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Activity Report on the 9th Biomedical Innovation and Entrepreneurship Training Course for SPARK Asia and Oceania 2021

Participants

SPARK BIE Training Course 2021 is meant to be an education platform which allows participants to simulate and experience how it feels like to bring discoveries from bench to market. Participants have a diverse educational background from university professor, medical doctor, engineer, programmer, product designer. Participants also come from different countries, Japan, Taiwan and Australia, having a diverse cultural background, way of thinking and point of view which has made BIE an exciting and full of challenges.

Course Overview

As shown in figure 1, the course started with participants with a diverse background being in the same online classroom. Despite of the technical challenges with the internet access, mic being muted, background noise, camera was not working; the course coordinator Professor Michael and Dr. Isabella had successfully kept everyone to stay active during the course, by maintaining a constant communication and by persuading participants to keep their camera on.

Figure 1.Representative figure on how the training course participants and the online platform used.

The course was created under one vision that is to accelerate the translation process of biomedical research to the market. To achieve this SPARK mission is to deliver an educational program by gathering both side of industry and academia in one room. Having participants from a diverse background to sit together finding the appropriate medical needs and technology/approach suitable to solve the issues. The aim of the course itself is to give the participants an idea on how to realize an idea into a product, starting from finding the right solution for the right medical needs, how to protect the ideas, how to fund the ideas, and how to appeal/present your ideas.

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The Program Schedule

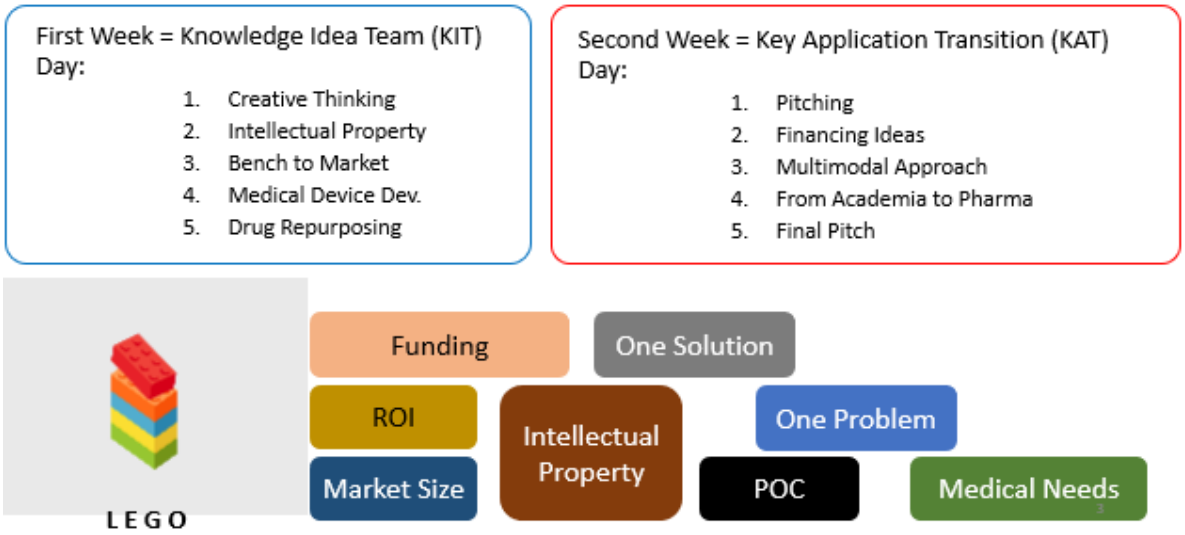

Figure 2. Representative figure showing the course outline differences between the first and the second week. The bottom part of the figure represents how each important point are important and building up one to another.

As described in figure 2, the first week of the course focused on learning more about the basic of bio entrepreneurship, ideas brainstorming, and team building. The first day we gathered was about getting to know each other interests, educational background and field of expertise. We had lecture on creative thinking and how in general the ideas brainstorming goes from the bench into the market. The second day focused on the intellectual property, what can be patented and how we can protect our ideas by patent or trade secret approach. The important point was that **any published study cannot be patented.** The reason behind this is any published findings have become a "public knowledge"; thus, it is impossible to make it as an exclusive right, or to apply for patent. The third day was summarizing on what we had learned on by having a simulation coordinated by Professor Michael. The fourth day was about the medical device development and how to conduct clinical study. Professor Laurence talk on medical device helped us in developing the business plan especially on the technology readiness level, medical device class category, and the 510k or de-novo pathway for the patent application with FDA. On the fifth day, Professor Grimes explained on drug repurposing, in which the same drugs can be repurposed for different indication by computational approach / through off-label examination. Drug repurposing would cut down the discovery phase cost, allowing pharmaceutical company to repurpose the molecules previously failed in the clinical trial. By the end of our first week, we were given a task to prepare a 5 minutes elevator pitch.

On the second week we had more workshops within our team, together with our mentors. In our case, we had an honor to have Professor Laurence Meagher as our supervisor as we focused on developing a medical device for joint implant maintenance. By the end of second week as our final

output every team was required to prepare for a 15-minute business proposal presentation. We had to come up with our business logos, mission, vision, value preposition, proof of concept, milestones, predicted results, freedom to operate feasibility study, market strategy, financial plan, and to reflect on the Return of Investment (ROI). The purpose of the pitch is to mainly appeal to investors on how our idea is unique compared to the competitors, have a real evidence of medical needs, how we can make sure if the business is sustainable and appealing for the investors. We did not have an opportunity for networking as the course was delivered online, but all in all it was a very insightful experience.

Take Home Messages

I would like to start by acknowledging Professor Michael Wallach, there are two things I learned from him: 1. Make it simple.; 2. One problem and one solution. The two advices were addressed during our team discussion because we had a lot of ideas, and our groups tend to drift away from the problems and focusing more on the solution. To make it simple means we need to deliver our message simply, so anyone could understand what we are trying to create, what is our goal, and how we are going to achieve this. One problem and one solution are about how we should start idea brainstorming from one problem, we need to keep our focus on the problem as detail as possible; finding the root of the problems was the key and we could achieve this by asking 5-Why's. Then we could proceed to try to address the issue by one solution, what is the one message we would like to address for the issue. In our case, we focused on the knee prosthetic join infection, occurred after total knee arthroplasty surgery. The solution is to provide a non-invasive joint maintenance for the knee implant. Finally, the advice from Professor Laurence Meagher: 1. Unlike any other medical product, medical device should at least have a 10x better performance / 10x more safety, anything but it must be at least 10x better to justify the idea. 2. With medical device it is important to have a multimodal approach, low-risk, and low-burden. Professor Laurence advice really reflected the tall orders of creating a medical device, we managed to proof how our product could relieve the financial burdens of the patients, but we were behind on proofing how our device could be a safer solution than the existing one. We were not able to come with a multimodal approach, but we do manage to show how we can keep our patient stay safe even with the heat being apply for the joint implant maintenance through the 3D IR monitoring system.

I believe research and entrepreneurship are two minds think alike, they are the same coin of different sides. As researchers, we are motivated with publications on higher impact journal, but on the other side most inventions must be replicable and often these can only be found on studies with a consensus at least within the science community. As researcher we often taught that no one should have known better than us on our study; but in entrepreneurship we are taught that there will always be someone who knows better than us, so always find that keyperson and collaborate. To sum it up, it was an extraordinary experience and really opens my mind on how inventions should be handled appropriately to bring them to the market.