



# MASTER

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## The Business Engineering Surgical Technologies Transfer "B.E.S.T.T."

*Healthcare Innovation Masters*

### Inspiring and Growing the Next Generation of Medical Innovators

World-changing innovations all share one thing in common. They start with people. People who care about solving problems, people with ideas, and most importantly people willing to do the hard work of bringing these ideas to market.

Developing innovative products is challenging, but nowhere are those challenges greater than in medicine. Challenging science, complex regulatory environments, intense competition, and high financing costs are just some of the headwinds that prevent many promising ideas from reaching patients.

At IHU-Strasbourg, we want to evolve the educational paradigm in medicine with the new B.E.S.T.T. Healthcare Innovation Masters. Through our educational framework and community, we aim to create an innovation culture and infrastructure to support new thinking about how to develop successful healthcare innovation. Each year, the program will select students from around the world to learn critical skills from experienced innovators in medicine.



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The IHU-Strasbourg and B.E.S.T.T. program is aligned with some of the top innovation centers in the world, including Stanford University, the University of Twente, Johns Hopkins, Cattolica University Rome, along with industry titans like Medtronic, Karl Storz, Apollo Endosurgery, Siemens and many others.

The curriculum includes specific educational courses focused on the framework of developing innovations, including finance, regulatory affairs, intellectual property, and product quality. These courses are taught by domain experts with experience in European, US, and global markets. Skills will also be taught in structured workshops on needs finding, brainstorming, concept filtering, and concept selection.

Students will also learn from doing. Clinical immersion at the adjacent University Hospital allows students to see real-time patient care, in an institution where pioneering procedures and novel therapies are provided to patients on a regular basis. Also onsite and accessible to students is IRCAD, the world class surgical training center that teaches the most groundbreaking procedures to thousands of surgeons from around the world. Here, students can access advanced training facilities to test and evaluate new surgical techniques and devices, along with real users experienced and interested in innovation.

Teambuilding is also a critical part of any innovative project. Students will form teams, identify a real clinical need, and throughout the two year program develop this need from concept to an actual business plan and potentially a real product for the market. Through this faculty-coached process, students will learn the importance of both individual effort and teamwork to accomplish complex tasks, and deal with colleagues with different skill sets, working styles, and cultural backgrounds.

Finally, real-world case studies led by experienced life science entrepreneurs will help bring the lessons from the classroom and the clinic into tangible, executable strategies. You will learn from successes, you will learn from mistakes, but most importantly you will learn from individuals who themselves have brought leading innovations to market. They will share their experiences with you, as well as their advice on how you might bring your own ideas to market.

No matter if you envision a career as a physician, an executive in a healthcare corporation, a venture capitalist, or an entrepreneur in your own start-up, the B.E.S.T.T. Healthcare Innovation Masters will offer you a unique experience through first-hand interaction with world class faculty and mentors, along with equally talented students handpicked from around the world.

# Program Details

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## 10 Students Accepted Annually

**Who should Apply?** Students who want to pursue a career developing medical innovations in biotechnology, medical devices, digital healthcare, or diagnostics.

**Requirements:** Bachelor's degree or equivalent required. Advanced degree in sciences or business and economics, and medicine preferred. Experience and background that demonstrates an interest and capability in developing innovations.

**Logistics:** 2-year program

**Location:** IHU in Strasbourg France.

**Application Deadline:** October 15<sup>th</sup>, 2019

**Courses Start:** November 1<sup>st</sup>, 2019

## Program Syllabus

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The B.E.S.T.T. Healthcare Innovation Masters program is an integrated 2 year program, which combines intense “immersions” around core subjects of medical innovation, and independent but supervised work that centers around a particular innovation that students identify on their own to work on. Personalized feedback from global leaders in the field and coaching from multi-disciplinary team will be provided by on-site interactive and virtual sessions. The program combines e-learning and virtual classes throughout the year, on-site workshops for a total of 5 weeks/year. During the first year, 6 weeks of clinical immersion and a 4-week summer externship are included in the program.

Year 1 provides the basic framework for commercialization of new products from concept to market, together with a framework for identifying needs, brainstorming products, and understanding the key elements of the healthcare innovation ecosystem. Workshops this year are focused around assuring the students can effectively screen and select their preferred concept.

During Year 2, students will have chosen their concept and will be working towards development and execution of a business plan. Educational immersions will be focused on practical matters of commercialization, including clinical evaluation, quality systems, manufacturing, and financing.

# Year 1

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Introductory Workshop: Summer 2019, Learning from the BEST- Introduction to Medtech Innovation and Team Building (Optional)

**Module 1:** Fall 2019, Healthcare Innovation Commercialization Overview and Clinical Immersion

**Module 2:** Winter, 2020, The Innovation Ecosystem and Choosing a Need

**Module 3:** Spring, 2020 Brainstorming, Prototyping and Protecting a Concept

**Module 4:** Externship

# Year 2

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**Module 5:** Product Development and Testing

**Module 6:** Leadership for Startups, and Running a Business

**Module 7:** Financing or Partnering for Your Idea

# Program Year 1

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## Module 1: Commercialization Process and Finding a Need through Clinical Immersion

### 1. BEST Bootcamp (6 days, Onsite Strasbourg) - Optional

The BEST bootcamp, run concurrently with the BEST Innovation Course, provides students with a comprehensive snapshot of the innovation process in medicine. Students learn strategies for understanding and interpreting clinical needs, brainstorming concepts, and screening the identified needs. They also learn the basic building blocks of a business plan. Faculty teach courses on specific application areas, such as intellectual property, regulatory strategy, and financing. In parallel, students work in small “entrepreneurial style” multidisciplinary teams on an actual medical need, and apply the lessons learned in the courses to their concepts. Immersive hands-on labs are provided to evaluate existing minimally invasive surgical technologies, as well as evaluate prototypes developed for their projects.

### 2. Needs Finding (3 days, follows BEST Bootcamp or Winter 2019 *estimated in November*, Onsite Strasbourg)

This section focuses on needs-finding methods in medicine. Clinical needsfinding is the process of examining current clinical practice, typically through observation and interview, and identifying opportunities for new products based on an unmet need in existing standard care. By directly observing the full cycle of care from diagnosis and treatment to recovery and billing and returning back home, students discover problems and opportunities. They watch what is done and how it affects the provider, the patient, and the system, while asking pointed questions that challenge the status quo. Throughout this section, students will be taught how to perform clinical needs-finding through various interactive educational formats, online, in class and during brief clinical rotations.

### 3. Clinical Immersion (6 weeks, Hospital centers across Europe)

During the first-hand observation period (clinical needs-finding), student teams collect hundreds of needs in various of care settings such as: low volume care centers, high volume centers, private centers, public centers and at-home care, initially without judging or prioritizing. This work will be conducted with IRCAD and its partner institutions around the world. During clinical immersion, needs are revalidated with various stakeholders and different care centers locally and across Europe to validate the gravity, frequency and impact of the needs identified. Lastly, during final need selection, students are asked to filter the list with rigorous objectivity, taking into account everything from the different stakeholders affected by each need to how much potential it has to improve care and/or save the system money. This is an intense and iterative process, with progressively

deeper dives into the needs that have the most potential. Ultimately, the student teams arrive at the two or three most promising needs.

## Module 2 The Innovation Ecosystem and Choosing a Need

1. Healthcare Innovation Ecosystem Bootcamp (2 weeks, virtual classes and 5 days onsite Strasbourg, Winter 2020 – *estimated in January week 3 or 4*)  
With potential needs identified through clinical immersion, the Healthcare Innovation Bootcamp introduces elements of the healthcare innovation ecosystem that impact effective commercial success of a product concept. We study this by first exploring the key stakeholders in the healthcare ecosystem: patients, physicians, providers, and payers. Understanding this interplay is critical to assessing clinical needs, as all stakeholders will have a role in impacting the ultimate success of a new innovation.
2. Next, students will explore the regulatory frameworks in the world that impact the approval, safety, and payment of medical devices and procedures. They will study the European CE, Medical Device Single Audit Program (MDSAP) and US FDA systems for approving the sale of medical products and new drugs. Another critical element of this module is understanding the regulations and systems set up to manage the safe design of new medical products, and how to run clinical studies for new drugs and devices.

Finally, we will delve into the complicated world of payment for medical products. The focus will be on the European and US public and private payment systems, and key global markets. We will also evaluate alternative healthcare economic strategies, including patient pay.

During this time, students will apply these lessons to the potential needs identified in the previous Module. A more detailed stakeholder analysis will help filter potential needs and allow students to finalize the clinical need they selected for their own project to move into the next phase.

Real world entrepreneurs will teach the fundamentals through case studies.

Sections:

- Healthcare Stakeholders Analysis (Entrepreneur Faculty)
- Global Regulatory Approvals: US FDA, Euro CE, other core markets (Regulatory Faculty)
- Quality Management Systems: ISO, GMP, GCP (Engineer Faculty)
- Global Healthcare Economics: US Economic Market, Key European Markets (Health Eco Faculty)

### Module 3: Brainstorming, Prototyping and Protecting a Concept

1. Brainstorming, Prototyping, and Protecting Ideas (1 week, onsite Strasbourg, early Spring 2020 – estimated in March)

During this bootcamp, students will begin to invent. While brainstorming is meant to be a creative and free flowing process, there are certain rules that make the process most effective and productive. They will brainstorm hundreds of potential solutions for each of their top needs identified in previous modules. Then, they will organize their ideas and objectively compare them against key criteria for satisfying the chosen needs.

Prototyping is a critical process in both testing a potential concept as well as communicating a concept to stakeholders and potential investors. During this phase, trainees create rough prototypes in a rapid “think-build-rethink” sequence. Students will be taught different methods of prototyping a concept, and will be given access to “maker labs”, where 3D printers, basic machining, and simulators can be used to evaluate concepts.

The final section of this workshop will focus on protecting your idea through patents in Europe, the United States, and other global markets. IP (Intellectual Property) is a critical piece of the innovation ecosystem that any innovator needs to understand, as it enables the commercial potential and protects the value of a novel idea. The concept of “freedom to operate” will also be introduced, which is important to ensure that our new ideas do not infringe on someone else’s previous invention.

#### Sections:

- Brainstorming methods
- Prototyping
- Intellectual Property: Idea Protection and Freedom to Operate

2. Commercialization Implementation Bootcamp (2 weeks, virtual classes and 5 days onsite Strasbourg, Spring 2020 – estimated in June)

The final bootcamp of Year 1 will bring all of the elements of the previous modules together around actual implementation of a commercialization strategy. Students will take the next steps in developing their concept into a tangible plan that can be used for raising the capital needed to fund the development of a new idea. Industry faculty mentors with deep business knowledge and experience will teach these sections, and discuss strategies for commercialization, including finding an industry partner or creating your own business startup. They will talk about funding sources that are suitable for a particular idea, as well as the strategy behind risk-based product development and financing.

Most importantly, industry faculty will work closely with student teams to advise them on the best approach for their concept, and how to pitch their concepts to actual investors.

This bootcamp will culminate by the students presenting their concept and business plan to the B.E.S.T.T. faculty and industry mentors. Presentations will be critiqued based on commercial potential, novelty of idea, depth of clinical need, and thoughtfulness around the development plan. Following this, team projects will be approved to move into the Year 2 Implementation Phase.

Sections:

- Building a development plan
- Fundraising
- Presenting your Idea

#### **Module 4: Externship (4 weeks, Summer 2020)**

During the summer following the completion of their first year, students will be assigned to “Externship” roles where they will be able to work first-hand with innovative companies and investors to explore the practical sides of healthcare innovation. Externships will be onsite in innovation hubs across Europe.



# Year 2

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## Real World Commercializing

Student teams will create an invention and a plan for execution that will be implemented in Year 2 to further develop their product, de-risk any technology issues, and to prepare for funding strategies. Modules will focus on the daily activities of building and testing the product, the practicalities of running a startup company or finding a development partner, and accessing capital for ideas.

Teams will build milestone-based plans to develop and test their concepts, and faculty supervisors will provide assistance in refining the plan and executing the plan through the year. Students will be given access to incubator facilities that will allow a physical nexus for their student team and ideas to be developed.

At the end of Year 2, students will have the option of continuing with their concept, and independently funding and running an actual startup company.

### **Module 5: Product Development and Testing**

### **Module 6: Leadership for Startups, and Running a Business**

### **Module 7: Financing or Partnering for Your Idea**