitalization

The digital transformation stands for a global change of economy and society, caused by the consistent penetration of daily life with information and communication technologies. Compared to the classical contents of engineering studies, competencies in a cross-sectional area are added that can be described as digital technical content. In 2025, up to 175 ZB of digital data will be produced daily (Healthcare is one out of four main industries beside Production, Media and Entertainment and Financial Services). 90 percent of the world's total data has been generated over the past two years. [7] These big data and the explosion of digital data will lead to infrastructure and application changes. In addition to IT-related content, this area also includes more extensive aspects such as the understanding of new, digitally induced business models, data security and protection, and social implications (e.g. technology assessment), this offers opportunities for a remote health system, but places high demands on data management and security. [3, 7]

Patient empowerment

Focuses primarily on people who receive health care services - people with physical and mental health needs. Fast communication, better education and the involvement of the wider public (citizens) in local planning and priority setting are important to get health across all policies and move away from societies that actively market unhealthy lifestyles [8]. Networks and information systems help patients to make their decisions - making the healthcare sector more transparent from diagnosis to therapy. There is clearly a significant overlap with health needs and services:

- Better understanding their condition.
- Participating in making decisions about their care.
- Being supported to better self-manage their health and treatment.
- Feeling confident to ask questions and challenge professionals and organizations.

- Having the chance to join networks or groups of other patients in similar circumstances.

Exponential technologies

Exponential technologies describe new, mostly digital, technologies that are experiencing exponential growth. These include Sensors, 3D Printing, Virtual Reality, Drones, Artificial Intelligence, Blockchain etc... These developments are based on Moore's Law, which states, exponential growth based on the example of integrated circuits. This development is the basis for the digital revolution we are currently experiencing. Every industry and every business will be affected by the consequences of this digital revolution. Exponential technologies offer innovative companies great potential in terms of cost and time savings.

There is a need to impart an exponential mindset to all innovative and future-oriented executives and decision-makers in order to jointly define extraordinary goals. Exponential technologies could lead to a dramatic change in the way that healthcare is delivered. Currently almost all of the national healthcare systems treat sick patients rather than to prevent people from becoming patients.

Climate changes

More clearly than ever before, the United Nations Climate Council (UN) warned in its World Climate Report (2019) of the consequences of the greenhouse effect. The controversy over climate change will also affect the healthcare system in future. The effects of anthropogenic climate change are already taking root in nature and society. Existing climate projections prove a future strengthening of already recognizable climate impacts.

Primary level of affection: The Human.

Increasing temperatures can lead to a change in the spread and activity of pathogens, particularly diseases transmitted by ticks and mosquitoes. Food-borne and water-mediated infections can increase the incidence of diarrhea. Heat waves put an enormous strain on the organism of old and ill people as well as children. Also the increase of allergies, e. g. through new immigrant plant species is possible [9].

Secondary level of affection: The Healthcare sector.

The markets are closely linked to production, storage and delivery. Here, new low-emission and environmentally friendly approaches are sought. Based on this, adaptation strategies and measures can be developed and implemented. These increase the resilience of the environment and society to current and future climate impacts. Increasing damage and costs of climate change are reduced [9].

Costs

Germany affords one of the most expensive health systems in the world. Last year, for the first time, more than one billion euros were spent daily (376 billion in 2019) [10]. Ascending trend. However, there is a lot of inefficiency in healthcare, up to 20 percent of healthcare expenditure could be saved (OECD) without quality loss. Starting points for savings would include less unnecessary double examinations, avoidance of unnecessary operations and a more reserved use of antibiotics. Many treatments that are carried out in hospital today could also be carried out on an outpatient basis.

2.1 Face these needs towards postgraduate education

We have to react adequately to the challenges and to build an interdisciplinary exchange in education - to enable the creation of creative and innovative clinic engineers who are not only interdisciplinary but interprofessional.

Disruptive trends will come with political, economic and social changes. But they also provide great opportunities to serve the sectors with new innovative ideas and establish not only new tools and equipment, but also services and business models. The trends not only generate costs but also have a significant impact on cost savings - with better process design (e.g. through digitalization). This requires a basic understanding of processes, decisions and impacts and increased need for innovative solutions with global focus.

Healthcare 4.0 is heading for a reduction of inpatient treatments and increased outsourcing of specialized clinical services. With higher quality and efficiency and a vertical integration between providers who offering various services, from preventive models to acute- care and after- care solutions.

The Biomedical Engineering education as we know them today will need to change to cope with these issues or adapt to become driving forces of innovation. Engineering students and early stage researchers need collaborative and problem-solving skills to perform in teams of high diversity. With the aim of translational research - to create new therapies, medical procedures, or diagnostics to act on the disruptive trends and handle the reactive trends.

3. The Graduate Program T²I²

The T²I² intends to foster the coming generation of health engineers to efficiently develop medical technology and ensure that this technology is a marketable resource. A structured education program with an interdisciplinary approach in the disciplines of Medicine, Technology and Economics is provided. Currently 13 international Ph.D. students (from Egypt, Mexico, Nepal, India, Iran, Taiwan and Germany) are in that structured doctoral program for innovation generation, technology transfer and business implementation of medical technologies. The participants have to successfully attend at least 300 hours of lecture or lecture equivalent study over a 36- to 48-month period. They work on topics and projects in the main area of medical imaging, minimally invasive therapy, image guided surgeries and catheter technologies. Soft skill development is a core challenge and objective. Close contact to clinical users, direct involvement of industry and application oriented research projects, an international exchange and regular further training are core components. The graduate school, while engineering oriented, is located and placed within the medical faculty of the Otto-von-Guericke-University in Magdeburg in order to create a close clinical relationship. The students are supervised jointly by a clinical and a technical professor. Additionally, a strong education focus is on the 21-century skills to approach complex challenges, teaching competencies like critical thinking, creativity, communication and collaboration. Furthermore, for individual and subject-specific education, an external stay of at least 6 weeks is required at a partner university with a similar research focus. For scientific literacy an early publication culture is cultivated.

Table 1: Core competencies for the Ph.D. students in the Graduate School Technology Innovations in Therapy and Imaging

	Journal Publications (>3)
Scientific literacy *(Knowledge, Action, Review)*	Conference Publications (>3)
	Subject-Specific Further Training (>300 h)
	OR- Observations
Clinical literacy *(Understanding Clinical Processes)*	Medical Co-Supervision
	Interdisciplinary Groups
	Start-up Projects
Entrepreneurship/ Business Modelling *(Costs, financing, market)*	Invention Disclosures/ Patents
	Industry driven projects
	Research proposals (>3)
Management Skills *(communication, leadership, organization)*	Master/ Bachelor Supervision
	Conference / Summer School organization

4. Discussion and Potential Clinical Impact

The aim of the graduate school is to bridge the gap between medicine and technology for products and services that have a clearly identified need. Students need to work more intimately with the medical users to gain a better understanding of their needs. This result in identifying much more useful equipment for the healthcare professionals. T^2I^2 will also focus on the innovative and entrepreneurial aspect of healthcare and teach students to make those innovations marketable. They will act local and think global including specific needs through disruptive trends und healthcare 4.0.

New device and services should help patients and doctors, create value and market share or at least return investment and should lower the overall cost of healthcare. Bioengineers must recognize these sometimes conflicting drivers for an innovation process. In this process, the open minded mind-set of the learners and especially the teachers play a crucial role. Then innovation can significantly improve health outcomes:

Better procedures by – reduced procedure time, improved procedure outcomes, reduced procedure/ device costs and fewer the people in the procedure room or efficient use of facilities, equipment and man power.

Less hospitalization by – fast recovery, reduced re-hospitalization and a shift of patient care from clinic to home.

Improved patient satisfaction – back to daily life, homebased recovery and improved health.

Author Statement

Research funding: The author state no funding involved.

Conflict of interest: Authors state no conflict of interest.

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Publication 3

A structured pathway towards Disruption: a novel Entrepreneurship Design Thinking Curriculum for Health Innovation

Fritzsche, H.; Barbazzeni, B.; Mahmeen, M.; Haider, S.; and Friebe, M.

Frontiers in Public Health, section Health Economics. Volume 9, September 2021.

DOI: 10.3389/fpubh.2021.715768

frontiers in Public Health

ORIGINAL RESEARCH
published: 03 September 2021
doi: 10.3389/fpubh.2021.715768

A Structured Pathway Toward Disruption: A Novel HealthTec Innovation Design Curriculum With Entrepreneurship in Mind

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OPEN ACCESS

Edited by:
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Reviewed by:
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Specialty section:
This article was submitted to Health Economics, a section of the journal Frontiers in Public Health

Received: *27 May 2021*
Accepted: *11 August 2021*
Published: *03 September 2021*

Citation:
Fritzsche H, Barbazzeni B, Mahmeen M, Haider S and Friebe M (2021) A Structured Pathway Toward Disruption: A Novel HealthTec Innovation Design Curriculum With Entrepreneurship in Mind. Front. Public Health 9:715768. doi: 10.3389/fpubh.2021.715768

The typical curriculum of training and educating future clinicians, biomedical engineers, health IT, and artificial intelligence experts lacks needed twenty first-century skills like problem-solving, stakeholder empathy, curiosity stimulation, entrepreneurship, and health economics, which are essential generators and are pre-requirements for creating intentional disruptive innovations. Moreover, the translation from research to a valuable and affordable product/process innovation is not formalized by the current teachings that focus on short-term rather than long-term developments, leading to inaccurate and incremental forecasting on the future of healthcare and longevity. The Stanford Biodesign approach of unmet clinical need detection would be an excellent starting methodology for health-related innovation work, although unfortunately not widely taught yet. We have developed a novel lecture titled HealthTec Innovation Design (HTID) offered in an interdisciplinary setup to medical students and biomedical engineers. It teaches a future-oriented view and the application and effects of exponential trends. We implemented a novel approach using the Purpose Launchpad meta-methodology combined with other innovation generation tools to define, experiment, and validate existing project ideas. As part of the process of defining the novel curriculum, we used experimentation methods, like a global science fiction event to create a comic book with Future Health stories and an Innovation Think Tank Certification Program of a large medical technology company that is focused on identifying future health opportunities. We conducted before and after surveys and concluded that the proposed initiatives were impactful in developing an innovative design thinking approach. Participants' awareness and enthusiasm were raised, including their willingness to implement taught skills, values, and methods in their working projects. We conclude that a new curriculum based on HTID is essential and needed to move the needle of healthcare activities from treating sickness to maintaining health.

Keywords: biodesign, design thinking, health democratization, bioengineering education, disruptive technologies, exponential medicine, future of health, twenty-first century skills

INTRODUCTION

Innovation has been defined as the result of implementing new or improved products/services/processes to enhance a specific value (1). In healthcare, innovation represents a novel technology, service, or care process that aims to bring benefits compared with previous methods due to its usability and desirability (2). Although an urgent need to facilitate the healthcare system while moving the value from diseases and treatments to patient care and prevention, innovation results faster and wiser in other sectors than in healthcare.

Nowadays, several issues should be addressed to face challenges when implementing innovation in the health domain: needs for funding, use of advanced technologies, a patient-centric approach, the possible need and adoption of a new health business model, payments processing and invoicing, cyber- and data security, regulatory changes and approvals, increasing costs of healthcare delivery, investment in IT procedures and many others (3). Moreover, the focus on short-term (3–5 years) rather than long-term (>10 years) developments has solely the effect of generating inaccurate forecasting on the future of healthcare while preventing innovation from being disruptive (4).

How can we imagine healthcare in 10 years? What will be the effects of available tools and devices for prevention and prediction on diagnosing and treating diseases and on a healthy longevity? How do we deal with inequalities in healthcare delivery, access and increasing costs? Is the current education geared toward the anticipated changes? Questions need answers, and the proper problem identification leads to innovative, applicable solutions.

The current way of training and educating future clinicians, biomedical engineers, health IT, and artificial intelligence (AI) experts in education silos does not lead to disruptions but rather to incremental innovations (5–10). The necessity for innovative and adaptive approaches to improve outcomes brought us to think about a health innovation related adoption of the Design Thinking Approach; a novel way of problem-solving that aims to find the best fit-solution between the customer profile and a new product/service/process, quickly prototyped, and iteratively refined (11).

When compared to traditional problem-solving methods, design thinking brings sustainable and applicable solutions, facilitating improvements for patients, care facilities and communities, while improving management and collaborations toward public health procedures. Based on the outcomes introduced by this approach a closer look at the traditional educational curricula in and around health-related programs (engineering, natural science, clinical science), currently lacking twenty first-century skills (e.g., problem-solving, stakeholder empathy, curiosity stimulation, entrepreneurship, and health economics) is needed. Abookire et al. integrated Design Thinking to develop a workshop through the collaboration between the Health Design Lab and Colleges of Medicine and Population Health at Thomas Jefferson University to enrich traditional public health education curricula (11). The workshop aimed to train public health students to more efficiently and effectively deal with complex problems as future healthcare professionals and providers. Students were engaged to investigate public health problems by applying viable and feasible solutions, demonstrating the valuable role of Design Thinking as an innovative and empathy-driven approach in improving the health of individuals and the wellness of the entire community.

Results from the survey evaluation indicated that the familiarity with design thinking approach procedures increased enormously through the workshop. The students started to realize their abilities to implement meaningfully key concepts of the taught approach. Moreover, students demonstrated a positive attitude toward the event, considering it relevant and applicable in their current academic path and professional career. Participants were also given 10 min to generate low-fidelity prototypes. Ideas included the generation of devices to assist with schedule management and mobile application interfaces to ease physical movements and dietary changes.

On a similar perspective, a Lean Design Thinking approach has been suggested (12), which is an innovative model intended to merge the design thinking and lean startup strategies to help entrepreneurs and intrapreneurs by improving their current projects. The lean design thinking approach can be considered a source of inspiration toward innovation, adopting relevant tools and methods of both strategies, managing and generating business innovation with a customer-centered design. With increased attention toward social and environmental determinants of health (13–15) the study of entrepreneurial-driven public health innovation emerged as one of the ultimate approaches to generate innovative interventions, products, and services by addressing public health issues (14, 16).

Becker et al. (17) investigated the perceptions of graduate public health students regarding Public Health Entrepreneurship (PHE) (17); the application of entrepreneurial skills to accomplish public health missions (18), and their training needs for becoming future health professionals (19, 20). As the first research exploring perspectives of PHE in the academic setting, results from the study demonstrated positive outcomes. PHE was offered to be introduced in the current curriculum where courses incorporated the Council on Public Health Education (CEPH) competencies, actively involving students. Public health trainees were stimulated to apply wealth knowledge into action by combining the existing public health training methods with new social innovation and entrepreneurship (16, 21). Several advantages were highlighted when implementing PHE. Such as the correct identification of evidence-based solutions accompanied with the active ideation and application of prototypes to ameliorate health (22) and the possibility to engage stakeholders involved in public health even beyond sectors and institutions traditionally associated with health. This study confirmed that PHE could be the new way to increase resources by facing twenty first-century challenges in public health across several disciplines or sectors aligned with CEPH competencies. Moreover, the need for specific educational programs in life science technology innovation was previously anticipated by Yock et al. (23) and (9).

Design thinking and entrepreneurship education are considered major drivers behind and to create successful innovation. The Biodesign Program at Stanford University provides a map of needs-driven MedTech innovation processes (identification–invention–implementation). Focused on training and educating students with a specific curriculum that integrates design thinking and commercialization processes, paving the way toward translational medicine (TM). In this context, Foty et al. (24) proposed an innovative curriculum design aimed at teaching scientists and leaders in the field of TM. A new curriculum was created to analyze the business scientific and regulatory aspects of TM, explore the challenges encountered by health professionals, develop critical thinking and communication skills by introducing the topic to a wide range of learners. TM is a new field of study that focuses mostly on integrating an idea, advancing clinical testing, and the final development of new technologies or drugs. For this reason, a broad set of skills are required and included in the TM program. Besides core concepts (e.g., ethics, regulations, funding, policy, etc.), TM skills include effective communication, interdisciplinary, personal reflection, and interprofessional collaboration.

Although the abundance of ideas and research projects in implementing a design thinking approach raises innovation in a health curriculum, these methods are not widely taught. The present research will describe a series of educational activities to advance health tech innovation. We developed a novel lecture titled HealthTec Innovation Design (HTID) offered for medical students and biomedical engineers that teaches a futuristic view and application of exponential trends. Besides that, we implemented a novel approach using the Purpose Launchpad meta-methodology combined with other innovative tools to define and further exploit an actual project. Additionally, we initiated and promoted with global teams the Sci-Fi Hive Future of Health, a science fiction comic creation event looking 20 years into the future; and the Innovation Think Tank Certification Program (ITTCP, by Siemens Healthineers) focused on the future of health, based on medical technologies with a mid-term vision of a large Medical Technology company. Surveys were conducted to investigate the effectiveness of these events in stimulating and enhancing awareness, curiosity, and expertise toward applying advanced design thinking methods in the field of health tech innovation. The presented research study aims to create the base for establishing a new educational curriculum in Health Technology Innovation Design by integrating advanced methods to prepare future healthcare professionals leading to disruptive and exponential innovation (see **Figure 1**).

MATERIALS AND METHODS

For the understanding and process description in complex systems, such as the healthcare sector, the principles of top-down and bottom-up design were used:

Top-down, based on a global view, the abstract becomes more specific and increasingly subordinate; an overall problem is divided into sub-problems. For this, the Sci-Fi Hive event provided a vision of a great and whole future that is always more detailed and specially designed and formulated.

Bottom-up in that context means the opposite direction. One starts with a specific problem and concludes with the general and higher-level. The ITTCP was used for that point of view. It started with a clinical problem (i.e., coronary artery disease) and used potential pharmaceutical, technical, and organizational solutions for prevention, prediction, diagnosis, intervention, care, and aftercare.

Thus, two fundamentally different ways to understand, describe and present the complex future health issues were employed. Both are used to recognize the future—and with that, the effect on current—needs to adapt the education for bioengineering-, and medical- students, as well as for related fields (e.g., health economics, data sciences, computer sciences). Before and after the events, a qualitative survey was carried out to check relevant characteristics and provide information about them systemically.

Sci-Fi Hive

Eight teams of 11 participants were put together and assigned to different healthcare topics: the democratization of healthcare, future of emergency/care hospitals, future of homecare, future of increased health-span/longevity, future of health diagnostic, and future of overall health/wellness. After a short introduction to the future of healthcare and exponential innovations, the event was conducted into four main stages.

In the first stage, teams met individually to know each other and brainstorm the first ideas on the chosen healthcare topic.

In the second stage, teams started creating comic characters and developing the hero's journey story around the future vision.

In the third stage, before starting with the prototyping, teams described and scripted the hero's journey story into a comic book format.

Finally, the teams were ready to create and prototype the science fiction comic book cover and individual story panels in the last stage.

Each stage was followed by a feedback session in which teams had the opportunity to share their learning and insights. In total, the event lasted 8 h. The realized Sci-Fi Hive comic book is provided here in Friebe et al. (25).

We designed a pre-and post-event survey in English language using GOOGLE Forms consisting of 14 questions pre-, and 13 questions for the post-event survey as multiple choice, checkboxes, three or five-point Likert scale, short answer or yes/no modalities. Thirty-eight responses were collected from the pre-survey analysis, and 29 responses were collected from the post-survey analysis. Pre- and post-event survey questions and answers are listed in Appendix A in **Supplementary Material**.

Innovation Think Tank Certification Program

Innovation Think Tank Certification Program (ITTCP) is an "experiential learning training" based on the experience of successful implementation and management of Innovation Think Tank programs and innovation labs at Siemens Healthineers and several prestigious institutions worldwide. During the ITT program, interdisciplinary participants work in teams using the ITT approach to generate strategic content that helps Siemens Healthineers shape the technology and disease pathway strategy. Also, it helps the host organizations

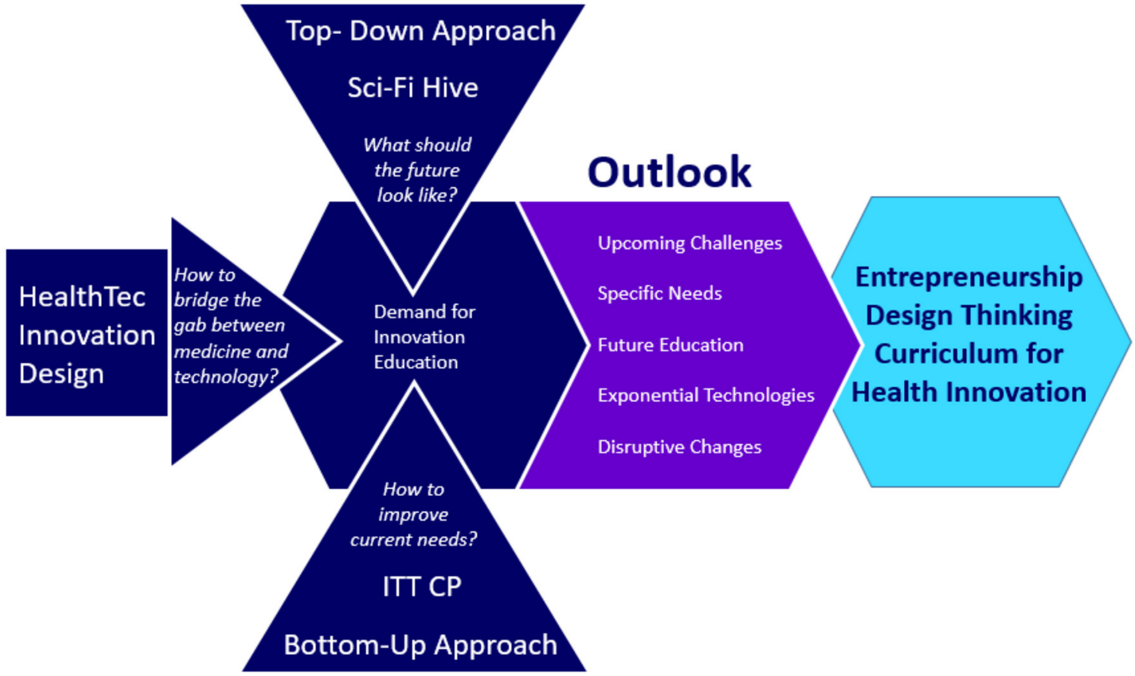

FIGURE 1 | Approaches for a new curriculum.

(customers) define concrete projects for further deep dives and research in the ITT lab. The interactive program is designed to develop creative pioneers capable of delivering innovative and customer-centric solutions to the world's most significant challenges in Healthcare in their field of profession.

For the data collection we designed a pre-and post-event survey in English language using GOOGLE Forms consisting of 14 questions pre-, and 11 questions for the post-event survey, again as multiple choice, checkboxes, five-point Likert scale, short answer or yes/no modalities. Forty responses were collected from the pre-survey analysis, and 28 responses were collected from the post-survey analysis. Pre and post-survey questions and answers are listed in Appendix B in **Supplementary Material**.

The survey answers from the Sci-Fi Hive and ITTCP were statistically analyzed based on the frequency distributions. The frequencies were computed based on the median distribution. In particular, the most frequent answers were transformed into their valid percentage.

HealthTec Innovation Design Lecture

At the Otto-von-Guericke-University (OVGU) in Magdeburg, Germany, we developed a semester-long lecture titled HealthTec Innovation Design (HTID) offered for medical students and biomedical engineers that teaches a futuristic view and application of exponential trends (23). The HTID, rated 5 ECTS, consists of 10 online lectures with 35 academic hours of teaching, and an additional 90 h of personal and team project assignments. Examples of personal assignments were identifying the personal Massive Transformative Purpose (MTP) and writing a manuscript in a research article format. Students were also asked to forecast and design the future of their current research/education project. Two interdisciplinary teams were formed during the lectures to exploit an actual project leading to developing health-tech innovative ideas. The teams were asked to develop the project using the Purpose Launchpad meta-methodology tool, the OpenExo tools, the classical Business Model Canvas and the Stanford Biodesign approach. In addition, teams were asked to write a short manuscript dedicated to their project proposal in a research article format. A final online examination with a multiple-choice test and a team project presentation concluded the semester earning a certificate of attendance of passed examination.

In further detail, during the lectures, a novel conceptual tool of identifying, validating, and implementation innovation using the Purpose Launchpad (26) was adapted to the healthcare field and combined with other innovative OpenExo tools (27), such as the OpenExo Canvas, to define and further exploit an actual project.

The Purpose Launchpad is a meta-methodology to evolve early-stages ideas into purpose-driven, exponential organizations generating massive impact. The Purpose Launchpad is defined as a mindset, a framework, and a methodology to develop an adequate innovative organization, business, product, or service. Moreover, this meta-methodology is articulated around eight principles (see **Figure 2**) purpose over a problem and problem over a solution, exploration over-optimization, talking to customers over market research, abundance over scarcity, sustainability over investment, mindset over processes and tools, validated learning over product building, qualitative over quantitative metrics.

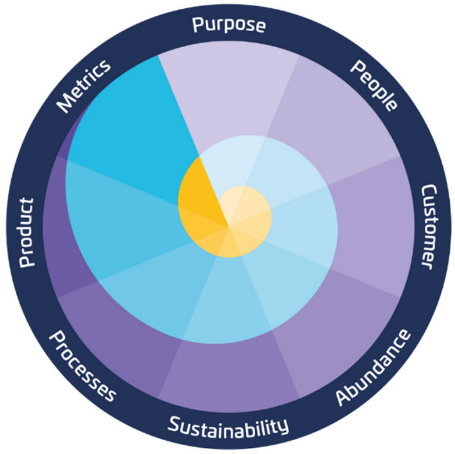

FIGURE 2 | Purpose Launchpad meta-methodology. The eight principles around which the Purpose Launchpad meta-methodology is articulated are represented: purpose, people, customer, abundance, sustainability, strategies, product, and metrics.

The Purpose Launchpad can be applied as a set of principles or an iterative process that evolves continuously over the above-mentioned key area axes (purpose, people, customer, abundance, sustainability, strategies, product, and metrics). To enhance learning, the Purpose Launchpad includes evaluating progress through constant assessments over three evaluation levels: discovery, validation, and growth. Lastly, through innovation Sprints, the team makes real progress evolving the Purpose Launchpad Axes over daily/weekly meetings (see **Figure 3**).

RESULTS

Sci-Fi Hive

Most attendees were male entrepreneurs (35–50 years old) interested in exploring innovative healthcare (86.8%) and mainly new to similar events from the pre-survey analysis. When asked which innovative technology is already implemented (3–5 years' perspective) in participant's work/project, digital healthcare resulted in the most common response (68.4%). Differently, when speculating about the future implementation of technologies (>10 years' perspective), AI (65.8%), VR/AR (57.9%), brain-computer interfaces, or digital healthcare (55.3%) resulted in the most selected responses.

Prevention over treatment, patient empowerment, and personalized medicine was considered the most impactful values/perspectives to generate meaningful innovation in healthcare. Similarly, competencies (problem-solving, collaboration, creativity, communication) and character qualities (curiosity, persistence, adaptability, leadership, initiative, social awareness) were considered very important "innovation mindset" skills over literacy. Moreover, participants defined *innovation* as "the translation of an existing product/service/process into something more efficient/effective/competitive" (31.6%). They reported that the most relevant reason for failure in a startup/business/research/industry project dealing with healthcare innovation is designing a product without considering the customer profile/market test (36.8%). Lastly, several factors were identified as responsible for the prevention of disruptive innovation, such as regulatory approvals, government/political interests, traditional not transparent business model, and fear of changes, as well as, attendee agreed that the gap between scientific literacy and application is not widely exploited by the current university-based education (73.3%).

Moreover, most responders were male entrepreneurs and medical doctors (>35 years old) from the post-survey. Participants reported that the Sci-Fi Hive highly matched their expectations, finding it very informative and insightful (92.6%). Several terms were collected when we asked to describe the most meaningful Sci-Fi Hive take-away in one word. The most common words were *collaboration, creativity, teamwork, insightful, engaging, enlightening, excited, fiction, comic, innovation, imagination, inspiring, relaxed, interaction, fun, big vision, discussion, diversity, interesting, members, think out the box, and great.*

Furthermore, participants declared to be willing to implement the learnings from Sci-Fi Hive into their work/life to improve a current research/business/education project (65.5%) and that the taught methods were likely to raise innovation in their current projects. We asked which growth mindset perspective Sci-Fi Hive has stimulated. Based on a growth mindset approach, participants mainly reported that they were more willing to "try new things" (69%), that "challenges help me to grow" (51.7%). Moreover, "optimistic thinking," "passion and purpose," and "long-term thinking" were the most relevant mindset/thinking strategies to raise innovation. In conclusion, participants reported that Sci-Fi Hive was very impactful in stimulating their awareness toward the challenges behind healthcare innovation and that twenty first-century skills in problem-solving, critical thinking, creativity, communication, and collaboration are fundamental to grow an innovative mindset.

Innovation Think Tank Program

From the pre-survey analysis, most attendees were female students (18–24 years old) interested in exploring innovative healthcare (65%) and mainly new to similar events. When asked which innovative technology is already implemented (3–5 years' perspective) in participant's work/project, digital healthcare resulted in the most common response (47.5%). Differently, when speculating about the future implementation of technologies (>10 years' perspective), AI (57.5%), digital healthcare (55%), and VR/AR (50%) resulted in the most selected responses. Moreover, when asked which factor comes into mind when thinking about healthcare, the top 3 answers were "medical devices and technologies" (77.5%), "healthcare management" (42.5%) and "diseases" (40%), and that "treatment over prevention" has been classified as the main problem in the current healthcare delivery (47.5%). Prevention over treatment, personalized medicine, digital health procedures, and patient-centric approach was considered very impactful values/perspectives to generate meaningful

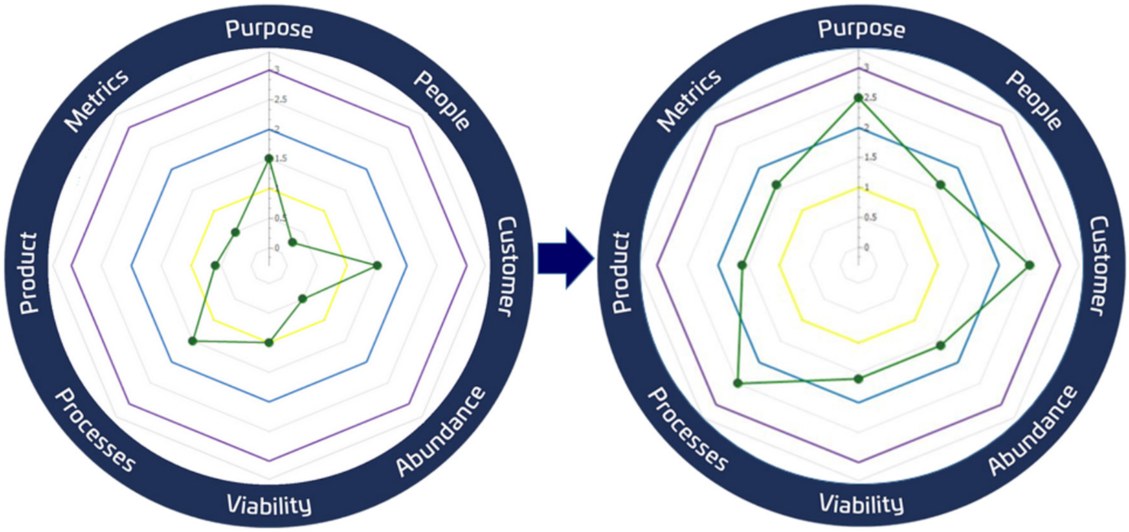

FIGURE 3 | Purpose Launchpad meta-methodology. To enhance learning, the Purpose Launchpad evaluates progress through constant assessments. In this way, the team makes real progress evolving the Purpose Launchpad eight principles over daily/weekly meetings.

innovation in healthcare. Participants defined innovation as "the translation of an existing product/service/process into something more efficient/effective/competitive" (35%). Lastly, several factors were identified as responsible for the prevention of disruptive innovation such as government/political interests, regulatory approval (e.g., CE, FDA), no transparent business model/markets, traditional/rigid education system, and a long time in the process of implementing new technologies, as well as, participants identified "training of twenty first-century skills" (45%) the main factor to close the gap between scientific literacy and feasible application to improve healthcare. Moreover, most respondents were female students (25–34 years old) from the post-survey. Participants reported that the ITTCP matched their expectations, finding it very informative and insightful (89.3%). Several terms have been collected when asked to describe the most meaningful ITTCP take-away in one word. The most common words were holistic view, mandate, teamwork, vision, interdisciplinary, informative, problem identification, methodology, insightful, enlighten, inclusivity and structure. Furthermore, participants declared to be willing to implement the learnings from ITTCP into their work/life to improve a current research/business/education project (60.7%). "Customer-centric thinking," "rapid experimentation," and "passion and purpose" were the three most crucial mindset/thinking strategies to raise innovation. In conclusion, participants reported that a "deep understanding of the problem to be solved" (46.4%) is the most challenging factor when implementing an innovation strategy/methodology to commercialize an invention. That "empathic and collaborative networks" (35.7%) is the most crucial factor needed to switch from the current healthcare methods to innovative healthcare strategy-approach and that "training of twenty first-century skills" the main factor to close the gap between scientific literacy and feasible application to improve healthcare (46.4%).

To summarize, the results obtained from Sci-Fi Hive and ITTCP can be compared, although some questions we provided were different between the two programs. In general, with a top-down approach, Sci-Fi Hive identified prevention over treatment, patient empowerment, and personalized medicine as the most impactful values/perspectives to generate innovation in healthcare, and that regulatory approvals, government/political interests, traditional not transparent business model, fear of changes were responsible factors to prevent disruptive innovation.

When forecasting the future implementation of technologies (>10 years' perspective) to generate innovation in healthcare, attendees reported that digital healthcare, AI, VR/AR and brain-computer interfaces would be the most preferred technologies. Moreover, twenty first-century skills were recognized as fundamental to grow an innovative mindset. Similarly, with a bottom-up approach, ITTCP identified the same factors as the most impactful values to raise innovation and those factors that prevent disruptive innovation and those technologies that preferably would be implemented in >10 years' perspective. Twenty first-century skills were again identified as necessary competencies needed to close the gap between scientific literacy and feasible application in healthcare. Attendees were satisfied and willing to implement the learnings from both events to improve their current research/educational project. A considerable difference between Sci-Fi Hive and ITTCP is related to the type of audience participating in these two programs, and so the way they would apply the learning into their current work project. From Sci-Fi Hive, most attendees were male entrepreneurs (35–50 years old), whereas from the

ITTCP attendees were mainly female students (18–24 years old), both categories interested in exploring innovative healthcare and mainly new to similar events. This factor results relevant when considering the educational/business meaning and goals behind these two events. Indeed, ITTCP starting with a bottom-up approach aims to identify clinical needs and search for possible solutions to generate a high-level frame of solutions. This approach would have a meaningful impact when educating and training future healthcare professionals because it teaches methods and strategies to solve unmet clinical needs. On the other side, Sci-Fi Hive starting with a top-down approach, aims to create a great and futuristic vision that can be successively divided into its parts, to make it happen. In this case, the approach can be relevant for healthcare entrepreneurs interested in translating an existing product/service/process into something more efficient/effective/competitive to solve unmet clinical needs through the best customer/market fit.

HealthTec Innovation Design Lecture

The semester-long lecture was completed successfully by all eight students from Medicine, Neuroscience, Biomedical Engineering, and Computer Science. The scope of personal assignment contents has been reached by students who have taken out meaningful insights. Divided into two equal interdisciplinary teams, students developed two projects to generate innovative solutions to satisfy unmet clinical needs. Teams demonstrated significant interest and involvement in their project, showing constant learnings during the semester. Moreover, the Purpose Launchpad meta-methodology, the Stanford Biodesign approach and the OpenExo tools were implemented successfully and appropriately. When asked students to present their team projects, presentations satisfied all the requirements, and the final examination was passed with good scores, meaning that students acquired the taught material with passion and purpose. Moreover, the HTID course with interdisciplinary students gave attendees the chance to know each other and exchange their expertise, learning and experiences, an optimal requirement in the perspective of healthcare innovation, and a revised educational curriculum. Finally, positive feedback from students suggested the continuation of this series of lectures with the vision of developing a novel curriculum in health-technology innovation design.

Currently, international differences in the education of the health science industry, the lack of emphasis on global healthcare care needs and interdisciplinary collaboration between healthcare providers, clinicians, research institutes and industries leads to the difficulty of identifying and satisfying clinical needs.

Thus, we aim to develop a novel educational curriculum based on the *I3-EME* as an educational concept (*Identify-Invent-Implement)* (28). The educational and teaching focus would be based on an interdisciplinary approach in which medical and engineering students would merge, working together on advanced clinical solutions based on the taught I3-EME Concept. The I3-EME aims to identify unmet clinical needs, invent feasible solutions and successfully implement them at adequate market needs. New technologies based on AI, AR, 3D, robotics, digital health, ethics, and future societal challenges, in line with medical technologies and services, will change the focus from inpatient to outpatient, prevention, reduction of costs, and democratization healthcare. Based on this educational content and the I3-EME concepts, students will have the opportunity to work and explore meaningful and valuable products/services to understand and solve global healthcare needs.

We proposed a study plan for this novel educational curriculum based on economy/business, medical/clinical/healthcare innovation and engineering study subjects, with corresponding credit points (CP). The medical and the engineering departments would interact with the hospital structures. The study plan will be structured into four semesters in which the subjects mentioned above will be covered (see **Table 1**).

DISCUSSION

How can we imagine healthcare in 10 years? What will be the effects of prevention and prediction on diseases and healthy longevity? How do we deal with inequalities and increasing costs? Is the current education geared toward the anticipated changes? We started with these questions to identify a proper solution.

When thinking about healthcare today, several obstacles should be addressed to overcome the current status and raise innovation. The main factors are the ever-increasing cost of healthcare provision, the disparity in quality care among countries and even inside countries from rural to urban, insufficient health insurance coverage, lack of empathy and communication between patient-providers, traditional and unilateral approaches, and fear of implementing new technologies.

These are just a few of the challenges that the healthcare system is facing nowadays. Although the urgent need to innovate and improve the healthcare system and services, the entire setup and management typically only leads to incremental rather than disruptive innovation. Incremental means that we observe improvements that do not significantly impact longevity but increase the cost significantly based on existing technologies and workflows.

One reason for this fact could be the current way of educating and training future clinicians, biomedical engineers, health IT, and AI experts in silos. The lack of transferability of scientific literacy to applicable solutions prevents the transformation of knowledge and ideas into innovative, feasible products to satisfy unmet clinical needs.

To close the gap between scientific literacy and application, we wanted to develop a novel lecture (dubbed HealthTec Innovation Design) for medical students and biomedical engineers that teaches a more futuristic view and includes applying exponential technologies in combination with teaching intentional disruption. We implemented a novel approach using the Purpose Launchpad meta-methodology and the Stanford Biodesign approach to define, experimentally validate and further

TABLE 1 | Proposed study plan suggestion for a novel master curriculum in Health Tech Innovation Design.

1. Semester	2. Semester	3. Semester	4 Semester
Marketing for Healthcare **5CP**	Value Based Technology and Innovation Management **5CP**	Entrepreneurial Finance and Venture Capital **5CP**	Master Thesis **20CP**
Market Research and Business Modeling **5CP**	Medical Innovation Needs 1 – Clinical Input (MI1) **5CP**	Discover UNMET CLINICAL NEEDS in a clinical Innovation Lab – think Entrepreneurial (UCN) **10CP**	
Innovation to Healthcare Democratization **5CP**	Individual Healthcare International – application of Value Proposition Canvas and Biodesign Principles (IHI) **5CP**		Health Economics and Reimbursement **5CP**
Healthcare Technology Innovation – future developments with high impact and need for change (HTI) **5CP**	Exponential Technologies and Designs for Extreme Affordability – Healthcare related (EXP) **5CP**	Medical Innovation Needs 2 – Screening, Diagnosis, Therapy, Prevention, Inpatient vs. Outpatient (MI2) **5CP**	Healthcare related Regulatory issues + Medical Product Risk Analysis (REG) **5CP**
20CP	20CP	20CP	30CP

The study plan articulates into four semesters covering economic/business with 50 CP (blue color), medical/clinical/healthcare innovation with 50 CP (purple) and the Innovation Lab in cooperation with the hospital with 10 CP (orange color).

exploit deep problem understanding to formulate an actual innovation project.

The learning from the global Sci-Fi Hive, a science fiction comic creation event, and the Innovation Think Tank Certification Program, both focused on the future of health but with different starting points, highlighted the need for a novel curriculum approach.

Through the implemented online surveys, we investigated the quality and efficiency of these educational programs and events. The survey results showed that most attendees were entrepreneurs, medical doctors, and students interested in exploring the topic of innovative healthcare. When speculating about the future implementation of technologies (>10 years' perspective), most responses were digital healthcare, AI, VR/AR, and brain-computer interfaces. Concepts like prevention over treatment, patient empowerment, and personalized medicine were considered the most impactful values/perspectives to generate meaningful innovation in healthcare. Factors like regulatory approvals (e.g., CE, FDA), government/political interests, unclear business model, and fear of changes were identified as responsible for preventing disruptive innovation. The lack of a customer profile/market test was the main reason for failure in a start-up/business/research/industry project dealing with healthcare innovation.

Moreover, innovation has been defined as the translation of an existing product/service/process into something more efficient/effective/competitive, and that twenty first-century competencies were considered very important "innovation mind-set" skills leading to innovation. More empathic and collaborative networks were identified with a deep understanding of the problem to be solved, respectively, as challenging and needed factors to generate an innovative healthcare strategy approach. Furthermore, attendees were satisfied regarding the overall programs/events outcome and willing to implement the taught methods to improve their current research/business/educational project. Attendees agreed that the gap between education and research application is still vast, estimating that training twenty first-century skills would be optimal to close this gap. A summary of the learned skills and continents from the different education programs leading to the novel curriculum development is reported in **Table 2**.

Based on our research results and the need of a revised education, our mission is to design a novel Master's Degree, called *Entrepreneurship Design Thinking Curriculum for Healthtech Innovation*, based on health technology innovation design, digital health methods, predictive and preventive medicine to reach our transformative goal in democratizing healthcare. Hence, we aim to establish novel curricula combining technical, economic, scientific and medical skills with twenty first-century skills to educate future health innovators and professionals. These curricula would comprehend programs taught in English, online teaching, on-site team projects and annual summer/winter schools. Through individual assignments, trimestral examinations, research team projects and tutoring support, students would be capable of reaching a novel degree in innovation generation aimed to generate the innovative mindset, attitude, and learning skills behind the feasible, valuable application of disruptive health technologies and finally moving the healthcare needle from sickness to health.

The master curriculum for Health Tec innovation design primarily aims at three interface areas for clinical innovation:

Healthcare economics (blue colored): Methods of health economic evaluation (benefit assessment, cost assessment, direct costs, indirect costs) play a significant role concerning healthcare democratization and require a deep understanding of economic processes and reimbursement for medical effectiveness and economic efficiency. Students are trained

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TABLE 2 | Summary of the learned skills from the different educational programs—Sci-Fi Hive, ITTCP, HTID—needed to formulate the novel curriculum in Innovation Tech Design.

Sci-Fi Hive	ITT CP	HTID	Novel Curriculum in Healthtech Innovation Design
Twenty-First century skills	Twenty-First century skills	Twenty-First century skills	Twenty-First century skills
Interdisciplinary teams	Interdisciplinary teams	Interdisciplinary teams	Interdisciplinary teams
Top- Down Problem solving approach toward Innovation	Bottom- Up problem solving approach toward Innovation	From lectures (literacy) to the development of innovative projects (application)	Academic Transfer Strategies/Commercialization of Research Results (from literature to application)
The hero's journey story	The ITTCP methodology	Purpose Launchpad meta-methodology, OpenExo tools, the Stanford Biodesign approach	The HTID teaching methodology, the Stanford Biodesign approach, I3-EME-Concept
"Try new things," "challenges help me to grow," "passion and purpose," "optimistic thinking"	"Customer-centric thinking," "rapid experimentation," "passion and purpose"	"Growth mindset" approach	The HTID teaching methodology, the Stanford Biodesign approach, I3-EME-Concept
Fun, curiosity, creativity, interdisciplinary interaction	Structure, insight, methodology, interdisciplinary interaction	"Thinking out of the box," "learning from mistakes" approach, creativity, methodology, personalization, empathy, interdisciplinary interaction	International academic and industrial collaboration across countries to identify individual needs of the global healthcare challenges

in a financial analysis perspective and can decide on broad expertise in various economic backgrounds for research and innovation projects.

Innovation Methodologies (purple colored): with various agile innovation methods in product development, students can resolve any problem quickly and in a goal-oriented manner. In addition to the basics and the constant exchange in interdisciplinary groups, the students also learn to apply the methods they have learned in real projects.

Application-driven research (orange color): Students cooperate with the Innovation Lab and clinical departments to apply economic knowledge and innovation methodologies to detect unmet clinical needs, solve them with the newest approaches, and change the whole process.

CONCLUSION

Currently, university-based educational programs lack twenty first-century skills and innovative approaches, essential for identifying and implementing exponential technologies designed to cover unmet clinical needs. The nowadays trend is to look at innovation as just an incremental process, disregarding what is instead disruptive. To overcome these limits and stimulate innovative thinking, we developed a new lecture titled *HealthTec Innovation Design* for clinical and biomedical engineering students to teach a novel methodological approach to develop and implement disruptive health technologies.

Moreover, *Sci-Fi Hive*, a science fiction comic event, and *Innovation Think Tank Certification Program* raised interest and awareness toward a growth mindset behind disruptive innovation. From the survey results, we can conclude that our educational and initiative programs have impacted a growing interest in innovation, focusing on a distinctive design thinking approach. Participants raised awareness toward those values and perspectives needed to overturn the innovation process from incremental to disruptive, from literacy to valuable competencies and feasible applications. The programs developed the basement of a creative growth mindset, sharing tools and methods necessary when identifying and implementing a new product/process to detect and fulfill unmet clinical needs.

Moreover, participants reported being enthusiastic and willing to implement these new skill sets and methods to enhance their current research/business/educational project solicited by passion, purpose, and optimistic thinking.

Prevention, prediction, personalization, empathy and democratization; with different skills and innovative setups, we can design the future of health toward exponential medicine. Based on our results, we are convinced that developing a new curriculum based on HTID and educational programs/events such as Sci-Fi Hive and ITTCP would be essential. Hence, our vision is to raise the awareness needed to upgrade the global way of training and educating healthcare professionals enhancing the future of healthcare.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

BB and HF carried out the experiment, wrote the manuscript with support from MF, and designed the surveys. MM and SH supported us with respect to Siemens Healthineers Innovation Think Tank Certification Program. MF conceived the original idea and supervised the project. All authors contributed to the article and approved the submitted version.

FUNDING

This research was funded by the Ministry of Economy, Science and Digitization of the federal state of Saxony—Anhalt by EFRE funding in the context of the ego—INKUBATOR program (ZS/2019/04/98209/IK 27/2019) and by the European Structural and Investmen Funds (ESF, 2014-2020) under the program "Sachsen-Anhalt WISSENSCHAFT Internationalisierung" project numbert (ZS/2016/08/80645).

ACKNOWLEDGMENTS

The authors would like to thank all partners at the Sci-Fi Hive–the Future of Healthcare Event and at the Siemens Healthineers–Innovation Think Tank Certification Program. Furthermore, the authors would like to thank Francisco Palao for providing the Purpose Launchpad.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.715768/full#supplementary-material

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Conflict of Interest: MM and SH are employed by Siemens Healthineers, Erlangen, Germany.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Publication 4

State-of-the-Art: Biodesign based Innovation Ecosystems in Europe

Fritzsche, H.; Mahbub, E.; Boese, A.; and Friebe, M.

Current Directions in Biomedical Engineering

DOI: 10.1515/cdbme-2021-2059

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State-of-the-Art: Biodesign based Innovation Ecosystems in Europe

Abstract: Today's healthcare challenges with unmet clinical needs, high regulation and certification standards, and increasing costs demand faster innovation and technical translation. To address this challenge, Stanford released a fellowship called Biodesign, where need-based healthcare innovation is taught with the approach identify, invent and implement. Since then, different European institutions have adopted the Biodesign innovation approach and organized within the Biomedical Engineering- Innovation, Design, and Entrepreneurship Alliance (BMEidea EU). The generation of successful healthcare innovation isn't only based on participating in an Innovation teaching program. It is much more a matter of having the right innovation ecosystem with an open creative mindset, experts, the respective stakeholders, and access to essential resources within reach (close to clinic).

Through a qualitative survey, seven Biodesign based teaching programs in the EU were examined. The study from an academic perspective contains information covering Resources, Activities, Academic Performance, and Transfer Performance.

The demand for new healthcare innovations, and especially innovation training programs that address challenges, developed collaboratively with the respective stakeholders, is increasing. Additionally, there is a growing expectation that innovation needs to reach the market quickly and be implemented accordingly.

A Healthcare Innovation Ecosystem, where different entities function as a productive unit with a shared vision and committed to application-driven research and technology transfer, will increase innovation's success and adaptation.

Keywords: Stanford Biodesign, Innovation Generation, Innovation Ecosystems, Start Up, Entrepreneurship, Technology Transfer, Medical Research Laboratory, Unmet Clinical Needs

https://doi.org/10.1515/cdbme-2021-2059

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1 Introduction

The innovation process describes the translation of new or existing knowledge into marketable solutions from idea generation through prototype development to market entry. Using promising technological opportunities of the 21st century requires a wide range of new knowledge, skills, and work habits, the so-called 21st Century Soft Skills. They include critical thinking, problem-oriented action, creativity, leadership skills, and collaborative and cooperative work [1, 2]. The focus of future innovations in the healthcare sector is the increasing life expectancy and improving the quality of life without increasing healthcare costs [3]. However, the research and development of medical technologies and devices are facing long and capital-intensive product development cycles, complex regulatory procedures, slow market uptake requiring the support of key opinion leaders and intensive follow-up with early adopters.

Additionally, the complexity and effort regarding patient care have increased, resulting in many unmet clinical needs (UCN). The current challenges in the healthcare sector, coupled with the new opportunities provided by the emerging technology [4, 5], calls for a need for agility within the development and adaption of healthcare innovations [6]. Ineffective communication, disagreement about priorities and benefits among stakeholders slows down the adaptation and diffusion of those innovations [7]. Accordingly, collaboration among each stakeholder, who share a common goal, is critical to reduce risk, cost, and time in the development and deployment of innovations [6, 8, 9]. To address this need, Stanford's Paul Yock has developed a fellowship called Biodesign. In this program, the necessary soft skills and the right mind-set and toolset to address healthcare innovation's new challenges and needs are thought. The Biodesign process follows a clear outline structured into three phases: ideate, invent and implement. It is a complex but well-structured process to turn an initial idea into a final product [10]. Much progress has been made in adopting the Biodesign approach in various EU academic programs. However, the participation of a Biodesign-based innovation teaching program alone will not lead to an innovative solution at the bedside. Experts such as medical doctors, patent attorneys, investors, and designers are needed at every stage of the healthcare innovation process [11]. Having access to critical resources such as hospitals, operating rooms, clinical test rooms, and prototyping facilities plays an important role. Various experts, resources, and access points must be in place during the ideation, invention, and implementation process [8, 11]. Only within the framework of a functioning healthcare innovation ecosystem know-how, necessary experts, and resources can make an essential contribution to the generation and adaption of successful healthcare innovations [8]. Each stakeholder plays a significant role in creating value within the larger ecosystem by turning new ideas into reality through access to human resources, financial capital, and other resources [12]. With the Biodesign mind-set and a shared vision, Healthcare Innovation Managers can bring solutions into the market faster. Close collaboration ensures the satisfaction of all stakeholders and thus accelerates the diffusion and adaptation of innovation within the healthcare sector [13].

Based on the Stanford Biodesign approach, the first BMEidea meeting was held in San Francisco in 2003. Professors who were teaching design in a Biomedical Engineering department or program realized that there were everyday needs that were not being met by current conference offerings. So, in 2013, the first Europe BMEidea meeting was held among programs there and is held annually. With the goal to:

- review the experiences of different university programs involved in innovation, design, technology transfer and entrepreneurship in biomedical engineering education.
- discuss objectives, challenges, and opportunities for further development of these programs – including industry and academic perspectives
- explore the potential for sharing resources and creating community-wide tools (e.g., web portal, national design contest).

In this work we analyse the innovation ecosystems of European BMEidea community to detect strengths and weaknesses and to learn for further improvement.

2 Methods

For approaching the analysis of Biodesign-based innovation ecosystems, members of the BMEidea EU network were asked from an academic perspective with a focus on:

1. Resources

Employees: The number of employees employed at the Institution is documented. The employees are teaching the program, organizing the projects, and are responsible for the network maintenance.

Network partners: This section records the individual network partners, the number of medical industry partners, non-medical industry partners, and other universities and research institutions.

2. Activities

Batch: The number and length of Biodesign courses that have taken place so far are registered here. Different program formats are considered, e.g., summer schools, semester courses within a curriculum or Ph.D. programs.

Participants: The number of participants is recorded. This number can be seen as an impact indicator. Participants which acquired the Biodesign tool- and mindset successfully will spread their knowledge and experiences.

3. Academic Performance

Unmet clinical need: This section captures the number of unmet clinical needs identified within the program.

Research Projects: Research projects based on identified unmet clinical needs indicate that these unmet clinical needs hold potential for future studies, patents, and papers.

Publications: Successful research projects are published in the form of a paper. Similarly, many patents as an indicator for transfer are based on previous research work. Therefore, the number of published papers is also recorded.

Studies: Clinical studies show the strength of collaboration and will for implementation. For this reason, the number of studies in collaboration with the industry or the clinic is recorded.

4. Transfer Performance

Patents: The number of filed patents is registered in this section. Patents are a first indication that these ideas hold promising potential. Therefore, patents are associated with a commercialization idea. Furthermore, these patents can be transferred to industries.

Transferred UCN: Not every idea or Unmet clinical need becomes a Startup. Therefore, transferring ideas, unmet clinical needs or prototypes to the industry might be a better option. For that, the question about the existence of transfer strategies is asked and number of transfers carried out is recorded.

Spin-off/ Start-Ups: The number of Spin-offs and Start-ups is recorded here.

For collecting of the data, a survey in English language using “Notion” was designed. The survey consisted of 29 questions formulated as multiple choice, checkboxes, short answers or yes/no modalities.

11 Institutions from the BMEidea EU Network were contacted to be part of the survey (see table 1).

Table 1: List of survey participants from the BMEidea EU network

Institution	Location
Department of Bioengineering	Imperial College London, England
Oxford Healthtech Labs	University of Oxford, England
CBH- School of Engineering Sciences in Chemistry, Biotechnology and Health	KTH Stockholm, Sweden
Faculty of Biomechanical Engineering	TU Delft, Netherlands
Biocat	Barcelona, Spain
BioInnovate	NUI Galway, Ireland
BioDesign Center	Acibadem University, Turkey
INKA- Application Driven Research	Otto-von-Guericke-University Magdeburg, Germany
MedInnovate	TU Munich, Germany
InnoX- Novo Nordisk Foundation	Aarhus University, Denmark
Innovation Think Tank Certification Program	Siemens Healthineers, Erlangen, Germany

3 Results and Discussion

Eleven different institutions from the EU, who offer an Innovation teaching program based on the Biodesign approach were surveyed. Only 7 of the 11 institutions surveyed completed the questionnaire. Four questionnaires could not be evaluated because they were not filled out completely. Results are summarized in Table 2. In the category "resources" the highest number of employees (Empl) was given - by Erlangen, followed by Acibadem and Magdeburg. In the case of "network partners" (Net) in industry and other research institutions, Erlangen is leading, followed by Magdeburg and Aarhus. In the "activity" category Magdeburg shows the highest number of program runs carried out (batch) followed by Munich and Erlangen. This is similar for the number of "participants" (Partic) who have participated so far. Looking at the numbers between employees, batches, and participants, one can see that Magdeburg and Munich have assisted the most participants. Munich runs the program twice a year, and the institution is exclusively available for the MedInnovate Fellowship. Magdeburg employees are also highly available for their innovative teaching program with offering different formats like summer schools, Master semester and Ph.D. Program. This is another reason why they have an increased number of participants. Erlangen with the Innovation Think Tank Certification Program reaches the most people due to their regular running certification courses (to students and industry fellows) and because of their huge network.

The academic performance includes the identified unmet clinical needs (UCN) led by Oxford, followed by Aarhus and Erlangen - the focus here is on "identify" and understanding the clinical needs. Research projects (RP) focused on "invent" in Magdeburg, followed by Erlangen and London. This result in an increased number of papers and publications (pub) and studies (studies). Finally, the transfer benefit category includes the number of patents (patent) led by Erlangen, followed by Magdeburg and London. The number of ideas, prototypes and unmet clinical needs (trans) passed on to industry is led by Acibadem, followed by Magdeburg and Aarhus, and the number of start-ups (divided into start-ups and spin-offs) led by Erlangen, Oxford, London and Magdeburg.

Table 2: List of the results of surveyed institutions from the BMEidea EU network partners

	Resources		Activities		Academic Performance				Transfer Performance			
	Empl	Net	Batch	Partic	UCN	RP	Pub	Studies	Patent	Trans	Startup	Spin-off
Erlangen	150	170	reg	8000	500	50	N/A	0	500	N/A	5	20
Aarhus	6	25	1	16	600	1	0	0	0	1	2	0
Acibadem	16	20	4	40	N/A	N/A	15	4	3	14	1	0
London	2	N/A	6	40	100	40	20	40	10	0	8	0
Oxford	2,5	7	4	18	2000	4	1	N/A	2	0	4	4
Magdeburg	12	29	14	150	150	85	262	10	64	5	3	4
Munich	2	9	10	110	30	4	2	0	0	0	5	0
Stockholm	2	N/A	10	80	N/A	N/A	N/A	N/A	0	N/A	7	N/A
Delft	50	N/A	15	2000	N/A	N/A	N/A	N/A	N/A	N/A	25	N/A
Galway	4	26	10	108	5000	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Barcelona	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

4 Conclusion

The demand for new healthcare innovations that address an unmet clinical need increases. A respective stakeholder network and access to different facilities are needed to fulfill the growing expectation that innovation needs to reach the market and be implemented accordingly quickly. The holistic overview of the different healthcare innovation ecosystems and their parameters from an academic perspective shows necessary access to resources, networks, and access that need to be in place within a healthcare innovation ecosystem.

In general, it is not easy to compare different EU programs because each program has its own strategic goals in research, teaching and entrepreneurial activities. There are also different running times, program starting points and follow-up strategies. For example, not every EU program can generate more Startups, register patents, cooperate with industry, or dedicate itself to research.

It can be seen that a broad and regular program offer (batch) reaches many participants and results in an increased number of projects - publications, patents and studies will then follow. Furthermore, if a broad network of clinicians and industrial partners is available, the project implementation is accelerated.

One indicator could be identified as a common denominator - the number of Startups and Spin-offs funded. Furthermore, to strengthen the Start-up generation, critical network partners in the ecosystem and essential topics in the teaching curriculum must cover regulatory affairs, reimbursement, market commercialization, and entrepreneurship.

Future research could examine the ecosystem from a clinical or industrial perspective.

Acknowledgement
The authors would like to thank all partners BMEidea EU Network Program.

Author Statement
Research funding: This research was financially supported by the Ministry of Economy, Science and Digitization of the federal state of Saxony Anhalt by EFRE funding in context of the ego.-INKUBATOR program (ZS/2019/04/98209/IK 27/2019).
Conflict of interest: Authors state no conflict of interest.
Informed consent: For this research no informed consent was required.
Ethical approval: For this research no ethical approvals was required.

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Publication 5

From 'bench to bedside and back': Rethinking MedTec innovation and technology transfer through a dedicated Makerlab.

Fritzsche, H.; Boese, A.; and Friebe, M.

The Journal of Health Design, 6(2). July 2021.

DOI: 10.21853/JHD.2021.13 3

The Journal of Health Design

RESEARCH PROTOCOL

From 'bench to bedside and back': Rethinking MedTec innovation and technology transfer through a dedicated Makerlab

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To Cite: Fritzsche H, Boese A, Friebe M, 'From bench to bedside and back': Rethinking MedTec innovation and technology transfer through a dedicated Makerlab. JHD. 2021;6(2):382–390. https://doi.org/10.21853/JHD.2021.133

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SUMMARY

This paper presents the setup, network environment, and some of the initial results and learnings from developing Innolab IGT, a medical, technology, and innovation laboratory at a university clinic in Germany over four years. We created a learning environment that had short distances between operating rooms and labs, quick, responsive communication, and direct identification of clinical needs. Everyone involved in this Innolab IGT network benefits, whether for scientific recognition (publications), economic translation (patents and startup generation), knowledge transfer, or economic stimulus.

Key Words

Innovation generation; biodesign; design thinking; clinical translation; biomedical engineering education

ABSTRACT

Background

Forthcoming healthcare delivery challenges and unmet regional/global clinical needs require new concepts for related purpose-driven R&D to ensure a quick translation to clinical use.

Aims

Establishing a medical, technology, and innovation laboratory directly within the clinic creates short distances between operating room (OR) and lab structures; facilitates quick, responsive communications for the testing and evaluation of prototypes; and enables direct identification of needs in a learning environment that helps students learn through prototyping workshops, simulation OR, and creative workspaces.

Method

We established a dedicated Innovation Laboratory for Image-Guided Therapies (Innolab IGT) to enable engineering students to work in a focused and interdisciplinary innovation environment alongside clinicians and users on projects that may range from the identification of unmet clinical

needs to a potential technology transfer. The creation of an innovation laboratory can also stimulate startup activities. Through accurate observation, empathy, process know-how, and subsequent analysis and evaluation, individuals engaged in Innolab IGT can generate clinically relevant and affordable innovations as a base for future entrepreneurial activities—for example, through involvement of companies or the creation and design of clinical studies by startups.

Conclusion

This paper presents the setup, network environment, and some initial results and lessons learned from the last four years of Innolab IGT. In our framework, everyone who was involved in the Innolab IGT network benefitted, either through scientific recognition (publications), economic translation (patents and startup generation), knowledge transfer, or through the generation of an economic stimulus.

BACKGROUND

Excellent communication structures, interdisciplinary exchange, and a well-connected network are inexhaustible generators of ideas. In the medical technology domain, meaningful development requires interdisciplinary work with the user.[1] Therefore, effective collaboration requires a short physical distance between the engineer's workplace and the user within a dedicated organisational structure.[2] Working toward creating product ideas that set future technology trends in image-guided minimally invasive therapy requires engineers to be engaged in an intensive exchange with the physician (ie, the user). Product ideas, innovations, and startup potential are generated through interdisciplinary work leading to the combination of medical necessity defined by the medical side and technical possibilities evaluated from the technical side. The Innolab IGT's goal is to engage with users to develop and translate innovations in the field of image-guided therapy for use in practice. Combining the Innolab IGT services with this type of collaboration creates potential options such as working towards possible startups as the lab focuses not only on technical/clinical R&D but also stimulates accompanying entrepreneurial activities. Entrepreneurship and business startups play an increasingly important role in business practice as well as in scientific research and funding.[3]

Currently, the potential for innovation and subsequent translation in startup companies is not within the scope of German universities or part of the scientific education.[4] A growing need exists, however, for professionals who specialise in interdisciplinary innovation generation and technology transfer that can bridge the gap between medicine and technology,[5] and who can manage tasks effectively and efficiently within an economic context.

The Innolab IGT, located within the medical faculty of the University Clinic in Magdeburg, has shown results that meet this need. Since 2016, the lab has brought together a network of clinicians, engineers, and industrial partners that have produced numerous inventor disclosures, patents, publications, and startups.

METHOD

The Innolab IGT represents how engineers and physicians should work together in the future to uncover unmet clinical needs and subsequently develop new product ideas for clinical applications. (Future) engineers should move away from their bench (ie, place of work or study) and visit the on-site clinic to observe and discover these needs during normal operations or surgical interventions by medical users within their study and graduate projects. Based on the Stanford Biodesign concept (Identify, Invent, Implement),[6] and the human-centered design thinking approach "to integrate the needs of people, the possibilities of technology, and the requirements for business success",[7] Innolab IGT develops many product and process ideas. These ideas are tested in short iterations (two-week sprints) for their usability and general feasibility (Figure 1). In addition to the technical implementation, the market potential of such products is of significant importance.

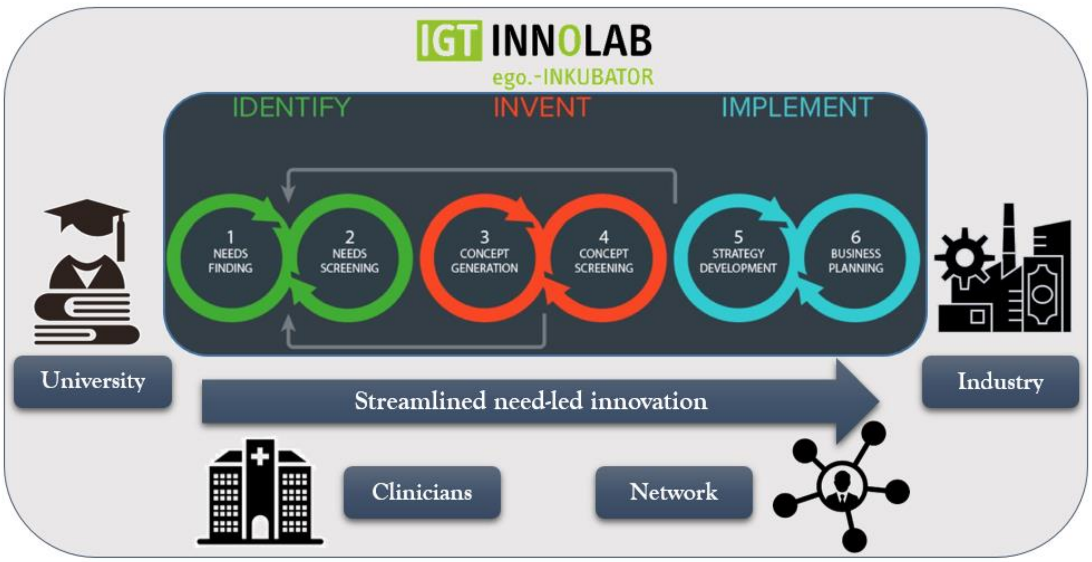

Figure 1: **Three-stage development process based on Stanford University's Biodesign concept with participating stakeholders (university, industry, clinics, and networks)**

The Innolab IGT is located directly at the university clinic (centrally located and close to all relevant medical departments), which facilitates cooperation between physicians and engineers. In the lab (Figure 2), it is now possible to review, verify, and improve prototypes in a "close to clinic" development environment that has direct involvement of physicians. The lab also has an innovation environment for simulation and/or fabrication labs for 3D prints, electronics, software solutions, and simulation and validation phantoms.

Figure 2: View into the innovation laboratory and the open creative space (above) with simulation operating room (bottom left) and one of the prototype workshops for hardware development and electronics production (bottom right).

University's Role: The basic idea is the concept of "innovation with and not only for the physician".[8] The university uses this concept and innovation generation lab to inspire and motivate engineering students and staff to think about starting a business based on their own verified product or related service ideas. A solid research infrastructure, equipment, and access to the clinic motivates students from different programs (bachelor, master, PhD) to apply and improve their knowledge and experience, especially for interdisciplinary work and core competencies like scientific, financial, and clinical literacy.

Clinicians' Role: The clinical partners provide the expertise for a patient-oriented system and outline items or issues that require improvement. They help with problem identification, technical improvement, and research activities. Current clinical cooperation partners (departments) include Ear Nose and Throat (ENT), Urology, Neuroradiology, Radiology, Nuclear Medicine, Vascular Surgery, Orthopedics, and Cardiac Surgery at the University Hospital Magdeburg. Each semester we formed interdisciplinary student teams of 3 to 5 members who visited surgeries to identify the clinical needs, generate ideas for each problem, and create first prototypes. The teams shared ideas regularly with the clinicians who come, see, discuss, and help improve the prototypes developed.

Industry Partners' Role: We also formed an industrial board with several small, medium and large companies from Saxony-Anhalt and other German regions. The companies provide market insights and future scope in a customer-oriented system. They focus on successful products, technical transfer (research results transferred into practice), and strong customer relationships. In the process of developing new prototypes, they are reliable partners from the business side and give feedback to the research teams accordingly.

Network Activities: Innolab IGT participates in networks such as the VDI, The Association of German Engineers; the Institute of Electrical and Electronics Engineers (IEEE) Branch; and the BME-IDEA/EIT Health Networks, which covers a wide range of industrial applications, partners, clusters, and research networks. A broad network activity through excellent communication and connecting people to disseminate ideas and needs enables different viewpoints from key opinion leaders, a community with shared interests, and funding opportunities. These networks focus on regional development and a functional connectivity between research and industry for fast and easy exchange between these partners. In addition, the Innolab IGT organises network meetings and conferences. The first BME-IDEA EU was held in Magdeburg, Germany, in 2017. In 2019, the IEEE EMBS ISC (Engineering in Medicine and Biology Society–International Student Conference) followed.

Benefits

Innolab IGT projects include therapeutic tools and systems focused on tumor removal under diagnostic image guidance, lymph node biopsies, catheter and vascular delivery systems, endoscopic components, etc. Here, the innovation process starts in the clinic (bedside) where teams detect potential needs through observation and empathic communication. An iterative development process follows using the previously mentioned Stanford Biodesign process.[5] This starts with ideation, proof of concept, and capture and development of business knowledge and strategies using input from industry (bench). It continues with creating product prototypes that are tested in the clinic to understand whether or not care is improved and to apply the learnings for further improvements or alterations (back to bedside). All partners participate in the innovation process to create a chain from the idea validations (value, market, user), over solution creation, to the proof of concept (technical, clinical), and finally, the transfer to industry or to a startup. The Innolab IGT will continue to stimulate and significantly increase cooperation between the parties involved in the innovation process. This creates added value for all parties (Figure 3).

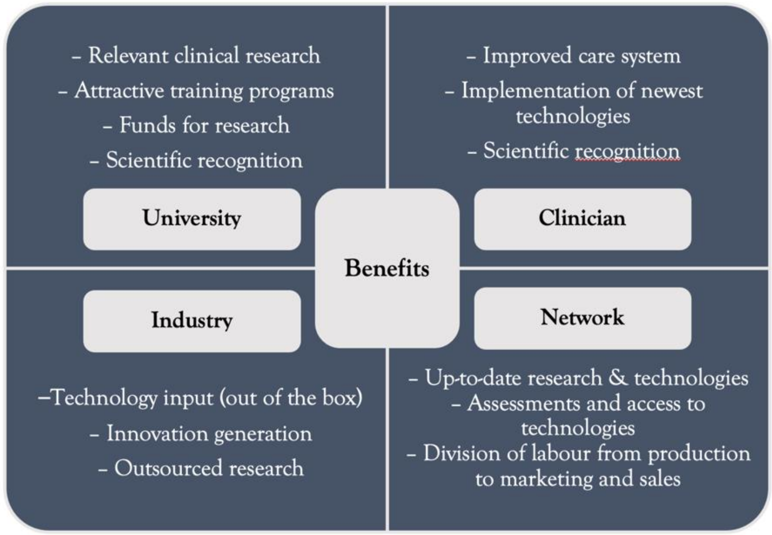

Figure 3: Benefits for involved parties (university, clinicians, industry, and networks)

OUTCOME MEASURES

Since it opened in 2016, the Innolab IGT has developed into a central development hub on the medical campus. It combines university education with interdisciplinary and application-oriented research. Clinical and industrial partners provide valuable input and assistance in realising the innovation projects. Students benefit from a wide range of facilities, equipment, knowledge, and transfer strategies. Three areas were defined as key performance indicators based on progress or degree of fulfillment and with regard to objectives or critical success factors within the research unit:

1. **Training/Education**, which focuses on the number of supervised students, completed projects, and international research engagement as part for internationalisation;

2. **Research activity**, which is disseminated and recognised in a scientific context with publications, patents, and clinical studies; and

3. **Transfer** in terms of performance indicators for commercial exploitation, including Transfer Projects (ZIM/IB), Generated money (funds, cooperation's) and founded startups.

During the period 2016–2020, Innolab IGT supervised and assisted 125 students and scientific staff. Ten of them (mainly PhD students) participated in international exchange programs with a stay >4 weeks. Exchange universities included the Indian Institute of Technology Kharagpur (India), Korea Advanced Institute of Science and Technology (Korea), Queensland University of Technology (Australia), Johns Hopkins University (US), Vanderbilt University (US), and Akademia Gorniczo-Hutnicza Krakow (Poland).

During this four-year period, the students identified more than 500 unmet clinical needs through surgical observations, internships, and reviewing clinical processes. After evaluating a clear need statement and technical feasibility, we processed 85 projects of these unmet clinical needs derived from the identification in the clinical process through prototype development and market translation—the outcomes were 37 invention disclosures, 17 patents, and 262 publications. In addition, there are 10 clinical studies/pre-clinical studies, mainly in the areas of data acquisition for tracking, and ultrasound (Table 1).

Table 1: Key performance indicators for Innolab IGT (preliminary results for 4 years)

Activity	Number
Training/Education	
–Students (BA, MA, PhD)	125
–Projects	85
–International Research Engagement	10
Research Activity	
–Publications	262
–Patents/Invention Disclosures	17/37
–Clinical Studies/Preclinical Studies	10
Transfer	
–Transfer Projects (ZIM/IB)	3
–Revenue Generated	€ 3.7 million
–Startups	6

Due to the clinical connection and the intensive integration of industry and networks, Innolab IGT completed three industry-driven projects (injection pump, thermographic imaging, and non-destructive testing). Six startup projects have been generated thus far:

1. **SURAG (Surgical Audio Guidance)**–auscultation system for sound-based tissue characterisation (eg, positioning of verres needles for laparoscopic interventions).
2. **InLine**–MRI-compatible surgical tools and assistance devices that help radiologists to perform safe, precise, and easy interventions.
3. **EasyJector**–a lightweight, inexpensive, easy-to-use (MRI-compatible) injection system for pharmaceuticals.
4. **Rad print**–Individual radioactive patches for treating superficial skin tumors.
5. **SmartReha**–a virtual reality-based training program for stroke rehabilitation for people with paralyzed limbs.
6. **MEDICS GmbH**–Medical innovation and certification services for supporting companies in regulatory and certification processes/quality and process management—especially in the context of new medical device regulations.

DISCUSSION

The Innolab IGT has created an innovation and idea generator that allows clinicians and engineers to collaborate in a simulated clinical setting on the university campus. Engineers are able to understand better the day-to-day clinical processes, and together with physicians, address issues and shortcomings in the clinical workflow, and identify potential new technical products. The close cooperation among the students, doctors, scientists, and industrial business partners is also unique. Solutions and innovative ideas are developed and implemented, changed, or rejected in constant consultation with the physicians. Testing and evaluation by clinical users, as well as business partners' wishes and suggestions, are continuously integrated into the individual development phases of new medical products and ensure a market-oriented product development. Due to the existing therapeutic and diagnostic infrastructure and the training concepts, the Innolab IGT itself represents an optimal development environment for future translation in the field of image-controlled therapies.

CONCLUSION

This paper describes the benefits of Innolab IGT for university, clinic, industry, and network partners within an innovation ecosystem on-site at the clinic. Our ecosystem provides methodologies to identify unmet clinical needs, rapidly screen concepts, and move more adeptly through the innovation and development process. The Innolab IGT concept and the process for innovation in the healthcare domain includes key performance indicators such as training students, creating publications and patents, and technology transfer. While the work is related to bioengineering education, innovation generation and translational processes, we show practical results and successful implementation of application-driven research.

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ACKNOWLEDGEMENTS

The authors would like to thank all clinical partners at the University Clinic Magdeburg and our cooperation partners from research and industry.

PEER REVIEW
Not commissioned. Externally peer reviewed.

CONFLICTS OF INTEREST
The authors declare that they have no competing interests.

FUNDING
This research was financially supported by the Ministry of Economy, Science and Digitization of the state of Saxony Anhalt by EFRE funding in context of the ego.-INKUBATOR program (ZS/2019/04/98209/IK 27/2019).

ETHICS COMMITTEE APPROVAL
N/A