OREGON CLINICAL & TRANSLATIONAL Research Institute

OHSU

Biomedical Innovation Program

Commercialization Readiness Program (BIP Corp)

Syllabus: Fall 2019

OHSU Office of Collaborations and Entrepreneurship

OHSU Office of Technology Transfer

OBI OTRADI Bioscience Incubator

FASTFORWARD medical innovation

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BIP *Corp*

At a Glance

Class Dates:	October 1 – November 4, 2019
Kickoff Class:	Friday, October 1, 2019 | 12:00 – 5:00 p.m. OHSU Southwest Waterfront
Webinar Classes:	Friday, October 11 | 8:30 – 9:30 a.m. Friday, October 18 | 8:30 – 9:30 a.m. Friday, October 25 | 8:30 – 9:30 a.m.
Final Class:	Friday, November 1, 2019 | 12:00 – 4:00 p.m OHSU Southwest Waterfront
Key Contacts:	Melissa Mudd muddm@ohsu.edu 503-494-1498 Jonathan Jubera jubera@ohsu.edu
Course Text:	BioDesign: The Process of Innovating Medical Technologies, Zenios et al *(optional)*
Tools:	Online Learning & Assignments: Sakai Webinars: Zoom
References:	Value Proposition Canvass ©Strategyzer Startup Owner's Manual, Steve Blank Business Model Generation, Osterwalder et al

BIP Corp: Weekly Course Topics

Week 1 – Validating your Value Proposition

- Aim for 5 Customer Discovery Interviews
- The Problem
- The Solution
- The Value Proposition
- Critical Stakeholders (Device Track)
- Target Product Profile (Therapeutics Track)
- Market Opportunity

Week 2 – Competitive Analysis & Intellectual Property

- Aim for 5 Customer Discovery Interviews
- Competitive Analysis
- Intellectual Property Strategy
- Relevant Prior Art

Week 3 – FDA & Regulatory Considerations

- Aim for 5 Customer Discovery Interviews
- Regulatory Summary Table
- Cont. Target Product Profile (Therapeutics Track)
- HIPPA & Federal Trade Commission (Device Track)

Week 4 – Business Case & Summary

- Aim for 5 Customer Discovery Interviews
- Business Strategy – Monetization & Reimbursement
- Business Case Presentations
- What's Next?

BIP *Corp*

Course Description

BIP Corp is a 4-week biomedical commercialization course designed for the busy medical academician and industry scientist with an early stage project. Modeled after the successful NSF I-Corps program and adopted from University of Michigan's Fast Forward Medical Innovation program, BIP Corp uniquely blends in-person and online experiential education to help scientists and clinicians learn the basic components of biomedical commercialization and prepare a competitive business case to successfully secure funding and partners.

Why Participate?

- Develop a competitive business case and pitch used to secure funding and attract collaborators
- Determine the commercial viability of your innovation
- Expand your network of innovation partners, mentors, and potential investors
- Develop greater self-confidence and business presentation skills

Course Strategy

Using a process similar to the "scientific method," which is familiar to all researchers, the course formalizes the search for a commercial pathway by building a business case through hypothesis testing. Tools such as the Value Proposition Canvas allow participants to frame and test hypotheses by running short experiments and collecting data during a process called Customer Discovery. The validation of hypotheses on a technology's clinical utility, intellectual property, regulatory pathway, and revenue model create a business case that is critical to engaging the required resources to commercialize the technology, regardless if that pathway includes a license agreement, R&D partnership, or an entrepreneurial startup.

Instructional Method

BIP Corp is a team-based approach that includes faculty, researchers, practicing clinicians, postdoc researchers, graduate students, industry scientists, and other individuals contributing to the development of the technology. Although the course provides some traditional lecture within the educational tracks of therapeutics and device/diagnostics/software, the majority of the learning takes place outside the lectures as the team develops their business case by conducting customer discovery interviews. Parallel to the development of the technology's business case, teams create materials, present to their colleagues, and receive weekly feedback from an experienced entrepreneur advisors. Due to this flipped classroom approach, project teams drive the direction of weekly presentations and get maximum value out of their interaction with the material and instructors.

Educational Tracks

Enrolled projects are divided into two tracks: Therapeutics or Devices/Diagnostics/Software. The individual tracks provide personalized instruction and mentorship within the product vertical. In addition, the project teams are able to learn from similar projects as their report their progress throughout the course.

Biomedical Topics

This course includes supplemental education topics unique to biomedical commercialization. Prior to each webinar report-out session, online modules provide further instruction on the value proposition and customer discovery, competitive analysis, intellectual property, and regulatory considerations, among other topics and case studies.

Presenting your Weekly Progress – Webinars

Project teams are required to present their weekly progress to the advisor team and other projects in their educational track. Each team will be given a template slide deck and instructions on presenting as part of the scheduled webinar. These are **brief** weekly updates.

Customer Discovery

The majority of the learning in this course is a result of customer discovery interviews. Participants are expected to spend a considerable amount of time scheduling, conducting, and recording interviews for feedback from the teaching team. Previous participants have reported as many as 8-10 hours per week spent of customer discovery; however, participating as a team can reduce the total number of individual hours spent.

Note: participants are not required to conduct a certain number of interviews, however the closer you can get to the suggested minimum, the better you will be able to understand your market/customer and validate your innovation.

BIP *Corp*

Course Schedule

Week 1	**Course Kickoff** *What is a Value Proposition?* *Identifying key stakeholders* *Conducting customer discovery*	***Assignment #1*** *Presenting Your Value Proposition*	All Tracks Together	
	Customer Discovery			
	Webinar 1	***Assignment #2*** *Market & Competitive Analysis*	Device/Diagnostic Track	Therapeutics Track
Week 2	Customer Discovery			
	Webinar 2	***Assignment #3*** *Intellectual Property Strategy*	Device/Diagnostic Track	Therapeutics Track
Week 3	Customer Discovery			
	Webinar 3	***Assignment #4*** *FDA & Additional Regulatory Considerations*	Device/Diagnostic Track	Therapeutics Track
Week 4	Customer Discovery			
	Final Presentations *What's Next?* *Commercial Pathways and Available Funding*	***Assignment #5*** *Reimbursement/Monetization Strategy*	All Tracks Together	

Team Formation

Team participation is recommended, but not required to participate in the program. Participating as a team can help alleviate time associated with the customer discovery process as well as provide a well-balanced foundation for your project. Team members can include faculty, researchers, clinicians, postdocs, graduate and undergraduate students, or others involved with the technology.

**Program administrators can help match team members to projects if desired.*

Student Team Members

Students from OHSU and regional universities are welcome to participate in this course. As team members, they will be available to help with scheduling and conducting interviews, as well as assisting with presentation materials.

Benefits to students:

- Connect with experienced professionals and contribute to an interesting and potentially life-saving innovation
- Learn basic skills in biomedical commercialization, innovation, and entrepreneurship
- Expand your network of innovation contacts to include faculty, staff, and other students
- Build your resume with a meaningful non-curricular activity
- Contact Melissa Mudd to see about receiving academic credit from your program

Project Examples from past participants

- Bone Mimetics: Regenerative Medicine & Disease Models
- SHIFT.AI: an artificial intelligence technology for detecting cancer
- Small molecule therapeutic for stroke
- Agent for image-guided surgery and intraoperative therapy
- Additive Care: Developing tools & services to streamline 3D printing as a clinical solution
- Novel Mouth Sealer to Improve CPAP Compliance for Obstructive Sleep Apnea Treatment
- A new support system for elderly populations in rural communities

Intellectual Property

All presentations should be considered public. No proprietary or confidential information should be included on presentations or during the course. The course and the customer discovery interviews are not intended to be focused on the details of how your technology works, which means NDAs are most often unnecessary. This course is IRB exempt.

Course Expectations

BIP Corp is designed to remain as flexible as possible while guiding participants through the learning materials and hands-on experiences. This course is participant driven; what you get out will be a reflection of what you and your team put in. However, the tools and skills you will build through the course will enable you to continue iterating and validating your innovation (or another one!) well after the term.

You will be assigned an advisor from the teaching team to help guide you through the course content and provide additional real-life expertise. Pairings will be based on background, experience, and availability. BIP Corp staff are available to help fill any gaps and make additional connections.

Attend meetings:

In-person: **Oct 4 12:00 – 5:00 pm**

Webinar: **Oct 11 8:30 – 9:30 am**

Webinar: **Oct 18 8:30 – 9:30 am**

Webinar: **Oct 25 8:30 – 9:30 am**

In-person: **Nov 1 12:00 – 4:00 pm**

Weekly tasks & assignments:

1. Schedule/conduct customer discovery interviews
    a. Depending on the size of your team, aim for 2-5 interviews per week
2. Review course materials on Sakai
3. Check-in meeting with your advisor
    a. Suggested topics, as needed: Review weekly progress, ask questions about course content, continue goal/milestone planning, pitch coaching, identify strengths and areas for improvement, identify any gaps in expertise/knowledge that BIP Corp admins can help connect
    b. This check-in is to be scheduled at the convenience of your team and advisor, ideally after you've reviewed the weekly materials and before the Friday webinar.
4. Compete weekly assignment (template provided in Sakai)
    a. Due Thursday's at 11:59pm
5. At least 1 team member should be present on the webinar to present your weekly progress

Webinars:

Participation in weekly webinars is expected for at least 1 team member. Each team is given approximately 5 minutes to present their weekly assignment to the group, followed by Q&A and feedback from the teaching team.

Final Presentation:

Throughout the course, you will be filling in weekly slide deck templates that culminate into a final business case to be used for your final presentation. You will have approximately 5 minutes to pitch your innovation, followed by an interactive discussion.

The Teaching Team

Expert advisors come from a variety of settings throughout academia and industry. Project teams are divided into educational tracks and each team is assigned an advisor to capitalize on their unique experience and maximize individual learning opportunities.

Ann Demaree, MBA, RN
VP of Marketing & Business Development
Cardiac Insight

A healthcare marketing strategist and innovator, Ann brings more than 25 years of medical device and healthcare IT industry consulting and commercialization experience, including marketing and corporate business, development leadership roles at Welch Allyn, CapsuleTech and numerous other disruptive medical technology startups.

Steve Runnels, BS, MT(ASCP)
Entrepreneur-in-Residence
Oregon Health & Science University

Steve has more than 28 years of successful and proven international business management experience in the healthcare industry. He has held the position of President and CEO of several startup biopharmaceutical companies in the US and internationally. Steve was executive vice president and board member of NeoTherapeutics, Inc. and vice president of marketing and business development at Sigma-Aldrich, a fortune 500 company. He has led drug discovery and in vitro diagnostic product development activities in the central nervous system, oncology, clinical cytogenetics, assisted reproductive technologies, immunohematology, and diseases of bone and cartilage. He recently held the position as CEO of ProteoTech, Inc., a private, clinical stage Company focused on the development of therapeutics for Parkinson's disease, Alzheimer's disease and AL Amyloidosis. He is a Senior Industry Advisor for the National Institutes of Health Commercialization Program (NIH-CAP) managed by the Los Angeles Regional Technology Association (LARTA).

Charla Triplett, MS
Founder & President
Catalyze Health

For over 20 years, Charla has worked with entrepreneurs, engineers, scientists, marketing and business teams, inside companies (large and small), nonprofits, and universities. Most recently, she worked as a product development strategist for a design firm and in business development for an interactive digital marketing agency. Prior to these Business Development roles, Charla spent over 15 years of her career focused on connecting industry and academia in the area of Biomedical Engineering, including founding and running a non-profit with this mission and working with over 60 Universities nationwide.

Tom Barrett, MD, MCR, FACP, SFHM
Founder & CEO, Sympano, Inc.
Hospitalist Physician, Portland VA
Associate Professor, Oregon Health & Science University

Tom is a hospitalist physician-educator with over 20 years of experience taking care of sick patients admitted to the hospital while teaching medical students, interns, and residents. Tom is a charter member of the Society of Hospital Medicine (SHM), and founded the Oregon Chapter of SHM. Tom has also worked with teams of engineers for over 10 years on translational research projects, and spun off the research into two biotechnology startup companies in the diagnostic space. Tom teaches biotechnology entrepreneurship to medical students, and founded the Portland Chapter of the Society of Physician Entrepreneurs.

Dick Rylander, MBA

Entrepreneur-in-Residence,

Oregon Health & Science University

Dick has more than 40 years' experience in pharmaceutical and biotech, covering a wide range of areas including sales, management, marketing, training, operations, market research, and IT. His ground-breaking work creating specialty distributions systems for Tracleer® and Zavesca® became the basis for the FDA's Risk Evaluation and Mitigation Strategies program. He is also an inventor and patent holder. His device development work in diabetes combined several technologies for a unique product.

Having launched several Orphan drugs, Rylander is well versed in identifying unique market niches as well as dealing with managed care, pricing, reimbursement, Medicare and Medicaid. He has also created call center support systems, including a unique software system for managing high-risk patients. Rylander has been involved in multiple startups and has consulted for companies evaluating new products. He has extensive experience in contract negotiation and management, performance review systems, and incentive planning.

Bill Newman, PhD

Managing Director, Northwest Technology Ventures

Biomentor, Oregon Bioscience Incubator

Instructor, Portland State University

Bill has more than 30 years of experience as a scientist, engineer, entrepreneur and venture capital investor. He started his career as a scientist at MIT, developing and validating techniques for planning and delivery cancer therapies based on non-ionizing radiation. His discoveries led to four patents. He left MIT to found a startup based on this research.

Dr. Newman then entered the venture industry to focus on early-stage investments, launching NTV in 2002. He serves on numerous corporate boards within the NTV portfolio and spends time advising students and entrepreneurs on strategies for business launch and growth.

Travis Woodland, JD, MS

Innovation Associate, Portland State University

Adjunct Faculty, NSF I-Corps

Travis has spent his professional career helping academic researchers and students navigate the worlds of academic politics, industry engagement, market assessment, licensing, contract negotiation, and startup formation. With 13 years working in university technology transfer, investment and grant management, policy creation, and public outreach, he brings a wealth of experience bridging research innovation to market needs and conversely bringing industry needs to academic innovators. Travis is committed to engaging faculty and students in ways that provide meaningful resources and advice to move innovation out of the lab for the public good. He believes in promoting programs that encourage entrepreneurial mindset, teach science and technology communication skills, and help students and faculty become more aware of industry needs related to their area of research. Travis enjoys working in a diverse team environment and working to address the needs of all stakeholders to ensure that novel research ideas are given the best chance possible to make an economic impact.