Biomedical Innovation Program fastPACE
(Program Accelerating Commercialization Education)

Syllabus: Fall 2018
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FastPACE Overview

Class Dates: September 26 – October 26, 2018
Kickoff Class: Wednesday, September 26, 2018 12:00 – 5:00 p.m. RLSB
Webinar Classes: Friday, October 5 4:00 – 5:30 p.m.
                  Friday, October 12 4:00 – 5:30 p.m.
                  Friday, October 19 4:00 – 5:30 p.m.
Final Class: Friday, October 26, 2018 12:00 – 5:00 p.m RLSB

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               Jonathan Jubera
               jubera@ohsu.edu  503-805-8179

Course Text: BioDesign: The Process of Innovating Medical Technologies,
             Zenios et al *(optional)*

Tools: Online Learning & Assignments: Sakai
       *(https://sakai.ohsu.edu/)*
       Webinars: Nexus

References: Value Proposition Canvass ©Strategyzer
            Startup Owner’s Manual, Steve Blank
            Business Model Generation, Osterwalder et al
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BIP fastPACE: Weekly Course Structure

Week 1 – Validating your Value Proposition

- 10 Customer Discovery Interviews
- The Problem
- The Solution
- The Value Proposition
- Critical Stakeholders (Device Track)
- Market Opportunity / Competitive Analysis
- Target Product Profile (Therapeutics Track)

Week 2 – Intellectual Property

- 10 Customer Discovery Interviews
- Intellectual Property Strategy
- Relevant Prior Art
- Target Product Profile (Therapeutics Track)

Week 3 – FDA & Regulatory Considerations

- 10 Customer Discovery Interviews
- Regulatory Summary Table
- Target Product Profile (Therapeutics Track)
- HIPPA & Federal Trade Commission (Device Track)

Week 4 – Business Case & Summary

- Business Strategy – Monetization & Reimbursement
- Financial Models
- What’s Next?
Course Description
fastPACE 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 Innovations program, fastPACE uniquely blends in-person and online experiential education to help scientists and clinicians learn the basic components of biomedical commercialization and prepare a successful business case to secure funding and partnerships.

Why Participate?
- Develop a competitive business case 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 fastPACE 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 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 teaching team. 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 they 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 teaching 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.

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.
### Course Schedule

<table>
<thead>
<tr>
<th>Week 1</th>
<th>Course Kickoff</th>
<th>Assignment #1</th>
<th>All Tracks Together</th>
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<tbody>
<tr>
<td></td>
<td>What is a Value Proposition?</td>
<td>Presenting Your Value Proposition</td>
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<td></td>
<td>Identifying key stakeholders</td>
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<td>Conducting customer discovery</td>
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<td>Customer Discovery</td>
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<td>Webinar 1</td>
<td>Assignment #2</td>
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<td>Market &amp; Competitive Analysis</td>
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<td>Device/IT Track</td>
<td>Therapeutics &amp; Diagnostic Track</td>
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<td>Week 2</td>
<td>Customer Discovery</td>
<td>Assignment #3</td>
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<td>Intellectual Property Strategy</td>
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<td>Device/IT Track</td>
<td>Therapeutics &amp; Diagnostic Track</td>
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<td>Week 3</td>
<td>Customer Discovery</td>
<td>Assignment #4</td>
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<td>FDA &amp; Additional Regulatory Considerations</td>
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<td>Device/IT Track</td>
<td>Therapeutics &amp; Diagnostic Track</td>
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<td>Week 4</td>
<td>Final Presentations</td>
<td>Assignment #5</td>
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<td>What's Next?</td>
<td>Reimbursement/Monetization Strategy</td>
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<td>Commercial Pathways and Available Funding</td>
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<td>All Tracks Together</td>
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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 student volunteers:

- Connect with faculty mentors 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

Project Examples from University of Michigan

- Augmented reality device for home-based physical therapy
- Mobile app for IBS treatment adherence and patient-physician communication
- A point-of-care diagnostic tool to measure immune response
- An ureteral stent tracking system

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.
The Teaching Team
The expert teaching team comes from a variety of settings throughout academia and industry. Project teams are divided into educational tracks and assigned a teaching team member to capitalize on their unique experience and maximize mentorship opportunities.

Medical Devices, Diagnostics & Software Instructors

Device Teaching Lead

Ann Demaree, MBA, BSN, RN
VP of Marketing & Business Development
Cardiac Insight
ademaree@cardiacinsightinc.com
206-596-2073

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.

Device Content Experts

Stevan Wittenbrock
Founder/CEO, SoMA Inc.
steve@somainc.com 530-241-1900

Expertise: Value Proposition, Customer Discovery, Market Analysis

Katie Peters
Director of Experience Strategy & Insights,
FutureBrand Speck
katherine.peters@speckdesign.com

Expertise: Market & Competitive Analysis

Wes Parker, JD
Shareholder, Schwabe, Williamson & Wyatt
wparker@schwabe.com 503-381-6385

Expertise: Intellectual Property Strategy (patents)

Michael Roberts, PhD
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Expertise: Intellectual Property Strategy

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Frank Curci  
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*Expertise: Intellectual Property Strategy*

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*Expertise: FDA & Regulatory*

Richard Wynkoop  
President/CEO, Vision 28  
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*Expertise: FDA & Regulatory*

Joe Hooyboer  
Assistant Director of Actuarial Provider Reimbursement, Cambia Health Solutions  
joe.hooyboer@regence.com  503-225-4829  
*Expertise: Reimbursement Strategy*

Tom Barrett, MD, MCR  
Founder/CEO, Sympano, Inc.  
barretth@ohsu.edu  503-273-5015  
*Expertise: Monetization Strategy*
**Therapeutics Instructors**

**Therapeutics Teaching Lead**

**Steve Runnels, PhD**  
Executive-in-Residence  
Oregon Health & Science University  
runnels@ohsu.edu  
949-291-9971

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).

**Therapeutics Content Experts**

**Dick Rylander, MBA**  
Executive-in-Residence, OHSU Technology Transfer & Business Development  
rylander@ohsu.edu  650-759-7107  
*Expertise: Value Proposition, Market Analysis*

**Charla Triplett**  
Senior Director of Product Development Strategy, FutureBrand Speck  
charla.triplett@speckdesign.com  
602-295-7406  
*Expertise: Customer Discovery*

**Nathan Lillegard, MBA**  
Program Manager, University of Oregon Lundquist Center for Entrepreneurship  
nlillega@uoregon.edu  541-346-3349  
*Expertise: Market & Competitive Analysis*

**Andrew Watson**  
Senior Director, OHSU Technology Transfer & Business Development  
watsonan@ohsu.edu  503-494-8309  
*Expertise: Intellectual Property Strategy*
Steve Eck, JD  
Senior Patent Manager, OHSU Technology Transfer & Business Development  
* ecks@ohsu.edu  503-494-8200  
* **Expertise: Intellectual Property Strategy**

Alyssa Thomas  
Owner/Principal Consultant, Allegiance Regulatory Consulting  
* alyssa@allegianceregulatory.com  503-539-8868  
* **Expertise: FDA & Regulatory**

Scott Zelmer  
Partner, Arpeggiate Consulting Group  
* scott@arpeggiatecg.com  503-708-2177  
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Bill Newman  
Managing Director, Northwest Technology Ventures  
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* **Expertise: Reimbursement & Monetization Strategy**

BIP fastPACE Course Administrators  

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JONATHAN JUBERA, MBA  
BIP Project Coordinator, OCTRI  
* jubera@ohsu.edu  503-805-8179
# BIP fastPACE Course Kickoff Agenda

## Wednesday, September 26, 2018 – RLSB 1S018

<table>
<thead>
<tr>
<th>Time:</th>
<th>Activity:</th>
<th>Speaker:</th>
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</thead>
<tbody>
<tr>
<td>12:00 – 12:05 pm</td>
<td>Welcome&lt;br&gt;Working Lunch</td>
<td>Aditi Martin, PhD OCTRI Awards Program Director</td>
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<tr>
<td>12:05 – 12:15 pm</td>
<td>Course Introduction</td>
<td>Melissa Mudd &amp; Jonathan Jubera</td>
</tr>
<tr>
<td>12:15 – 12:30 pm</td>
<td>Project Introductions&lt;br&gt;Tell us what you’re working on</td>
<td>All Project Teams</td>
</tr>
<tr>
<td>12:30 – 12:50 pm</td>
<td>Paths to Commercialization&lt;br&gt;Using this course to get to the goal line</td>
<td>Ann Demaree</td>
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</tbody>
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**10 Minute Break & Move to Breakout Session Space**

<table>
<thead>
<tr>
<th>Therapeutic – RLSB 1A005 Teaching Lead: Steve Runnels</th>
<th>Device/Diagnostic – RLSB 1S018 Teaching Lead: Ann Demaree</th>
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<tbody>
<tr>
<td>2:00 – 2:30 pm</td>
<td>The Target Product Profile (TPP)</td>
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<td>2:30 – 3:30 pm</td>
<td>Creating your TPP</td>
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**10 Minute Break & Move to RLSB 1S018**

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<tr>
<th>Time:</th>
<th>Activity:</th>
<th>Speaker:</th>
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<tbody>
<tr>
<td>3:40 – 4:20 pm</td>
<td>Intro to Customer Discovery</td>
<td>Stevan Wittenbrock &amp; Charla Triplett</td>
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<tr>
<td>4:20 – 4:30 pm</td>
<td>Market Analysis &amp; Customer Discovery Resources</td>
<td>Robin Champieux</td>
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<tr>
<td>4:30 pm</td>
<td>Closing: Assignment #1</td>
<td>Melissa Mudd &amp; Jonathan Jubera</td>
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Project Teams – Fall 2018 Cohort

MEDICAL DEVICES

PROJECT 1 – OHSU
Project: A measure for circulating blood volume, plasma volume, and red cell volume
Ted Hobbs, Head of Surgery – OHSU/QuantiPort, Inc.

PROJECT 2 – Additive Care
Project: Surgical replicas of MRI & CT data to enhance the pre-surgical planning process
Elliot Parker, Founder/CEO – Additive Care

PROJECT 3 – OHSU
Project: Regenerative medicine & disease models – mimics bone function for in-vitro research and regenerative therapies
Luiz Bertassoni, Assistant Professor – Restorative Dentistry
Katherine Huynh, Student – Biomedical Engineering

PROJECT 4 – OHSU
Project: Novel mouth sealer to decrease oral leaking and improve compliance with nasal CPAP for treatment of Obstructive Sleep Apnea
Kimberly Hutcheson, MD Associate Professor – Neurology

PROJECT 5 – OHSU
Project: Custom-fitted nasal CPAP prongs for preterm infant treatment
Kelli Lund, Research Fellow – Pediatrics

PROJECT 6 – OHSU
Project: Machine learning algorithm
Geoffrey Schau, Student, Biomedical Engineering and Computational Biology
Erik Burlingame, Student, Biomedical Engineering and Computational Biology
PROJECT 7 – OHSU
*Project: Handheld device for intracranial hemorrhage prediction*
Susan Rowell, Associate Professor, Surgery

PROJECT 8 – OHSU
*Project: Nerve specific fluorophores for fluorescence-guided surgery*
Connor Barth, Senior Research Associate, Biomedical Engineering

PROJECT 9 – OSU/OHSU
*Project: Agent for image-guided surgery and intraoperative therapy*
Olena Taratula, Assistant Professor – OSU Pharmaceutical Sciences

PROJECT 10
*Project: Shoe soul to reduce knee joint pressure*
Anil Kumar, Engineer

HEALTH IT/SOFTWARE

PROJECT 11 – OHSU
*Project: Phone app development to assist clinic patients*
Khahn Nguyen, Assistant Professor – Vascular

PROJECT 12 – OHSU
*Project: Web-based tinnitus app*
Candice Manning, Assistant Professor/Research Audiologist – Otolaryngology

PROJECT 13 – Bio Lab Analytics, LLC
*Project: Pain management app*
Paul Sochacki, Founder, Bio Lab Analytics, LLC
PROJECT 14 – OMIC
Project: Genomic medicine platform
Gabe Richman, CEO, Omic
Steve Muller, Head of Engineering, Omic

DIAGNOSTICS

PROJECT 15 – OHSU
Project: Early cancer detection
Thuy Ngo, Research Assistant Professor – CEDAR

PROJECT 16 – OHSU
Project: Early cancer exosome detection
Ting Zheng, Associate Specialist – CEDAR

PROJECT 17 – OHSU
Project: Enzymatic detection of low abundance sequences
Josiah Wagner, Postdoctoral Researcher – CEDAR
Namita Chatterjee, Postdoc – Cell, Developmental and Cancer Biology

PROJECT 18 – OHSU
Project: Quantifiable cell surface proteome analysis method
Viktoriya Dubrovskaya, Specialist – CEDAR

THERAPEUTICS

PROJECT 19 – Flora Medicine
Project: Probiotic face cream
Piper Dobner, ND – Flora Medicine
PROJECT 20 – OHSU

Project: Nanofiber and drug delivery
Negin Mokhtari, Assistant Specialist – CEDAR

PROJECT 21 – Neuralexo

Project: Small molecule therapeutic for Stroke
Marie Foss, Senior Research Scientist – Neuralexo

PROJECT 22 – Asterism Healthcare

Project: Kampo herbs
Pabel Delgado, President & CEO, Asterism Healthcare
Madoka Fukuoka, Asterism Healthcare