

## REVIEW ARTICLE

# Educating Scientists in Translational and Entrepreneurial Medicine: Unmet Needs and Challenges

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**Abstract:** Translational medicine is a complex and multidisciplinary network of activities that requires a large number of different competencies. There is a high demand of people with the necessary skills to successfully coordinate these processes. These skills range from understanding scientific and regulatory processes to intellectual property and entrepreneurial related aspects.

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While it has become clear that new programs are needed to educate such specialists, not many programs addressing this demand are currently being offered.

In this review, we will discuss the need for translational and entrepreneurial medicine and its challenges, the importance of educating people with very unique skills to embrace these challenges and discuss available educational programs in translational medicine in terms of their curriculum, but also pedagogical concepts. Finally, we will present a new program in translational and entrepreneurial medicine, which we are developing at the newly created Swiss Institute for Translational and Entrepreneurial Medicine.

**Keywords:** Translational medicine, translational research, entrepreneurship, medical translators, knowledge brokers, blended learning, digital innovation, convergence of technologies.

## 1. INTRODUCTION

Major advances in the development of new technologies and basic research have been achieved upon completion of the Human Genome Project. Already at an early stage, the NIH put much emphasis on the importance of being able to translate new findings “from the bench to the bedside” and launched in 2004 a “Roadmap”, a collection of various initiatives designed to improve the translation of research into practice. In addition, the Clinical and Translational Science Awards (CTSA) Program was initiated “to develop innovative solutions that will improve the efficiency, quality and impact of the process for turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public.” (<https://ncats.nih.gov/ctsa>).

Despite the scientific achievements and programs launched to translate these new findings “from the bench to the bedside”, however, the gap between scientific discoveries and novel treatments [2] is still significant. In fact, research

and development productivity (i.e. number of new drugs brought to market per billion US dollars of research and development spending) has actually declined over the last years, a phenomenon called Erroom’s Law[3, 4].

Consequently, in recent years, the focus has been on understanding the factors responsible for this gap, also called the “valley of death” [5, 6]

Various reasons as to why translation from findings in basic science to clinics is difficult have been discussed such as lack of understanding of translational processes within institutions, inadequately trained people, lack of interaction between groups within universities and hospitals, but also between academia and industry and a university system that rewards the success of an individual rather than successful collaborations between different groups [7].

Fudge *et al.* [7]. concluded in their study that, among others, interdisciplinary collaborations facilitate translational research practices. They were especially successful with teams with key members who could act as knowledge brokers. Similarly, Ward *et al.* [8] and Shahzad *et al.* [9] reported the importance of such knowledge brokers, or medical translators, respectively, to overcome the barriers of this complex and multidisciplinary network of activities in medical translation. An entrepreneurial attitude among scientists seems to be another facilitator of successful

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translational research [7,10,11]. Consequently, there is a clear need for universities to educate life science specialists with entrepreneurial know how, thus enabling them to manage the entire complex translational medicine continuum [1,12].

In response to this development, the Swiss Institute for Translational and Entrepreneurial Medicine (sitem-insel AG) has recently been created in Bern, Switzerland with the aim to bridge weaknesses in the translation process. It pursues three strategies to address this problem: 1) training specialists in translation (Swiss School for Translation and Entrepreneurship in Medicine) with the aim of professionalizing the process, 2) providing infrastructure and personnel (Enabling Facilities) at the interface between industry, non-clinical research departments and the university hospitals to promote cooperation, and 3) establishing Translation Promoting Services to optimize the administrative/regulatory effort along the route from laboratory bench to commercial product.

In this review, we will discuss the challenges to close the gap between basic science and development of novel treatments and the importance of training specialists with very unique interdisciplinary skills. Finally, we will present our training program in translational and entrepreneurial medicine, which has been newly created with the aim to overcome the current barriers in translational medicine.

## **2. TRANSLATIONAL AND ENTREPRENEURIAL MEDICINE**

### **2.1. What is Translational Medicine?**

The terms “translational medicine” and “translational research” have become quite fashionable in the last couple of years. The number of peer-reviewed publications in PubMed indexed by either term has increased exponentially since 2000 [13,14]. However, there is no universal definition what the term “translational” really means or implies. Following the creation of the “Roadmap” by the NIH, NIH institutes have defined the term “translation” as “the process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease”, in short a “bench to bedside” process. According to NIH translational research “includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans (T1). The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science (T2).” Others have extended this model and described translational research as a process of three [15] four [16] or even six phases [17]. Others pointed out that, while “translational research” has become a buzzword in recent years, its concept is not new and has been known earlier as “applied research” [18].

For this review, we will refer to translational medicine or translational research as a multidisciplinary network of activities relevant for the “bench to bedside” process.

### **2.2. Successful Translational Medicine**

Despite the prominent scientific achievements in the post-genomic era, research and development productivity has not improved. This widening gap between basic scientific findings and clinically relevant applications has become a cause for concern and the focus of ongoing discussions.<sup>5, 6, 15</sup> As mentioned earlier, there are many reasons for causing this “valley of death” such as lack of understanding of the whole translational process, inadequately trained people, a missing communication between key players and inadequate infrastructure to facilitate the complex interactions of key players [19]. Some have argued that an important factor is the disproportion of large investment into basic science and not enough for other activities involved in the translation process [20].

It is undisputable that changes are needed on very different levels to improve translational medicine. Communication between stakeholders in academia, industry and policy makers needs to be improved, efforts in academia and industry should be better integrated and alliances between the two partners facilitated. The awareness of basic scientists of what is really needed in practice and what risks are to be expected has to be increased [21]. Given the complex and multidisciplinary network of activities that requires a large number of different competencies teaming up is a crucial element. However, many times this may pose a problem in the academic community, where the achievements of a scientist and the chance for successful grant applications is measured by the number of publications in top-tier journals and successful grants. Thus, achievements of collaborating partners with similar levels of responsibilities are hard to evaluate with the current system. Other evaluation models to assess the quality of translational scientists in academia should be implemented.

In summary, successful translational medicine is not about scientific and clinical achievements of a small group of individuals, but about the efficient coordination and integration of educational, financial, ethical, social, regulatory and legislative and scientific activities with the ultimate goal of developing novel treatments [13].

## **3. EDUCATING PEOPLE SPECIALIZED IN TRANSLATIONAL AND ENTREPRENEURIAL MEDICINE**

### **3.1. Need for New Advanced Programs**

Shahzad *et al.* [9] suggested that key players, which they called medical translators, “involved in accelerating product research and development in the health care, biotechnology and pharma industries must have a full understanding of human medicine principles including disease progression, basic and human pharmacology, along with an in-depth knowledge of clinical trials, regulatory agencies and industrial business affairs.”

The need for new training programs teaching such skills is indisputable. Many working groups have been created to address this need and what actions should be taken [22,23]. While many companies offer already in house teaching programs, there are many reasons why universities should offer new programs

focusing on translational medicine and innovation. One reason is certainly that companies might tend to educate people specialized for a given product, while universities provide a training that goes beyond that. Also, the academic environment may be more multi-disciplinary than a company [23]. However, this implies that universities should be provided with the necessary resources for effective teaching and mentoring [22]. So far, training programs of people with the skills needed for a successful “medical translator” are typically not offered or focused on by traditional advanced degree programs [24,25].

Other crucial, but many times scarce skills among translational scientists are entrepreneurial skills [10,26,27]. Shaywitz *et al.* [1] pointed out in their review that instead of educating highly specialized scientists, clinicians or entrepreneurs, it is essential to actually develop training programs with the goal to educate life-science entrepreneurs or entrepreneurial life scientists and clinicians. There are already many Master, PhD and MBA programs being offered focusing on bioentrepreneurship [12,26-31]. In recent years, few similar programs have also been developed in Europe [26,32]. However, most programs put a strong weight on the entrepreneurial and less on the scientific, technical aspects such as quality management and regulatory affairs.

There are even less training programs available for professionals, which aim at teaching all aspects of translational medicine. While educating students at the undergraduate and graduate level in translational medicine is certainly essential to adjust for the new trends in medical product development and provide the society of a much needed new type of skilled workforce it is also important to provide opportunities for professionals who face a situation where in depth knowledge of translational medicine is required [33,34]. For instance, a life scientist may choose first a typical training in basic science, but later would like to create a start-up motivated by his or her research results.

### 3.2. Convergence of Technologies in Translational Medicine

Yock *et al.* [23] raised the question whether training programs in life science innovation should be specific for drug and medical device development. According to them there are significant overlaps, but there are also fundamental differences and universities make a mistake when combining the two fields. While we agree that there are indeed fundamental differences, which should be taken into account when developing a training program, we also think given the newest developments in technologies that it is imperative that a people working in translational medicine should have a good notion of both paths.

In fact, “the convergence of biotech, nanotech and information technology in new products will likely blur the distinctions between the traditional turfs of the biotech, device and pharmaceutical industries” [35].

This convergence poses a challenge for all players involved in the translational process. For instance, the development of new mobile apps to be used in combination with medical devices offers a huge opportunity to provide cost-effectiveness and patient empowerment [36]. However, the development of high quality, safe, effective and custom friendly medical device software is a difficult undertaking,

which comprises many processes, activities and tasks [37]. Still, most mobile apps developers lack the notion of providing safe apps to patients and providers with respect to regulatory guidelines [38]. On the other hand, many times the regulatory process lacks behind the development of new innovation. This clearly shows the need to educate people, which have a global understanding of these new innovative trends, but at the same time also a good notion of the implications on other aspects relevant in translational medicine such as regulatory processes.

## 4. A NEW PROGRAM IN TRANSLATIONAL AND ENTREPRENEURIAL MEDICINE

### 4.1. Motivation for Creating a New School

In light of the clear need to facilitate the interaction between the key players in successful translational projects and to improve the overall understanding of the key players involved, the new Swiss Institute for Translational and Entrepreneurial Medicine (sitem-insel AG, <http://www.sitem-insel.ch>) has been funded. Its strategy is based on three pillars:

- sitem Swiss School: University-level courses given by lecturers from industry and academia designed as continuing professional development for specialists.
- sitem Enabling Facilities: Specialized research and development labs and facilities for translation for joint use by industry and academia.
- sitem Promoting Services: Services for optimising the administrative and regulatory affairs from bench to commercialization.

The main objective of the school (<http://sitem.biomed.ch>) is to generate professionals who possess the necessary combination of scientific and medical knowledge and entrepreneurship skills to successfully coordinate the commercialization of biomedical technologies.

### 4.2. General Organization and Structure

The program is organized by sitem in collaboration with Health Sciences eTraining (HSeT, Lausanne, Switzerland). Upon successful completion of the curriculum a Certificate of Advanced Studies (CAS), a Diploma of Advanced Studies (DAS) or a Master of Advanced Studies (MAS) is awarded by the University of Berne.

The MAS is a two-year lasting full-time program, consisting of a master thesis focusing on a real, practical translational project (80%) and theory (20%). The master thesis is supervised and judged by a partner from a private-sector company and an academic clinician. The theoretical knowledge acquired during the 6 modules (see below) is directly and specifically applied to the Master project, according to the “learning by doing” concept. In the master thesis presented at completion of the MAS, participants are expected to present a mature project from both a translational and entrepreneurial aspect (see below).

Professionals may also choose only some specific topics—that is some selected modules—and be awarded

either a CAS or a DAS depending on how extensive the selection is.

#### 4.4. Detailed Content of the Program

The curriculum consists of prerequisites and six independent modules of various sizes.

- Prerequisites:

A collection of quizzes on basics of biopharmacy, pharmaceutical technologies, medical technologies, OMICS technologies, biostatistics and epidemiology associated with online content to review the topics that need refreshing according to each individual's needs.

- Module 1: Research and development

The module reviews basic heuristic principles related to the discovery and development of diagnostic and therapeutic biomedical products.

- Module 2: Quality management and good manufacturing practice

The focus of this module is the understanding of aspects essential to ensure that all activities linked with a translational process maintain the desired level of excellence required by the regulatory agencies.

- Module 3: Intellectual property

The different types of intellectual property and specific legal aspects for biomedical products are studied.

- Module 4: Regulatory affairs

The role of the different regulatory authorities along the translational pathway and the product specific requirements for the various items are analyzed.

- Module 5: Clinical trial design and performance

The module discusses all aspects relevant for clinical trials—that is clinical study design, trial conduct, good clinical practice, insurance and financial issues.

- Module 6: Biomedical entrepreneurship and leadership

The module focuses on various aspects of entrepreneurship such as product management, business administration, and strategies to commercialize successfully biomedical products.

For postgraduates aiming for the MAS study, the core of the program is the Master project – a project in a field of translational medicine (diagnostics, drugs or medical devices) which has to be presented and defended by the candidate to the curriculum committee prior to admission to the study. The successful candidate will be accompanied during the course of the MAS study by a referee from academia and a co-referee from the industry (or vice-versa) in order to bring his project to completion from a scientific/technical but also entrepreneurial point of view.

#### 4.3. Blended Learning as Method of Choice

##### 4.3.1. Challenges Facing Adult Students

The target students of advanced studies have clearly another profile than the traditional undergraduate or graduate

students. Most adult students face a balancing act between school and life responsibilities such as their job and family. Having time to attend classes many times poses a very big challenge. Another issue are costs. While study costs are challenging for everybody, for adult learners they pose an even bigger barrier as they are faced with limited access to student loans and other day to day costs such as mortgage, daycare. Thus, training programs for adult students should provide a flexible study plan and be cost efficient.

##### 5.3.2. Teaching Methods

With the improvement of informatics tools the use of online education has increased and many universities embrace this trend as means to increase flexibility, improve access, and reduce costs [39,40]. To which extent this really holds true is still a topic of ongoing discussions.

Miller *et al.* [41] reviewed in detail The National Center for Academic Transformation (NCAT) study reports. The various NCAT projects aimed at comparing costs and learning efficiency among students of traditional face-to-face, pure e-learning and hybrid teaching methods (i.e. blended learning). Overall, the reports suggest cost savings in essentially every case and improved student learning outcomes. However, it is imperative to note that they compared the results achieved by a redesigned e-learning/blended learning course with the results of the traditional proceeding variant of the same course. As such, these studies have not been designed to generate robust results. Unfortunately, a lack of a well-controlled study design (i.e. a design in which students are randomly assigned to the face-to-face format or the online/hybrid format) holds true for many other similar studies [42] which conclude that e-learning might be superior to traditional teaching methods.

A meta-analysis done by Means *et al.* [43] found that “on average, students in online learning conditions performed modestly better than those receiving face-to-face instruction. The advantage over face-to-face classes was significant in those studies contrasting blended learning with traditional face-to-face instruction but not in those studies contrasting purely online with face-to-face conditions.” However, they pointed out that studies using blended learning also tended to involve additional learning time, instructional resources, and course elements that encourage interactions among learners, which could introduce a confounding variable. Additional research is needed to account for these confounding variables.

Despite the challenges when comparing different teaching methods, there seems to be a trend that blended learning may have significant advantages overall compared to traditional face-to-face teaching and pure e-learning models [44]. According to Sharpe *et al.* [45], the top three advantages of blended learning for students are: “1. the flexibility of being able to complete assignments in any place/at any time; 2. the convenience of not having to come to campus as often; 3. the benefits of the online component when job responsibilities and other commitments make it difficult to attend face-to-face classes.”

One of the most important factor, if not actually the most important, in terms of assessing the different teaching methods is the learning achievement. Similar to other

factors, it is very difficult to compare the various teachings methods as there is hardly any data available from well designed and controlled studies with sufficient large sample sizes. However, a recent, well designed study, [46] which compared traditional, fully on-line and blended learning in 151 students in terms of in learning achievements, concluded that the blended learning group had the best learning achievement among the three groups.

In summary, blended learning seems to be an efficient way to account for the much called for flexibility for adult learners without jeopardizing learning achievements [47].

Consequently, we believe that for professionals this approach is ideal for our study program because of various reasons. Dealing with a group of professionals with a rather heterogeneous background (i.e. medical doctors, life scientists, engineers) having e-learning components in the program is essential that the students can follow a customized study plan. The students have enough freedom to organize their daily workload and to devote their study time where most needed according to their background.

On the other hand, having face-to-face sessions is crucial for networking with experts in the field. Moreover, personal contact may facilitate the interaction and communication between students.

The combination of e-learning and face-face sessions in our opinion is especially efficient for our program where most teachers are from the industry. For obvious reasons having only a limited number of face-to-face sessions facilitates the collaboration with lecturers from industry, but at the same time the students can profit from the specialists' expertise via the e-learning platform in a structured manner.

#### 4.4. The Three Levels of Expertise

In order to educate people with a solid knowledge of the scientific development process of a medical product, but also a strategic and entrepreneurial understanding we have defined three general learning objectives. The first objective focuses on providing the students with the necessary technical and scientific knowledge in order to achieve the second objective, i.e. being able to critically assess scientific findings at each step of the discovery and development process. Knowing how to do so eventually should enable them to achieve the third objective—that is to develop the necessary skills to take the necessary steps and decisions in the strategic planning.

#### 4. CONCLUSION

In summary, large efforts have already been undertaken to translate findings in basic science into novel treatments. However, the high expectations in the post genomic era for the development of novel treatments could not be upheld. A lack of efficient coordination of the complex and multifaceted network of activities and a lack of communication between the key players seem to be some of the most relevant reasons. Indisputably, educating people who have a profound understanding of the whole translational process will contribute to a more successful translational process.

#### CONSENT FOR PUBLICATION

Not applicable.

#### CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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