Empowering Translation of New Ideas - a Eit Health Clinmed Summer School Overview

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Abstract: Translational research training is crucial to convert academic research ideas into efficient real-life solutions. In this paper a summer school supported by EIT Health is presented. Its main goal is to integrate clinical knowledge in the development of new medical devices, from ideas to post-market approval, in the clinics. Students were immersed in clinical centres where they had close contacts and engaged discussions with clinicians and patients to identify and assimilate clinical unmet needs. From this immersive stage resulted innovative solutions that were further investigated with the support of plenary lectures and by interaction with experts of the medical field, from clinicians to Medtech company representatives. This experience proved to have a positive impact on the student's understanding of the clinical development life cycle from research findings or new ideas into medical devices.

1 INTRODUCTION

Despite the ground-breaking innovations that have been made in many clinical indications less than 5 % of all medical findings made in academia are translated into commercially available solutions, such as new medication, diagnostics or devices. And with each passing year the gap between the biomedical research and the clinical applications fields increase (Gehr and Garner, 2016). The reason for the low rate of translation comes down to the struggle to transform innovative ideas from publicly founded academic research into commercially available products manufactured by the industry (Duda et al., 2014). A medical device must be conceptually designed to satisfy a real clinical need identified by end-users in the field. Its product development must be aligned with the market expectations and be realistically designed, producing a scalable, manufactory robust, cost-effective and user-friendly product while fulfilling its intended clinical function (De Pieri et al., 2018).

While clinicians and academic researchers have their competence in identifying clinical needs and finding conceptual and technical approaches, companies have an established experience in product development, large clinical trials, regulations and manufacturing. Already at this background collaborations and

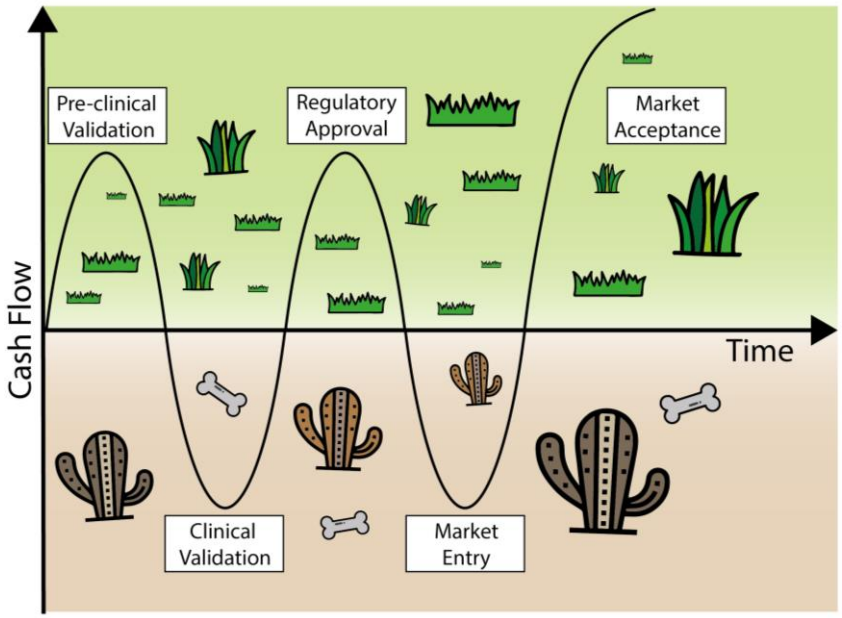

Figure 1: Valleys of death in translational research. The figure illustrates the two valleys of death that can occur during medical device new product development.

exchanges of knowledge between the private and public stakeholders seem to be reasonable and necessary to improve translation. A study from 2016 showing the relative contribution of industry, academia and private-public-partnerships in regulatory approvals of medical devices underlines this idea. With 82% of the medical devices obtaining approval after clinical trials, the majority were developed by the industry. However, the importance of collaborations between academia and industry showed to be relevant since they had a better regulatory approval rate (13%) than the devices developed by academia alone (5%) (Marcus et al., 2016).

During the commercial development of a medical device it is common to reach a stage referred to as 'valley of death' at an early point when the idea begins to be translated into potential clinical solutions (Figure 1). The main hurdle to overcome at that point is the lack of financial resources, mainly for very innovative projects (Farragher et al., 2015). A second valley of death may come after pre-clinical and clinical validation of the product and the completion of the regulatory approval process. This second valley comes from the difficulty to gain market acceptance and reimbursement and it is the main cause for the failure of 42% of start-ups in the medical devices area. To overcome both valleys of death is it crucial to precisely define the unmet need and to pave out a clear path to both clinical acceptance and reimbursement (Murphy and Edwards, 2003). Therefore, paying a great attention to unmet clinical needs and the product usability and acceptance from the very early stages improves the chances of success and allows for a reorientation of product development early if needed. Nowadays there is an increased difficulty to develop an innovative solution due to an increased number of regulations and the fact that complex solutions require more and more sophisticated technology and knowledge.

New translational research programs have been created in the last decade with the goal to educate scientist and clinicians on product development and how to make their research attractive to warrant further development and commercialization (Gehr and Garner, 2016). In the US several project-oriented educational programs have emerged inside the universities to install entrepreneurship in academia, an understanding of drug development in industry and project-management skills. In one of these educational programs, SPARK-Stanford, the success rate is high with more than 55% of projects/year being licensed, entering the clinic or becoming commercialized (Gehr and Garner, 2016).

In the EU similar programs, educational curriculums and summer schools have been developed. European Institute of Innovation & Technology (EIT) Health is responsible for innovative collaborations between research, education and industry with over 140 partners. EIT Health has supported 122 start-ups that have attracted €27.9M in investment, has trained over 8 thousand

graduates, professionals and executives and has launched 10 products or services on the market. It is based in three program areas. Accelerator supports innovation and business, Campus was designed for education and Innovation Projects is to build new ideas and collaborations.

The European regulation 2017/745 imposes the obligation to produce clinical data for the CE marking of any type of medical device. But during the year 2016, more than 13,000 new medical devices were registered with the CE marking, while only 1,600 clinical studies were registered on a medical device in Europe. In 95% of the cases, European medical device companies are SMEs and start-ups. They lack the skills and resources to respond to this increased regulation. Filling this gap is an integral part of the EIT Health core mission.

ClinMed summer school is a project developed with support of EIT Health to address the gaps previously presented regarding the need for translational research program derived from the heavier regulation imposed on medical devices development in the present time.

2 METHODOLOGY

2.1 The genesis of the summer school

To maintain the competitiveness of European medical device companies, the challenge of this summer school is to strengthen internal skills of companies and/or to recruit knowledgeable staff on the clinical evaluation. A needs analysis focusing on the market of Medical Devices and e-Health applications was performed at European level during the FP7 European ITECH project (2014-2016) co-lead by INSERM CIC-IT network. The ITECH project describes the process of going from research to market; identifying the gaps and barriers existing at all stages. The summer school benefits from results and recommendations of the ITECH project; specifically, to quickly reinforce clinical study capacities and Human Factors Engineering.

Within the Tech4Health network of F-CRIN (the French branch of European Clinical Research Infrastructure Network) French partners of this proposal have organized 3 annual training sessions (2015, 2016 and 2017) on "Specificities of clinical research for medical devices". Two-days training courses were designed for academics, hospital staff and industrials. But these short courses unfortunately didn't trigger the opportunity to set up formal collaborative projects.

ClinMed is a summer school of EIT Health co-organized by public and private partners: INSERM (Public, France), Karolinska Institutet (Public, Sweden), University of Grenoble-Alpes (Public, France), University of Lisbon (Public, Portugal), Medtronics (Private, Ireland), Becton Dickinson (Private, France) and Madopa (Private, France). The great variety of clinicians, academics and industry representation from start-up and large companies is a unique aspect to the ClinMed summer school. It was intentional from the part of the committee to make sure the participants had interactions and knowledge from all players of the medical device sector.

This summer school is extending these initiatives with an action-based training and the use of innovative educational methods, tools and pedagogies such as experiential learning, co-design and teamwork based on mixed-skills. EIT Health would give credibility and open up this international training, especially for all European stakeholders.

The ClinMed summer school aims to train participants on the technological innovation in health care by providing a global vision of the maturation cycle of a medical device, i.e. from the idea to the market, using the concept of experiential learning.

As declared by the operational committee, the summer school was organized "to identify new challenges on unmet needs, to co-design new solutions and to implement realistic and feasible projects to solve important health problems".

The link to other CAMPUS activities is bi-directional: the ClinMed project can benefit from the Innovation and Accelerator EIT Health pillars, and those pillars can also take advantage of the summer school. More particularly, projects arising from the summer school can be implemented either in the VALIDATE EIT Health program if the project is already well defined, or within the Innovation Journey program for innovative ideas that have emerged from the summer school. The participants of ClinMed also have the possibility to register in the EIT Health Alumni network, which connects alumni from the different EIT Health programs of Campus, Accelerator and Innovation projects with one another, partners and entrepreneurs.

2.2 The pedagogical logic adopted and main goals

ClinMed summer school was based on the pedagogical concepts of experiential learning (Kolb, 1984), design thinking (Plattner, 2011) and competency-based approach (Frank, 2010); concrete ideas of innovative products from a first observation

was developed by teams through workshops with the contribution of coaches and experts. It begun with an unprecedented immersive experience in a healthcare service: subgroups of participants were invited to have a fresh look, to identify problems, and needs that innovative solutions could meet and later share their ideas within the clinical setting, through meetings with healthcare professionals and patients, and direct observations.

The aim is twofold. The first one is to provide multiple knowledge and skills necessary to develop a new medical device into the market by giving lectures in several thematic sessions. The second one is to allow the different teams of participants to confront their ideas and discuss problems with the clinicians and potential users, to work on a project using the knowledge acquired during the lectures and to carry the project towards EIT Accelerator or within the INSERM structures that supervise this school. Another unique aspect of ClinMed summer school was to communicate not only theoretical information, but also practical accompaniment from the lecturers after their session. The lecturers were encouraged to go through the teams and give advice on the development of their specific product. Moreover, the teams benefitted from regular meetings with the coach belonging to the immersive site.

The participants are supposed to learn, at the end of the program, how to assess the clinical and market need for the development of a new medical device; understand the rules for protection and property; know how to find the adequate regulations; define a development plan; recognize the state of the art, understand the objectives and methods of usability studies, clinical investigations and post-marketing follow-up studies and work in a multidisciplinary team.

2.3 Summer school organization

The ClinMed summer school was organized between the 21st and the 31st of August 2018. The attendees were divided in team of 4 to 6 participants and hosted for 3-day in a hospital or living lab where they interacted with healthcare professionals and patients in order to understand unmet needs in a specific field that requires technological innovation. Afterwards, all the participants gathered at the main site of the summer school, located in Villard de Lans, a village located in the French Alps near Grenoble (France), to develop the projects through lectures and coaching from professionals in academic and industrial sectors.

2.3.1 Online session

Students were invited to attend courses offered on a private e-learning platform on the theme of Health Technology Innovation before the beginning of the summer school. These courses, exclusively in English, have been developed by the CIC-IT network. They are part of teaching since 2011 in 4 master's courses in France (Besançon, Bordeaux, Grenoble and Nancy), with more than 700 graduate students. The first part focuses on translational research, the core business of CIC-ITs, explained in the form of 2 conferences filmed during international congresses and illustrated by 5 videos of 6 minutes each showing examples lived in CIC-ITs (with testimonies from clinicians, researchers and industrialists). A very concrete example of a DM (insufflation mask) which led to the creation of a start-up is developed more precisely. The other courses explore different innovative topics in the world of medical devices: Computer Assisted Medical Interventions, Biomaterials, evaluation of medical device safety in MRI and Usability.

2.3.2 Immersive stage

The ClinMed summer school began with an immersive experience in a healthcare service or a living lab. This unique experience allowed the participants to share their ideas within the clinical setting, through direct observations and meetings with healthcare professionals and patients. This exceptional contact between students and real-life situations permitted to grasp a real-life clinical problematic presented to them by the healthcare providers.

Each location had a specific theme. The locations and themes are displayed in Figure 2 and are: Lyon, Garches Lisbon, Lille, Besaçon, Grenoble, Tours and Nancy.

The participants' goals were:

- Observe the current situation;
- Identify problems and needs;
- Prioritize the issues to be addressed;
- Formalize the technical specifications to be achieved with a solution;
- Gather information on the problem and existing solutions.

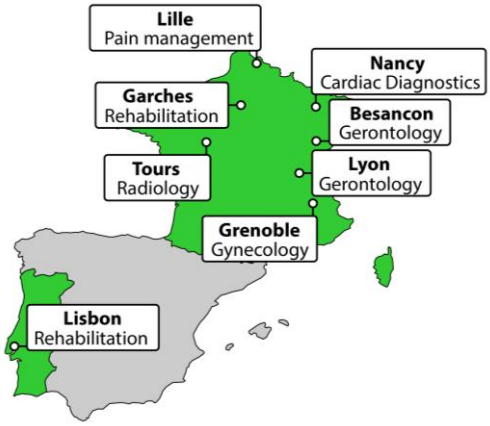

Figure 2: Location and corresponding themes for the immersive stages possible during the ClinMed summer school.

2.3.3 Plenary sessions

After the immersive stage, participants met up at the main site of the ClinMed summer school in Villard de Lans to develop their projects through lectures and coaching from lecturers and mentors.

The lectures were divided into thematic sessions which were new product life cycle development, regulation of CE marking, essential requirements, risk analysis, pre-clinical testing, clinical investigation, suitability for use, post-market monitoring and the "market approach" (business plans, protection and property management).

The daily agenda consisted of a first session of lectures in the morning, followed by a period of time dedicated for the participants to work on the project assisted by the invited speakers and mentors. A second session of lectures followed after lunch. Before dinner the participants were encouraged to continue the elaboration of their work or to participate in social activities organized by the committee and the participants to stimulate the networking between participants.

During this second part of the summer school students worked on the conceptualization phase of their solution to the unmet need refining the problem to be solved and identifying the missing skills if necessary.

The participants' goals at this stage were to get a clear idea on the key components of clinical translation process, such as:

- Define the broad outlines of the development plan for their new medical device;
- Perform a state of the art;
- Describe the market, the competition and the means to afford the market;
- Assess the possibility of technical, biological and clinical equivalence of the innovation with an existing product;
- Define the class of the new medical device and find the regulations and essential requirements needed;
- Perform the risk analysis of the product;
- Define tests and experiments;
- Precise the business plan, protection and property management.

2.4 Lecturers, mentors and clinicians

Lectures and mentors were invited to share their knowledge and expertise with the students. This unique opportunity allowed the students to have a close interaction with experts that are in the top of their field and enhance their project.

The ClinMed summer school had 25 lecturers and mentors, from 9 different countries, who are professionals from hospitals, companies and academia (Figure 3A). They have expertise in diverse

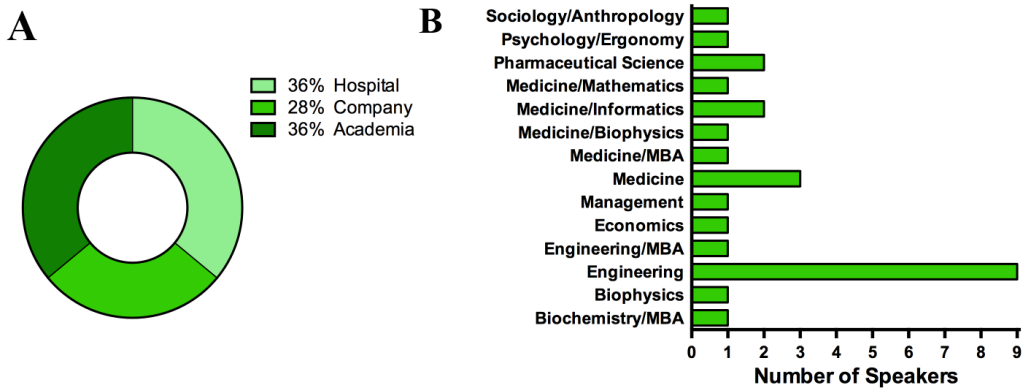

Figure 3: Speakers background, A- distribution in percentage of professional backgrounds, B- distribution of speakers' fields.

fields such as medicine, sociology, biomaterials, medical imaging, engineering, health informatics, ergonomics, marketing and economy (Figure 3B), which guaranteed a comprehensive approach.

It was also made possible to obtain a feedback from clinicians within the EIT Health network. Each group developed an idea to satisfy a clinical need. This solution was shared with clinicians and their feedback was taken into account for the development of their projects.

2.5 Recruitment procedure and participants

The summer school accepted 37 participants. A selection committee evaluated the participants' experience, academic performance and motivation. The evaluation was based on their curricula and motivation letter.

The aim of the selection committee was to put together a group of attendees that came from diverse educational and professional backgrounds with high motivation in developing new solution in the medical field.

The participants had Bachelor's or Master's degree in the fields of biomedical engineering, medicine, biology, ergonomics, health informatics, economy and pharmacy. Most of them came from university whereas five students came from industry (Figure 4A).

The participants came from all over the world, with a total of 17 different countries, with the majority coming from European countries (Figure 4B). The participants were divided in the following groups at the start of the program: 4 students in Lyon, 4 students in Garches, 4 students in Lisbon, 6 students in Lille, 5 students in Besaçon, 5 students in Grenoble, 4 students in Tours and 5 students in Nancy.

2.6 Evaluation

After the immersive stage and after an initial lesson on how to pitch, the participants made their first day in Villars de Lans a first pitch to an audience to present their idea. Feedback was given regarding the content and the efficiency of the pitch by other participants and mentors. Afterwards it was encouraged for the groups to keep working on the pitch.

The participants performed another pitch to two mentors with experience in industry in order to obtain a more detailed and constructed feedback.

As a final evaluation each group presented a written report and an oral presentation, in form of a pitch, in front of an international jury of experts in the field followed by Q&A session. Each group project was evaluated according to the criteria used for the assessment of European projects, i.e. *excellence*, *impact*, *quality and efficiency of the implementation*, *quality and efficiency of the pitch*.

3 LESSONS LEARNED

During the ClinMed Summer School 8 projects were developed in the fields of home assisted health, self-monitoring devices, rehabilitation solutions and

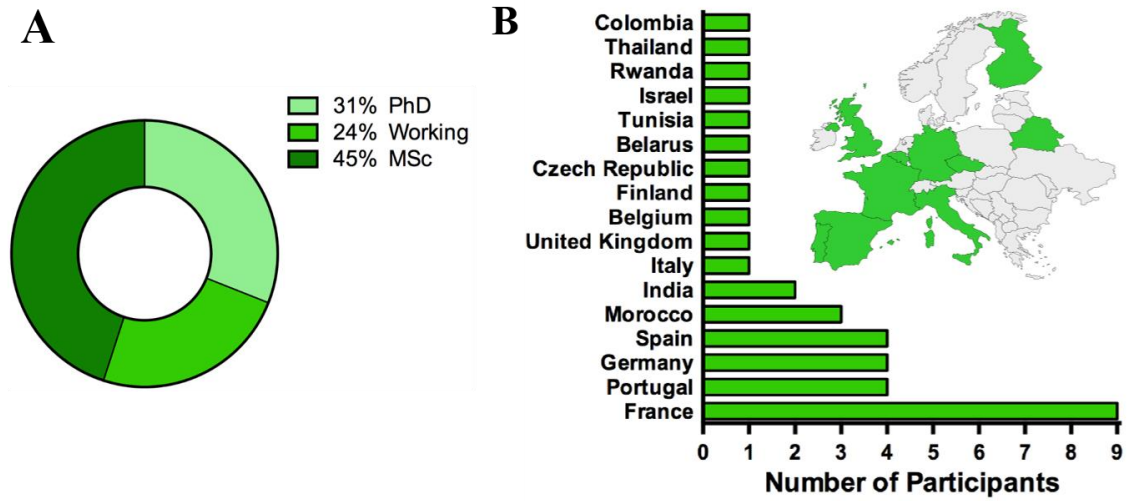

Figure 4: Background of the participants of the ClinMed summer school. A- Distribution in percentage of the participants' background; B- Countries of origin of ClinMed summer school participants.

diagnostic products. All projects originated from a clinical need suggested by the clinicians involved and further developed during the course of the summer school.

The evaluation process gave an overview of the quality of the projects based on criteria related to i) excellence (eg. relevance of the proposal, innovation potential, credibility of the proposal, accuracy of risk analysis);

ii) impact (eg. presentation of market, economic viability, potential to improve healthcare);

iii) quality & efficiency of the implementation (eg. co-design and interdisciplinary approach, clinical impact, intellectual property management, exploitation and dissemination of results);

iv) quality & efficiency of the pitch (eg. presentation quality and answers to the jury's questions, team's ability to convince).

3.1 Feedback

At the end of the summer school, students were asked to fill a feedback survey. The questionnaires covered topics of satisfaction of the program, organization, accommodation, quality of lectures, educational point of view (i.e. immersive experience, common core and team project), social events and general aspects related to the understanding gained through the summer school. The questionnaires had both scale questions (1. Very Satisfied-2.Satisfied-3.Rather Satisfied -4.Indifferent -5.Rather Disappointed-6.Disappointed-7.Very Disappointed) and free commentaries.

In Figure 5A is represented the overall satisfaction expressed by the participants. 55.6% of the participants replied that they were very satisfied, while 41.7% were satisfied and the remaining percentage (2.8%) were rather satisfied. Some of the positive comments refer to the high quality of lectures, the comprehensive overview of the medical devices field, the unique opportunity to work and interact with people with diverse backgrounds, as a few examples. A few more negative comments refer that the time of the year (end of the summer) was not ideal for the immersive stage due to the limited number of people available, some of the lectures were too detailed and extensive for the type of summer school and there was not enough time to work on the final report.

In Figure 5B is represented the satisfaction from an educational point. 94.5% of the participants stated they were very satisfied or satisfied. While from a Scientific point of view (Figure 5C), 83.7% of the participants were very satisfied or satisfied, 11% were rather satisfied while 5.6% were indifferent.

When asked if the participant had a better understanding of the maturation cycle of an innovative medical device, the majority of the participants replied yes (97.2%) (Figure 5D).

From the different concepts presented during the summer school, the students singled out some as the most difficult ones to comprehend, such as business model and regulatory affairs. It is to be expected that students that have different backgrounds would find specific biomedical topics more difficult to grasp.

4 CONCLUSIONS AND FUTURE PERSPECTIVES

Looking at the present view of translational research it is clear that there are many challenges left to overcome. Using research findings for improving clinical medicine needs the combined expertise of basic researchers, clinicians and the industry. At the initial stage of the development of a medical device it

Figure 5: Representation of data (in percentage) obtained from the participants' reply to a survey. A- Overall satisfaction; B- Satisfaction from an educational point; C- Satisfaction from a scientific point; D- If the participant had a better understanding of the product maturation.

is crucial to clearly identify an unmet need and to optimize the product usability in order to improve the chance of success. This notion, as simple as it may seem, needs to be thought through and put into practice by young researchers and developers.

In this paper a report of the ClinMed summer school was given. This program gave an up-to-date general perspective of the life cycle of a medical device: from the initial concept until it reaches the European market. Its uniqueness came from the immersive stage and the close contact between participants and experts of the medical field. It main goal was to empower students to become developers and innovators.

According to the feedback obtained at the end of the summer school, students believe that the experience improved their knowledge of the medical device field, broadened their comprehension of possibilities for the development of devices. The participants believe that the impact of this summer school will be presented to them only in future projects of innovation in medical devices.

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