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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

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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

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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.

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