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RESEARCH PROTOCOL

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

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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.

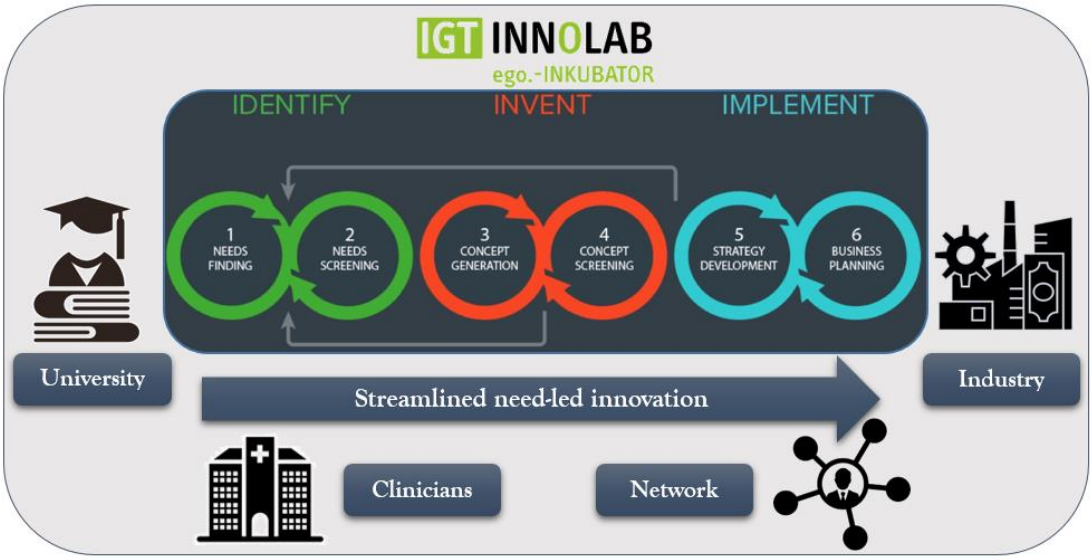

Figure 1: **Three-stage development process based on Stanford University's Biodesign concept with participating stakeholders (university, industry, clinics, and networks)**

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).

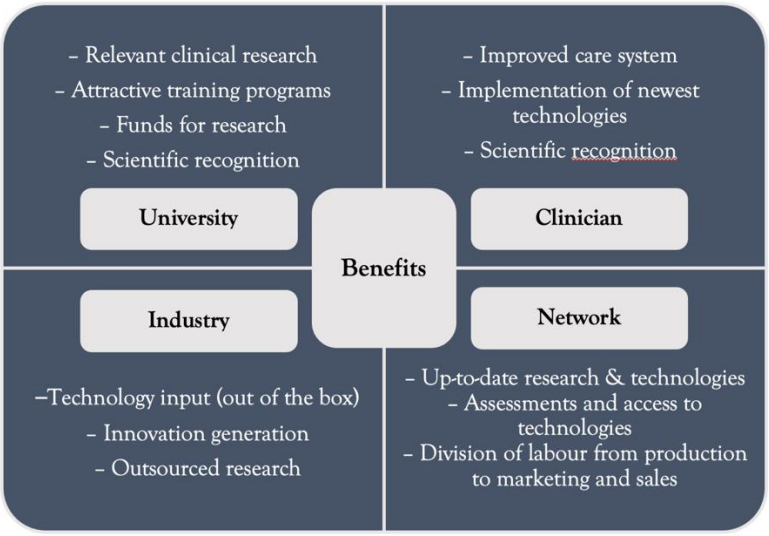

Figure 3: Benefits for involved parties (university, clinicians, industry, and networks)

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.

REFERENCES

1. Blank S. The Key to Startup Success? Get Out of the Building. [Video]. 2014. Available from: https://www.inc.com/steve-blank/key-to-success-getting-out-of-building.html [Accessed January, 12, 2021].
2. Allen TJ, Tomlin B, Hauptman O. Combining organizational and physical location to manage knowledge dissemination. *International Journal of Technology Management*. 2008;44(1–2):234–50.
3. Wilson K. Entrepreneurship Education in Europe. In Potter J, *Local Economic and Employment Development (LEED) Entrepreneurship and Higher Education*. Paris: OECD Publishing; 2008 p. 119–38.
4. Fritzsche H, Boese A, Friebe M. INNOLAB- image guided surgery and therapy lab. In: *Current Directions in Biomedical Engineering*. 2017;3(2):235–7. Doi: 10.1515/cdbme-2017-0049
5. Hartley S. Bridging the gap between health care professionals and communities. *Community Eye Health*. 2004;17(51):38–9. PMCID: PMC1705732
6. Yock PG. Biodesign: *The Process of Innovating Medical Technologies*. Cambridge: Cambridge University Press; 2015.
7. Brown T. Design thinking. *Harvard Business Review*. 2008;86(6):84.
8. Boese A. *Lösungsfindung mit dem Endnutzer, ein neuer Ansatz in der methodischen Produktentwicklung am Beispiel der Medizintechnik*. 1st ed. Maastricht: Shaker; 2016.

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

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ETHICS COMMITTEE APPROVAL
N/A