

BIODESIGNING WITH EUROPEAN UNDERGRADUATES: ADAPTATION, TRADE-OFFS, AND OUTCOMES

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ABSTRACT

Biomedical engineering innovation and entrepreneurship education poses challenges that are not addressed in general entrepreneurship education courses or even in technology-based entrepreneurship education programs. We have adapted the Stanford Biodesign Program to be included in the Bioengineering Master's program running at the Faculty of Engineering of the University of Porto (FEUP). As part of the curriculum, we offer a one-semester, medical device-specific innovation and entrepreneurship course in which students work with technologies under development at the university. Our work shows how it is possible to adapt an American postgraduate course to a European undergraduate setting, involving both researchers and students. We present the course evolution from our original proposal to an elective, and then to a core course in the Master's curriculum. We also address the process of directly sourcing technologies from researchers, major challenges faced in the course design and administration, and the students' view on the course.

Introduction

Technology commercialization and technology-based entrepreneurship are essential processes in bringing innovations to the market (Shane 2004). The innovation process requires highly qualified skills, not only technological, but also in commercialization and product development under high uncertainty. These skills are clearly related to the entrepreneurship process, which involves the recognition of an entrepreneurial opportunity, together with the development of an idea for how to pursue that opportunity, the evaluation of its feasibility, the development of the product or service that will be provided to customers, assembly of human and financial resources, organizational design, and the pursuit of customers (Shane, Locke, and Collins 2003).

In 2008, the European Commission report "Entrepreneurship in Higher Education, Specially in Non-business Studies" concluded that "the teaching of entrepreneurship is not yet sufficiently integrated in higher education institutions' curricula" and that very few of the existing entrepreneurship education efforts engage engineering and science students. Moreover, there is a clear need for engineers to develop entrepreneurial skills such as opportunity identification, understanding of market forces and business models, and commercialization of new technologies (SEFI and BEST 2012). The biomedical and biotechnology industries are highly technological, and highly dependent on innovations and on their market exploitation. Therefore, it is important to train students on how to bring biomedical and biotechnological innovations to the market.



There is an ample body of literature in entrepreneurship education (EE), with several papers being currently published on this subject (Fayolle 2013; Rideout and Gray 2013). This body of literature shows that there is no consensus on how to teach entrepreneurship or what the effects of the different teaching methods are. Despite the lack of supporting theory and methodologies in EE, entrepreneurship theory suggests the exposure to enacting experiences as a way to improve entrepreneurial behaviors (Baker and Nelson 2005; Barr et al. 2009; Vanevenhoven 2013). Enacting experiences are *quasi* real-world experiences, in which students work on real problems and real solutions, with short-term deliverables that require rapid iteration. They increase self-efficacy (Bandura 1977) that allows students to develop not only their skills, but the confidence with which they face similar challenges in the future.

For several years we had been teaching COHiTEC, a European adaptation of a technology-based entrepreneurship education (TEE) program called TEC (Barr et al. 2009). This program is grounded in the idea that effective entrepreneurship education must be based on real-world experiences. COHiTEC is a four-month version of TEC, which lasts three semesters. We had experience with medical and pharmaceutical technologies, and understood the specificities of these areas. As do others (Crispeels et al. 2008), we agreed that “one size does not fit all,” as biomedical technologies were very different from other technologies (e.g., the construction industry).

Following this principle, the book *Biodesign: The Process of Innovating Medical Technologies* (Zenios, Makower, and Yock 2010) provides a specific textbook to support courses on the introduction of biomedical innovations to the market. This textbook contrasts with other support materials in the area. It provides medical device-specific guidance on the process of needs-finding and screening, concept generation and

selection, and development strategy and planning. It addresses other critical issues such as intellectual property, regulatory, and reimbursement strategies.

The Bioengineering Master at FEUP was launched in 2006 and aims at preparing students to approach, in a multidisciplinary way, biomedicine and industrial biotechnology problems. This integrated master (a five-year course, integrating both B.Sc. and M.Sc. levels) offers three different specializations (Biological Engineering, Biomedical Engineering, and Molecular Biotechnology) after a common branch of two years. In view of SEFI and BEST’s recommendations (2012), we proposed the introduction of an elective course for the fifth year, teaching innovation management and entrepreneurship skills to students in the Biomedical Engineering specialization. Our starting points were the TEC methodology (Barr et al. 2009), which we had been using in the context of COHiTEC, and the syllabi of Stanford University Biodesign Program/Biodesign Innovation courses.

We start by presenting course contents and deliverables. Then, we will discuss the advantages and disadvantages of directly sourcing technologies from researchers, and reflect on the value of the course for the students.

Stanford University Biodesign Program

The Biodesign Program started in 2001, with the mission of helping to train leaders in biomedical technology innovation (Brinton et al. 2013; Zenios, Makower, and Yock 2010). It is offered at a post-graduate level to a diverse audience that includes engineers and physicians who will eventually hold Master’s or PhD degrees (the Program Fellows). The program lasts ten months and a different clinical focus is defined each year.

The program starts with a one-month boot

camp, comprising an initial exposure to the chosen clinical area and lectures on clinical practice and research, as well as engineering and business fundamentals for medical technology innovation.

After the boot camp, the needs identification process starts. It is set in three distinct steps over a period of four months:

- needs gathering and validation in a clinical setting and need statements generation;
- needs filtering, supporting the decision of which needs to focus on, by collecting clinical context information (e.g., disease incidence) and market information (e.g., current and emerging treatments and related costs/benefits); and
- needs specification, bringing together all the relevant aspects of the opportunity that must be addressed by the ultimate product, considering all the stakeholders (e.g., physicians, nurses, patients, providers).

The selected top 12-16 needs then move into a concept creation phase. It consists of designing a solution, establishing intellectual property, reimbursement, and regulatory pathways, addressing technical feasibility concerns, and defining the business model. One final product concept is selected, and the implementation phase begins. Implementation includes a detailed analysis of key areas such as the intellectual property landscape, the regulatory pathway, technical issues, business model specifics, and funding potential.

The Program Fellows also lecture in Biodesign Innovation, a course for graduate students. In Biodesign Innovation, students work on the needs developed throughout concept creation, but not through implementation. Similar to the program, students explore the selected need, brainstorm product concepts, assess clinical and market potential, plan for implementation, and define patent and regulatory strategies, developing either business plans or a detailed licensing plan.

The outcomes of the Biodesign Program and Innovation courses have been assessed in the context of the career trajectories of fellows and students, invention output, and regulatory clearance (Brinton et al. 2013).

Innovation and Entrepreneurship in Biomedical Engineering at FEUP (IEB)

In light of its contents and specific focus on the biomedical field, we used the Biodesign Innovation course as a starting point to design a course to be offered from 2011/12 onwards to the fifth-year students of the Biomedical Engineering specialization of the Integrated Master in Bioengineering at FEUP.

A major challenge in the adaptation of the Biodesign Innovation course is the lack of opportunity for a clinical immersion where students could conduct observations in a clinical setting. Based on our previous experience in technology commercialization in different areas, developing technologies into products and drafting business plans, we felt it would be feasible to overcome this challenge by sourcing technologies under development at the University of Porto.

After performing a thorough characterization of the technology, it is possible to understand what unmet clinical needs it could address. From then on, students can start working on needs identification and filtering, developing need statements, characterizing the disease, identifying current and emerging treatments, ascertaining stakeholders, and evaluating the market.

With a clear sense of the need statement, students then engage in product concept design, considering issues such as intellectual property, regulation, and business models. In the Biodesign Program, we would be prepared for prototyping. However, as our course is just one semester long (lectures and in-class activities last four months), we do not have the time to carry out this stage, so we replace it

by developing prototyping roadmaps with detailed bills-of-materials, activities, and milestones. By the end of the course, the students present a business plan. A summary of the differences between inputs, contents, and outputs of Biodesign Innovation and IEB can be found in Table 1.

Table 1. Comparison of inputs, contents, and outputs between Biodesign Innovation and IEB.

	BIODESIGN INNOVATION	IEB
INITIAL INPUTS	Clinical needs	Technologies under development
CONTENTS	Needs validation	
	Concept development	
	Business model analysis	
	Intellectual property and regulatory issues	
	Prototyping	Implementation planning
OUTPUTS	Business plan/licensing plan	Business plan

It was our goal to have students not only understood the process, but also have training in entrepreneurial skills such as opportunity recognition and exploitation (e.g., through interviews with potential customers/users of the conceptualized product). The TEC methodology (Barr et al. 2009), that we have been using through COHiTEC has notions of self-efficacy (Bandura 1977) and entrepreneurial bricolage (Baker and Nelson 2005) deeply embedded. Individuals develop skills by repeatedly being exposed to real and complex problems, and iterating on their solution. In order to provide this aspect of the training, students have weekly deliverables, supported by worksheets. The full set and main contents of each worksheet can be found in Table 2.

To find the information required for each deliverable and worksheet, students look for secondhand information in reports, articles, textbooks, and databases, but are also encouraged to engage with users, patients, or other relevant stakeholders (e.g., hospital logistics managers or insurance company executives). Students obtain feedback on the worksheets from the faculty by the middle of the week, so they can iterate for the next class. Moreover, when students find significant information that affects past data in previous worksheets, they update them to reflect the most current information.

To design these worksheets, we used mainly biodesign innovation concepts, which we complemented with some more generic innovation frameworks and tools, such as Geoffrey Moore's Elevator Test (1991), and the Business Model Canvas (Osterwalder, Pigneur, and Clark 2010). The Business Model Canvas was used not only to support the definition of the business model itself but, in particular, to understand the impact of intellectual property and regulatory issues, and the need for them to be incorporated in the business model.

Table 2. Worksheets used in IEB

WORKSHEET NAME	MAIN CONTENTS
PROJECT DESCRIPTION	Technology description, including technology advantage and possible areas of application.
NEED STATEMENT	Problem and need statement, need criteria, need classification.
DISEASE STATE FUNDAMENTALS	Includes, among others, pathophysiology, clinical presentation and outcomes, economic impact.
TREATMENT OPTIONS	Clinical, economic, and utilization profile of current treatments, emerging treatments.
STAKEHOLDER ANALYSIS	Cycle of care, flow of money, stakeholders, and trade-offs.
MARKET ANALYSIS	Market segmentation and quantification (top-down and bottom-up), Porter's Five Forces, and SWOT analysis of competitors.
PRODUCT CONCEPT	Value proposition, requirements, and features (physical, performance, approvals, etc.).
BUSINESS MODEL	Business Model Canvas.
PATENT LANDSCAPE	Main patents in the area of the product concept, and how they affected freedom-to-operate.

So far, in the two editions of IEB, 62 students have participated in the course, working on 11 technologies provided by 9 researchers, from multiple research units affiliated with the University of Porto (in different areas such as new biomaterials for neural regeneration or cancer detection, new microbiology in vitro diagnostics kits, bioelectric signal processing for vital signs or stent placement monitoring, or image processing and pattern recognition as aids for imaging or surgical planning). In the first year, the course was offered as an elective for Biomedical Engineering students, and was assigned 5 ECTS (European Credit Transfer and Accumulation System) (European Commission 2013), corresponding to 42 hours of contact and 135 hours of work in total. In the current year (the second edition), it is being offered as a core course to Biomedical Engineering and Molecular Biotechnology students. However, it has been assigned only 3 ECTS, with 42 hours of contact and 81 hours of work in total. This reduction led us to replace the final deliverable with a less ambitious “Business Project” – a business model for commercial exploitation, which includes intellectual property and regulatory issues.

Technology Sourcing

In technology commercialization education programs, the local Technology Transfer Office (Thursby 2005; Barr et al. 2009; Wright et al. 2009) or the participant researchers themselves (Kington, Baker, and Debo 2010) are the most common sources of technologies. While these sources work quite well in general technology entrepreneurship education, the same may not apply in very specific programs such as IEB.

The main difficulty with sourcing technologies from the local TTO is the fact that it has a broad patent portfolio, covering a wide variety of areas. Having analyzed local patents, they tended to be either old or more centered in the pharmaceutical and biotechnology areas. Furthermore, the dynamic nature of the course requires a close interaction with the researcher (the owner of the technology), and it was unclear whether or not such interaction could be achieved by sourcing the technology from the TTO.

Therefore, another alternative was to source technologies directly from researchers actively working in the medical devices area. Having a diverse network across the University of Porto, we put out a “call for technologies” directed



at researchers affiliated with the medical school, the engineering school (FEUP), and biomedical research institutes. We then set up meetings with the researchers who applied, with three main goals: understanding what the technology did, its uniqueness and its stage of development; providing a detailed explanation of the work to be developed in IEB, and its main deliverables and outcomes; and explaining what kind of involvement was expected from the researcher.

In both course iterations so far, the number of technologies have exceeded the number of student teams, meaning that the teams have had some leeway in choosing the technology that they wanted to work with.

During the course, the researcher is expected to provide support in technology-related areas, such as explaining the uniqueness of the technology, clarifying what it does and does not do, suggesting technology applications, and validating the technical feasibility of the product concepts. The benefits for the researcher are immediate: a business plan that includes an early market analysis of the products derived from the technology under development, including intellectual property and regulatory strategy, as well as a go-to-market roadmap. Usually, researchers have their own opinion on possible products to be derived from the technology, and they may either have a loose sense of ownership of product design and are willing to tailor the product, or have a very strong opinion on what the product should be.

After selecting the technology, students go through the previously presented process, having multiple interactions with the researcher during the course. As students are encouraged to contact potential product users and stakeholders involved in the cycle of care, they are often confronted with a view about the product different from (and sometimes opposite to) the one that was originally presented by the researcher. It is

important to understand that students tend to emphasize these opinions more than the opinions that confirm the original views. We have observed two kinds of student behavior in these situations: they either challenge the researcher into adapting their original view on the product, or they do not. The final product concept can be different from the initial one, according to the researcher's attitude toward product concepts. The product concept can thus be classified in four distinct categories, according to the behaviors of the students and the researchers (Figure 1):

- **Students challenge the researcher with new information; furthermore, the researcher is willing to discuss it.** The final product concept is quite distinct from the original one in terms of features and/or target market. It is a **“distinct”** product concept.
- **Students challenge the researcher with new information; however, the researcher is not willing to discuss it.** A conflict appears, as the researcher is not willing to give up or adapt his original idea. Students feel frustrated, as the researcher does not recognize their work. This situation is closely related to the “I’m Smart and You Are Not” researcher attitude previously identified by Kingon et al. (2010). Once the conflict is foreseen, faculty step in to mediate it and keep it to a minimum, seeking to bridge the students’ information and the researcher’s view. If a consensus is not possible, students can integrate market data into the product concept. The final product concept is near the original one in terms of features, considering non-technical characteristics (such as regulatory issues) derived from the target market. In light of a compromise that must be reached in order for the work to continue, we call it an **“agreed”** product concept.
- **Students do not challenge the researcher with new information; furthermore, the researcher is not willing to discuss it.** When students feel that the researcher is not willing to accept new and opposing

information (e.g., the researcher may be very assertive when expressing opinions), and they want to avoid conflict, they do not challenge the researcher with new information. Students only pass on information they feel is in line with what the researcher is expecting. Therefore, the final product concept closely resembles the initial one, as it does not go through iterations that may challenge the researcher’s view. It is an **“upgraded”** product concept.

- **Students do not challenge the researcher with new information; however, the researcher is willing to discuss it.** We have never observed this case. Considering all other outcomes, in this case, the final product concept would be similar to the initial one (as there are no external inputs), so we would be facing a **“stale”** product concept. Nevertheless, this case could quickly evolve to a “distinct” product concept, if students were to challenge the researcher with new, relevant information.

		Researcher willingness to discuss new information	
		Low	High
Students challenging researcher with new information	Yes	Agreed product concept	Distinct product concept
	No	Upgraded product concept	Stale product concept

Figure 1. The product concept evolution matrix according to the researcher and students’ attitudes towards receiving and giving new information.

It is important to stress that IEB is one of the few courses during students’ education that is not aimed at developing hard skills. Moreover, IEB challenges them to think differently and to go beyond what the researchers think. In many cases, the researchers have been their teachers and/or are current thesis supervisors. Therefore, we believe that, when students do not challenge the researcher with new information, they do it in part because they are not used to challenging their teachers (even if there is sound evidence) and they want to please the researchers.

Main Challenges in the Adaptation

The context of the course administration is quite different from the original one. Geographically speaking, while Stanford University is near several medical device companies’ headquarters, in Porto there is a lack of medical device companies nearby. Although this is not representative of all the industry, in December 2013, only three companies producing medical devices in the district of Porto were affiliated with the national healthcare cluster (Health Cluster Portugal 2013). This significant absence of nearby contacts impacts the access to executives with the required business and market expertise. Therefore, when students are working in business related areas (e.g., industry landscape or business models) it can be hard to find contacts to address specific questions. As the medical device industry spans a huge diversity of different technological fields (e.g., electronics, material science, or textiles), this is even more dramatic, as one company working in medical textiles may not be an interesting contact when students are working on in vitro diagnostics. We seek to address this challenge by engaging with medical devices distributors and making contacts at both the national and international levels.

Culturally, it is important to understand that meeting with students or scientists to talk about clinical needs, product design, or marketing strategies is not on top of the agenda of physicians and business executives. There is also a lack of specialized venture capitalists and business angels, who are able to understand which business models are viable. To address this difficulty, we have extensively used our own network to set up meetings between experts and students,



facilitating introductions. We also encourage students to leverage online technologies, contacting relevant companies through their websites and/or cold calling their R&D, product development, and business development departments.

Despite the low industry density, and the difficulties in contacting clinical experts and business executives, we have succeeded so far in being able to assure real-world feedback for the work carried out in IEB.

The course contents have also required some important adaptations. For instance, intellectual property law, medical devices regulation, and reimbursement in Europe differ from the US. However, the content related to the US is kept, as it is a very important market for medical device technologies. The European basics are added so that students understand the strategic and operational implications of the differences.

The Students' View

During the course, we collect feedback from the students in a very informal manner. As there are weekly meetings, we can see the progress of the students, but they also comment on the course process. A major comment that continues throughout the entire course is that it is “too much work” for the level of ECTS assigned. However, this is not easy to reconcile with the fact that working in teams of five or six students means, for 3 ECTS, a weekly dedication to IEB of 12.5-15.0 hours (excluding the lecture time), which matches the level of work that we have observed.

At the end of each semester, FEUP carries out pedagogical surveys. From the 23 students in the first iteration, 10 answered the survey (a 43% response rate). Globally, the course was rated 6.80 in a scale of 1 to 7, with a standard deviation of 0.42. The students also have the opportunity to provide written comments in this survey. Only two respondents wrote

comments, both mentioning the workload and the pertinence of the course for their professional lives. We plan to carry out a more detailed and longitudinal evaluation of the course's impact in the future.

Conclusion

This work shows how it is possible to adapt a specific innovation education program to a culturally different setting, dealing with time constraints and cultural differences, while maintaining its core and focus. The worksheets introduced set clear goals for the next session, keeping students focused on the process and in their learning, and successfully incorporating enacting experiences into IEB. This enabled students to develop effectual and causal behaviors (Sarasvathy 2008), as well as entrepreneurial bricolage skills (Baker and Nelson 2005).

The adaptation process removed the clinical immersion step of the Biodesign Innovation Program, which was replaced by the sourcing of technologies under development at the university. By working with a real technology, we make sure that the learning is as close as possible to a real-world situation. However, as explained, this also has drawbacks, often due to the students' young age and a certain underdeveloped critical thinking. In terms of the interaction with researchers, we see similar situations to those described by Kingon et al. (2010), but we also add some new ones. Our findings suggest that practitioners should identify, as early as possible, the different attitudes, both from researchers and students, as they can promote or hinder the student's progress and learning. During the course, mitigation strategies such as further involvement of the researcher could lead to a more open attitude and progress on product concepts. On the other hand, it may be impossible to do so, and a distancing of the researcher should be considered, protecting the student team and their learning. Other strategies can be implemented before the course starts, such as selecting technologies

that are not yet “productized,” and are farther away from commercialization. The impact of technology maturity on the learning process is clearly a research opportunity in TEE, as there is a lack of studies on this subject.

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