From Idea to Business Plans: Designing a Seminar for Teaching Digital Health Entrepreneurship

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Abstract: Technology entrepreneurship, together with its subfields such as digital health entrepreneurship, is gaining increasing attention, with digital transformation playing a pivotal role in shaping its landscape. This transformation has the potential to revolutionize various industries. However, technology entrepreneurship, in particular, demands a unique set of entrepreneurial competencies. To address this, we designed a seminar focused on the healthcare sector, enabling graduate students to explore the field of digital health entrepreneurship. The seminar guides students through the process of developing a Software as a Medical Device (SaMD) business model with a focus on the European Union (EU). This paper presents the conceptual design of the seminar and evaluates its effectiveness based on seminar results and participant feedback. In the seminar, students work in teams, assuming the role of an early-stage startup team in the digital health industry. Through a multi-stage design process, they identify healthcare needs, apply creative ideation techniques to generate business ideas, and refine them into comprehensive business models. The final stage involves pitching their business concept to potential investors. Additionally, seminar participants are introduced to EU medical device regulations and reimbursement pathways to develop viable revenue models. The seminar is structured around an action-based learning approach. Students first receive theoretical input, which they then apply practically to their case studies. Their work is presented in intermediate sessions, where they receive feedback from peers as well as supervisors. To support collaboration and interactive learning, several custom-designed canvases are integrated into digital interactive tools. Seasoned entrepreneurs hold guest talks to give a complementary perspective through their experience. Having been conducted over multiple semesters, the seminar has received positive feedback from participants. This work offers valuable insights into the key aspects of developing a seminar for the entrepreneurial journey of building a SaMD in the EU. It may serve as inspiration for other researchers and facilitators in the fields of technology entrepreneurship and broader entrepreneurship education.

Keywords: Digital health, Entrepreneurship Education, Seminar, University, Teaching, Software as a Medical Device

1. Introduction

Technology entrepreneurship is a tool that supports growth for individuals, businesses, regions, and nations (Bailetti, 2012). Bailetti (2012) defines technology entrepreneurship as: "…an investment in a project that assembles and deploys specialized individuals and heterogeneous assets that are intricately related to advances in scientific and technological knowledge for the purpose of creating and capturing value for a firm." (Bailetti, 2012, p.5). A central outcome of technology entrepreneurship is the emergence of new technology-based firms (NTBFs). These NTBFs are particularly important in tackling issues prevalent in today's world (Presse and Terzidis, 2017). They are acknowledged for their strong potential to drive growth and make a substantial impact on the broader economy (Ferguson and Olofsson, 2004). NTBFs play a key role in spreading technological innovations and driving industrial development (Arantes et al, 2019). In healthcare, technology entrepreneurship can be described as the process of creating, initiating, and growing ventures that design new technologies, products, and services aimed at delivering value to patients and various stakeholders such as medical staff, healthcare institutions, and insurers (Kulkov et al, 2023). With healthcare systems worldwide facing challenges such as rising costs (Wulfovich, 2020) and a lack of qualified healthcare staff, in recent years, digital health technologies have provided the potential to tackle them. Nowadays, digital health solutions can provide treatment support for diseases, they can help track fitness, make diagnoses, and support the prevention of diseases. Digital health can be seen as an umbrella term (WHO, 2019). It encompasses concepts such as mobile health and telemedicine (WHO, 2019).

However, despite its potential, entrepreneurs in the digital health sector are confronted with several challenges, especially if they develop Software as a Medical Device (SaMD). These include strict regulatory requirements, complex stakeholder landscapes, and difficulties in securing funding to cover pre-market expenses. In addition, aspiring founders should have unique knowledge and entrepreneurial competencies to successfully establish a startup. University-based educational programs can equip prospective entrepreneurs with the knowledge and competencies needed to address these challenges. They can guide entrepreneurs in the development of a sustainable business model, which is crucial for success. In complex industries where many startups are not able to bring their solutions into the market successfully, a university seminar can provide essential preparation for

navigating early-stage challenges. To our knowledge, there is no existing literature that explores how seminars can be designed for highly-regulated, multi-stakeholder environments, and less specifically for the SaMD domain. Therefore, we formulate the following research question (RQ):

- RQ: How can we design a university seminar on digital health entrepreneurship that enables participants to develop a business model for a SaMD in the European Union?

The seminar focuses on the SaMD industry of the European Union (EU) as a subfield of the digital health sector. The focus was chosen for several reasons. First, the growing SaMD sector offers opportunities to tackle pressing healthcare issues, including the lack of quality care and the shortage of skilled medical personnel. Second, the SaMD industry is perceived as particularly complex, especially due to strict regulations and multiple stakeholders. This is exactly where a seminar can provide the most valuable support. Lastly, a specialization allows for in-depth coverage of the topic and the delivery of detailed information.

Our work provides valuable insights into structuring a digital health entrepreneurship seminar focusing on the EU SaMD industry. Researchers and facilitators in the fields of digital health entrepreneurship and, in a broader sense, entrepreneurship education can benefit from the seminar design approach and apply it in similar industries. Additionally, our work is of value to the literature on entrepreneurship education. By focusing on the development of a SaMD business model in the EU, our seminar fills a crucial gap and stands out as a unique contribution.

The following work is structured as follows: In the subsequent subsection, we will provide an overview of related work. Thereafter, we will focus on the methodological approach followed in this work. The third section gives an overview of the results. In the fourth section, we discuss the results before we conclude the work.

1.1 Fundamentals and Related Work

SaMD is software intended to be used for at least one medical purpose that is performed without being part of a hardware medical device (IMDRF, 2014). In the EU, SaMD is regulated under European Union medical device regulations. SaMD includes a wide range of software, from apps used by private individuals to manage conditions like migraines to clinical tools used by physicians for disease diagnosis.

Several papers focus on the design of entrepreneurship seminars, with some of them focusing on entrepreneurship in the medical device industry. For example, Suryavanshi et al (2004) describe a course designed to promote entrepreneurship among students interested in medical informatics. Yock, Brinton, and Zenios (2011) focus on teaching biomedical technology innovation. Greven et al (2020) developed a course designed for studies that focuses on teaching entrepreneurial fundamentals in combination with the challenges of home healthcare for older adults, enabling students to develop practical solutions. One of the most well-known processes of innovating medical technologies is the Biodesign Program at Stanford (Yock et al, 2015). Stanford Biodesign's goal is to educate future pioneers in health tech innovation (Fuerch, Wang and Wert, 2021). The process consists of three phases: identify, invent, and implement (Yock et al, 2015). The *Identify* phase involves finding and screening needs. Based on the selected needs, concepts are generated in the *Invent* phase. The generated concepts undergo a screening process, after which the optimal solution is chosen. In the final phase, the *Implement* phase, a strategy for the selected concept is developed as well as a business plan. The process is iterative, allowing for adaptations along the way (Yock et al, 2015). Despite these works, to our knowledge, there is no seminar explored in the literature that specifically focuses on teaching the development of a SaMD business model in the context of digital health entrepreneurship.

2. Method

This paper adopts the case study methodology by Yin (2009). We build upon a single holistic case study design to report on the design of a university seminar focused on digital health entrepreneurship. In the following, we provide the five key components of a case study design according to Yin (2009), including the study's question, proposition, unit of analysis, the logic for linking data to the proposition, and criteria for interpreting the findings.

Based on the previously introduced research question, the **proposition** of this case study is that a seminar on digital health entrepreneurship can be designed to enable students to develop a business model for a SaMD in the EU. The **unit of analysis** is a seminar conducted at Karlsruhe Institute of Technology (KIT), a technical university located in the south of Germany. In three seminar runs, a total of 58 graduate students from disciplines such as industrial engineering and computer science participated. To **link data to the proposition**, we

collected two types of data during the seminar. Primary, session artifacts such as student pitch decks and business plans were analysed. These data were subsequently triangulated with the results from the standardized KIT seminar evaluation questionnaire collected for all three seminar sessions. The evaluation focused on dimensions such as perceived learning outcomes, relevance of seminar content, and overall satisfaction. This triangulation enables the establishment of patterns consistent with or diverging from the initial proposition. **Criteria for interpreting the findings** included the quality and completeness of the pitch decks and the business plans. Additionally, criteria include frequency and consistency of positive student evaluations and alignment between the intended learning outcomes and student-reported gains. Patterns of improvement or consistent challenges across both seminar runs were also used as indicators of effectiveness and reproducibility.

3. Results

3.1 Seminar Design

The overarching goal of the seminar was to teach graduate students from various disciplines on the topic of digital health entrepreneurship, thereby enabling them to develop entrepreneurial competencies to found a startup in digital healthcare. The following learning objectives should be achieved through the seminar. First, students should be encouraged to take on the role of entrepreneurs to develop relevant competencies and entrepreneurial thinking. According to Stagars (2014), entrepreneurship is rather a mindset than a job. Students should be taught and experience the required mindset in a simulated environment. Therefore, they identify unmet needs and use ideation methods to find solutions. Second, students should be taught the basics of the digital health industry, in particular the SaMD industry. The SaMD sector is highly complex. Therefore, topics include the EU medical device regulations, reimbursement strategies, besides classical entrepreneurship topics such as business models and pitching. Lastly, the students learn soft skills that are important for founders. By working in teams and regularly pitching their ideas and current status to all seminar participants, the students improve their presentation and communication skills as well as teamwork capabilities.

3.1.1 Pedagogical Framework

The seminar builds on an action-based learning approach, which is grounded in the work of Revans (1957). One aspect of this approach is that students work in teams throughout the seminar. The seminar, therefore, functions as a simulator for developing a potential SaMD business model. It consists of short theoretical input sessions from the facilitators, followed by time-boxed group work and intermediate presentations of the results, during which facilitators and other team members can provide feedback. Warm-up elements are integrated within the seminar so that students get comfortable with the setting and to encourage participation. Outside the seminar, students were expected to complete assignments that were started in the seminar. Digital collaboration tools are used to document the work within and outside the seminar and enable remote teamwork. These digital collaboration tools were set up with a mixture of custom and established canvas-like tools to support the work. Custom tools focused especially on SaMD-specific elements, such as medical device regulations and essential business model elements. Additionally, the seminar is supplemented by input talks from seasoned entrepreneurs.

3.1.2 Seminar Structure

The seminar consists of six full days, held every one to two weeks. It begins with an introduction to digital health entrepreneurship, followed by a team-building activity designed to foster collaboration among participants. Research shows that larger, more personality-diverse startup teams show an increased likelihood of success (McCarthy et al, 2023). Therefore, diverse teams are formed based on individual personality traits.

After this initial session, the seminar proceeds through a structured five-phase approach, which includes the phases: Identify, Invent, Decide, Define, and Sharpen. These phases are inspired by the Biodesign process (Yock et al, 2015), a methodology traditionally used for commercializing medical technologies. Much like the principles of design thinking, this approach encourages an iterative process, allowing participants to revisit and refine previous phases as needed. This flexibility supports deeper insight and more effective problem-solving, as illustrated in Figure 1.

Towards the conclusion of the seminar, each team presents their project pitch in front of a jury, showcasing the results of their work. Additionally, a comprehensive written business plan must be submitted.

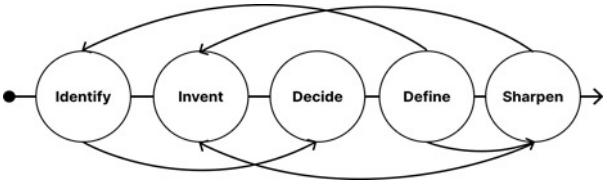

Figure 1: Overview of the five-phase approach applied in the seminar

In the first phase, *Identify*, the topic of digital health is introduced by stating its origin and showing a selected number of successful digital health startups. Thereby, it is already shown which startup develops a SaMD to foster initial understanding of the concept. Subsequently, the goal of the seminar is introduced, which is to develop a business model for a SaMD. Next, the concept of need statements was presented, which is inspired by Biodesign (Yock et al, 2015). Therefore, healthcare problems are identified by students, which can be summarized in a specific need that can potentially be addressed by a digital solution.

In the *Invent* phase, which is the second phase, the focus lies on ideation. Here, students are required to use creative techniques such as brainstorming to develop first draft solutions for each of their problem statements. This ideation process is time-boxed and supported through ideation anchors, which are used to take a certain perspective on the solution space. Therefore, different ideation anchors are introduced, such as different digital technologies, the healthcare cycle of care, and the specific medical speciality levels, which can serve as a focused perspective to generate ideas. Participants cluster their ideas thematically after the ideation.

In the third phase, *Decide*, goodness criteria are used to create a ranking of the best to worst idea. Ideas should be precise enough so that they can be rated. Rating is conducted within the startup team and with experts from the domains of business, medicine, regulatory, and engineering. Finally, the top three ideas are selected, and the best idea is followed for the consecutive steps. Still, at a later stage, the startup team can make the decision to return and continue the process with another idea, if deemed necessary.

In the subsequent phase, *Define*, potential customers are identified through the persona concept. Additionally, frameworks like the jobs-to-be done framework (Ulwick, 2016) are utilized to empathize with potential customers and ultimately develop a value proposition through the Value Proposition Canvas (Osterwalder et al, 2014). Additionally, the understanding of medical devices and the regulatory requirements of EU medical device regulations are discussed and identified by the students for their selected ideas.

In the final phase, *Sharpen*, a key consideration is potential revenue models, including self-payer options, business-to-business models, and reimbursement pathways. Students are introduced to various reimbursement pathways through which revenue can be generated from payers such as health insurers. This is a crucial element of the entire process. Additionally, other essential elements in this phase include competitors, market potential, relevant stakeholders, and core activities within the scope of the idea.

Finally, after going through these phases, the students put their learning together into a business model. Once the business model is set, a pitch preparation session helps the students to understand relevant aspects of an investor pitch. The final pitch takes place in a more official setting in front of a jury of experts. Within this seminar element, students pitch their idea and then have to answer the jury's questions before the seminar concludes.

3.2 Evaluation

To evaluate the seminar's outcomes, two researchers reviewed the pitch decks and business plans. For the evaluation, the researchers followed the structure and key section points outlined in the EXIST Business Start-up Grant template (EXIST, 2025). Furthermore, specific elements relevant to digital healthcare were considered, including revenue models such as reimbursement and the medical device strategy. In addition to content, the presentation itself was assessed: the pitch needed to follow a coherent narrative and be delivered in a persuasive and engaging manner. The visual design of the pitch deck was also considered as part of the overall evaluation.

The analysis of the pitch decks showed that the teams were able to generate viable business models, containing the typical elements of pitch decks just mentioned.

The seminar itself was evaluated through the standard seminar evaluation questionnaire of the KIT. Within this questionnaire, Likert-scaled questions are used to assess the seminar. The results from the three evaluation rounds are described below. The questions most relevant for this work from the KIT evaluation questionnaire

are shown below in Figure 2 for a sample of 58 participants. Some participants omitted responding to all questions. Participants provided feedback on aspects such as learning outcomes, course structure, clarity of objectives, presentation feedback, instructional support, and discussion opportunities. The mean ratings ranged from 1.98 to 2.44, indicating consistently positive responses across items, especially for the overall course rating. Standard deviations ranged from 0.71 to 1.04, reflecting moderate dispersion in participant responses. The results are visualized using horizontal reference lines and error bars to represent mean scores and standard deviations.

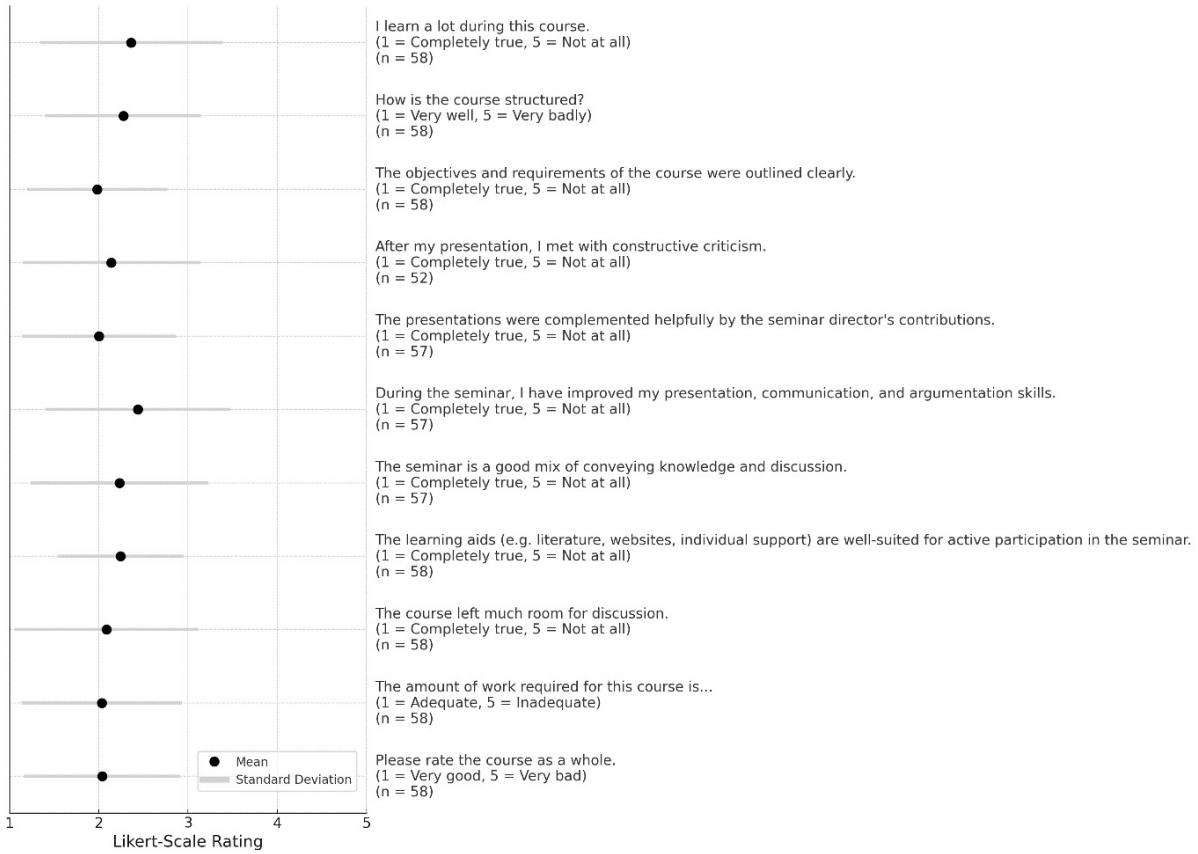

Figure 2: Results from the Karlsruhe Institute of Technology seminar evaluation questionnaire

4. Discussion

4.1 Key Findings

Based on the data collected, a key finding was that both the pitch decks and the business plans were of high quality. Several factors may explain this outcome. First, the seminar provided students with a strong foundation for developing their business models. Second, the students participated in a dedicated pitch training session before the final presentations. In this session, they practiced their pitches in front of the facilitators and received targeted feedback.

To continue, the evaluation of the seminar showed that its design is effective in preparing students to potentially become SaMD founders. Students reported that they acquired substantial knowledge and particularly appreciated the constructive feedback provided by the facilitators. Accordingly, the seminar design offers a transferable model for facilitators in this field, supported by its proven success in multiple prior implementations.

The action-based learning approach proved to be effective and was highly appreciated by the students. Applying newly acquired theoretical knowledge immediately in team settings was perceived as both efficient and engaging. To support this, theoretical inputs were deliberately kept short to maintain students' attention, allowing more time for group work, discussions, and questions. In the subsequent student presentations, the content was directly linked to their practical work, making the discussed topics more tangible and easier to understand.

For the last two seminar rounds, the final pitch took place at the facilities of a health insurer, which also had a representative on the jury. In addition to the students and the jury, the event was open to external guests, creating a broader and more diverse audience. This setting gave the final pitch the character of a professional event, with refreshments and a realistic presentation environment. The format has proven effective, as students tend to take the situation more seriously, and the involvement of a health insurer in the jury adds a layer of authenticity through relevant and practical questions.

4.2 Theoretical and Practical Contributions

From a theoretical perspective, this work contributes to the field of entrepreneurship education within the context of technology entrepreneurship. We demonstrate that it is feasible to design a university seminar on a complex topic, which is the development of business models for SaMD in the EU context. In doing so, we expand existing knowledge by identifying key elements that such a seminar should include. These include effectively integrating often underestimated but highly relevant aspects of entrepreneurship, such as regulatory requirements and diverse revenue models. Practically, the seminar could serve as a blueprint for other seminars in the domain of digital health entrepreneurship, as well as other technology entrepreneurship seminars that are highly regulated and have multiple stakeholders.

4.3 Limitations

This work is not without limitations. One limitation is that we report on a case study in which we are facilitators. This can induce potential bias. We tried to reduce this bias by collecting sufficient data regarding the pitch decks and from students themselves. Furthermore, we discussed potential biases within the team and followed the case study methodology of Yin (2009) to reduce biases further. Additionally, the data reported within this study do not enable the study of group differences between the three seminars.

4.4 Next Steps

Next steps for this work could be to run an additional round of this seminar to gather additional data, or to even let external experts rate the pitch decks to gather more objective data. Lastly, the transition from problem description to ideation was sometimes perceived as too abrupt by seminar participants. In future iterations, dedicating more time to preselecting and refining need statements could help, although this remains challenging given the seminar's six-session format.

5. Conclusion

This study demonstrates that a university seminar can be effectively designed to foster understanding of the key aspects relevant for developing a business model for a SaMD. By combining action-based learning, interdisciplinary teamwork, and structured content grounded in the Biodesign process, students were able to gain entrepreneurial competencies, digital health knowledge, and essential soft skills. The seminar outcomes, including high-quality pitch decks and positive student evaluations, support the proposition that such a course structure is both effective and reproducible. The findings contribute to both theory and practice by offering a blueprint for entrepreneurship education in regulated and complex fields such as SaMD and digital health.

Ethics Declaration

The research was conducted in accordance with relevant ethics guidelines of the Karlsruhe Institute of Technology, and it was exempt from human participant ethics review.

AI Declaration

The authors used the generative artificial intelligence tool ChatGPT with GPT-4 for spelling, grammar, and style improvements.

References

Arantes, F.P., Caetano, M., De Paula, V.A.F. and Freitag, M.S.B. (2019) "New independent technology-based firms: differences from other NTBFs and future research agenda for technology innovation management", *International Journal of Entrepreneurship and Innovation Management*, Vol. 23, No. 1, pp. 1–23.

Bailetti, T. (2012) "Technology Entrepreneurship: Overview, Definition, and Distinctive Aspects", *Technology Innovation Management Review*, Vol. 2, No. 2, February, pp 5–12.

EXIST (n.d.) "EXIST-Gründerstipendium – Downloads", [online], EXIST – Existenzgründungen aus der Wissenschaft, available at: https://exist.de/downloads/#exist-gruendungsstependium (accessed 23 May 2025).

Ferguson, R. and Olofsson, C. (2004) "Science Parks and the Development of NTBFs—Location, Survival and Growth", *The Journal of Technology Transfer*, Vol 29, No. 1, pp 5–17.

Fuerch, J.H., Wang, P., Van Wert, R. and Denend, L. (2021) "Turning Practicing Surgeons Into Health Technology Innovators: Outcomes From the Stanford Biodesign Faculty Fellowship", *Surgical Innovation*, Vol. 28, No. 1, pp 134–143.

Greven, A., Rasche, P., Droege, C. and Mertens, A. (2020) "Digital Health Engineering and Entrepreneurial Innovation – Education for the Development of ICT for Older Adults", In: *HCI International 2020 – Late Breaking Papers: Digital Human Modeling and Health, Safety, Ergonomics and Risk Management*, Springer, Cham, pp 400–415.

International Medical Device Regulators Forum, (2014) "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations, [online], International Medical Device Regulators Forum, https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf

Kulkov, I., Ivanova-Gongne, M., Bertello, A., Makkonen, H., Kulkova, J., Rohrbeck, R. and Ferraris, A. (2023) "Technology Entrepreneurship in Healthcare: Challenges and Opportunities for Value Creation", *Journal of Innovation & Knowledge*, Vol 8, No. 2, Article 100365.

McCarthy, P.X., Gong, X., Braesemann, F., Stephany, F., Rizoiu, M.-A., Kern, M.L. (2023) "The Impact of Founder Personalities on Startup Success", *Scientific Reports*, Vol. 13, Article 17200.

Osterwalder, A., Pigneur, Y., Bernarda, G. and Smith, A. (2014) *Value Proposition Design: How to Create Products and Services Customers Want*, John Wiley & Sons, Hoboken, NJ, USA.

Presse, A. and Terzidis, O. (2018) *Technology Entrepreneurship*, Springer International Publishing, Cham.

Revans, R.W. (1957), "The Contribution of University to Management Education", Reprinted in *The Origins and Growth of Action Learning* (1982), Chartwell-Bratt: Broomely.

Stagars, M. (2014) "University Startups and Spin-Offs: Guide for Entrepreneurs in Academia", Apress, Berkeley, CA.

Suryavanshi, T., Lambert, S., Lal, S., Chin, A. and Chan, T.M. (2020) "Entrepreneurship and Innovation in Health Sciences Education: A Scoping Review", *Medical Science Educator*, Vol. 30, No. 4, pp 1797–1809.

Ulwick, A.W. (2016) *Jobs to Be Done: Theory to Practice*, IDEA BITE PRESS, San Francisco.

WHO (2019) "Recommendations on Digital Interventions for Health System Strengthening", [online], World Health Organization, https://www.who.int/publications/i/item/9789241550505

Wulfovich, S. (2020) *Digital Health Entrepreneurship*, Springer International Publishing AG, Cham.

Yin, R.K. (2009) *Case Study Research: Design and Methods*, 4th Edition, Sage Publications, Thousand Oaks, CA.

Yock, P., Zenios, S., Makower, J. et al. (2015) *Biodesign: The Process of Innovating Medical Technologies*, 2nd Edition, Cambridge University Press, Cambridge.

Yock, P.G., Brinton, T.J. and Zenios, S.A. (2011) "Teaching Biomedical Technology Innovation as a Discipline", *Science Translational Medicine*, Vol. 3, No. 92, Article 92cm18.