



From Benchtop to Bedside
what every scientist needs to know

**A course for scientists, physicians, and graduate students
who want to commercialize innovations
and move research discoveries to the patient**

Course Syllabus
January 23 – April 17, 2018
CLRES 2730 Section 1040

Babs Carryer, Director Education & Outreach, Innovation Institute

bcarryer@innovation.pitt.edu

<http://innovation.pitt.edu>

Office: 412-624-3172; Cell: 412-310-3502

From Benchtop to Bedside

Course summary

This 12-week course is offered by the University of Pittsburgh's Innovation Institute, which supports innovation and entrepreneurship across campus to faculty, staff and students. The Benchtop to Bedside (B2B) course is designed to give research scientists, clinicians, graduate students, and other interested parties the basic information necessary to assess the business potential of research discoveries. The B2B course helps scientists develop focused information, such as proof of concept and validation experiments, that can increase the value of the technology and reduce the investment risk. B2B also gives scientists insight into how intellectual property and other differentiators can create barriers to competition. The course covers the fundamentals of investment from the private sector to help finance the climb over regulatory hurdles and meet critical developmental milestones.

The B2B course content consists of highly interactive seminars that outline the steps necessary to develop a scientific or clinical discovery from the laboratory to the patient. Topics covered include how to:

- recognize an opportunity,
- develop the commercial potential of a scientific discovery,
- protect the intellectual property,
- disclose the invention to the university,
- initiate the university licensing process to a partner company or startup;
- begin early development of a drug candidate or a device for clinical use;
- plan for success within the regulatory and reimbursement guidelines; and
- clarify the scientist's expected role and responsibilities as the process moves forward through clinical and commercial development.

The B2B course can be taken for credit (3 credits) or non-credit. This is a project class, and all attendees must join a group commercialization project. Each project will be presented multiple times during the course. In addition, there are numerous guest speakers throughout the course.

Goals

Upon completion of B2B, attendees are expected to understand the following:

- A process that a scientist can use to screen an invention for commercial potential as a therapy, diagnostic, or device for ultimate use in people;
- How to map out and participate in the process of moving an invention to an innovation to the market, through a road map through regulatory, reimbursement and commercialization hurdles;
- The University and regional resources available to clinicians and researchers to help them move an innovation from the lab to the patient; and
- The need to thoroughly prepare in order to present new technologies to companies and investors, and how to conduct effective interactions with key customers and industry.

Course instructor

Babs Carryer, MPM, Director of Education & Outreach for the [Innovation Institute](#), is a serial entrepreneur, writer and educator. Her role at the university encompasses programs to encourage and support innovation & entrepreneurship across campus to students, faculty, researchers and clinicians. For 15 years, Babs helped to build the entrepreneurial ecosystem at CMU, teaching entrepreneurship and other roles, including as Embedded Entrepreneur for [Project Olympus](#), and Innovation Advisor for the [Institute for Social Innovation](#). She was Director of Training & Faculty Development at [VentureWell](#), (formerly the National Collegiate Inventors and Innovators Alliance). Babs is President of [Carryer Consulting](#), and has worked with hundreds of companies and startups to grow their businesses. Babs is a co-founder of [LaunchCyte](#), with a portfolio of five companies which have commercialized university technologies into marketplace products. Babs has a Masters in Public Management (MPM) from Heinz College at CMU, and a BA from Mills College in CA. She is a co-founder of the [Pittsburgh Chapter of Women in Bio](#) and is currently chapter President of [Sisters in Crime](#). Babs is the author of two books about entrepreneurship (*HD66: search for a cure or a killer?* and *Startup Briefs*); she also blogs about entrepreneurship on [NewVenturist](#).

Projects

There is no exam at the end of this class. The final project for this class is a group presentation of a business opportunity around a new technology. Historically, these projects are in the life sciences field, and are often developed from a biomedical research project. However, the presentation can also be around an original idea developed by the group, as long as the technology exists and is feasible. See project handout for more detail. There will be preparatory presentations leading up to the final presentation. Course attendees are encouraged to invite guests to the final presentations.

For those taking the course for credit there is are three extra projects:

1. Blog post about a topic around innovation and entrepreneurship that interests you (see handout)
2. Interview with an entrepreneur (see handout)
3. Written business plan (see handout)

Logistics

The course is held in Benedum 102 Tuesday evenings from 5-7:30pm from January 23 until April 17, excluding March 6, which is spring break. You are welcome to bring food to class.

Babs can be reached by cell at 412-310-3502, office 4-3172, or by email bcarryer@innovation.pitt.edu.

Course materials

We will use Blackboard (Bb) for all course materials plus secondary materials including articles and publications relating to a particular topic. To access Bb, you need to use your Pitt username and password to log onto the course web system at <http://courseweb.pitt.edu>. Please print/access your own copies of powerpoint presentations.

Required reading for this class is Babs Carryer's "Startup Briefs, the ultimate, no-holds-barred guide to startastartup." You can find it on Amazon in kindle and paperback at: <http://bit.ly/startupbriefs>.

Guest Speakers

In addition to the Babs, there will be numerous guest speakers, including:

- **Barbara Barnes, MD**, is Associate Vice Chancellor, Continuing Education and Industry Relationships for the University of Pittsburgh and Vice President, Sponsored Programs, Research Support, and CME for UPMC. In these roles, she is one of the individuals responsible for implementing the Health Sciences and UPMC industry relationships policy, overseeing commercial support for continuing education, administration of the contracting of industry-initiated clinical trials, and monitoring compliance with billing of clinical services associated with research conducted in UPMC facilities. Barbara is also past chair of the board of directors of the Accreditation Council for Continuing Medical Education, participated on the Association of American Medical College's task force on industry relationships and medical education, and serves on the AAMC's steering committee for the Forum on Conflict of Interest.
- **Eric Beckman, PhD**, is a co-founder and Senior Scientist at Cohera Medical. Eric is the primary inventor of the company's proprietary adhesive technology. He joined Cohera Medical on an entrepreneurial leave of absence from his position as George Bevier Professor of Engineering at Pitt's Department of Chemical Engineering, where he is also co-Director of the Mascaro Sustainability Initiative. Eric received his PhD in Polymer Science and Engineering from the University of Massachusetts. He has held positions in industry, including positions at Monsanto Plastics and Resins and Union Carbide's Silicones and Urethanes Intermediates Division. Eric received the 2002 Academic Presidential Green Chemistry Challenge Award from the EPA, and was honored by the Engineers' Society of Western Pennsylvania as the 2005 Engineer of the Year.
- **Dottie Clower, PhD**, is Chief Scientific Officer at Cohera Medical. Dottie was instrumental in the early formation of the company, dating back to 2003, and led the development of Cohera from its ideation to its successful seed financing. She currently leads Cohera's R&D efforts, and her team successfully brought the company's lead product TissuGlu® Surgical Adhesive from laboratory prototype through human clinical trials. Prior to joining Cohera, Dottie specialized in commercializing early-stage technologies through her leadership position in the University of Pittsburgh's Office of Enterprise Development. Dottie is a neuroscientist and chemist with over 20 years of research experience in both industrial and academic environments. Her work has been published in *Nature*, *Journal of Neuroscience*, *Journal of Neurophysiology*, *Cerebral Cortex*, and *Plastic and Reconstructive Surgery*. Dottie brings experience from Baxter Healthcare where she worked on the development of pre-mixed IV drug delivery systems within Baxter's Pharmaceutical R&D Division. Dr. Clower holds a BA in Chemistry from Northwestern University, and a Ph.D. in Neuroscience from Emory University.

- **Max Fedor, MBA**, is the Executive Director of Pittsburgh CREATES at the University of Pittsburgh, a transdisciplinary collaborative that supports training, education, and sponsored research for advanced surgical technologies. Before joining CREATES, Max was the Director of the Coulter Translational Research Partners II Program, also at the University of Pittsburgh, providing qualified faculty-directed biomedical research teams with funding, support and mentorship to accelerate the translation of their innovative technologies to commercialization. Max brings over 30 years of industry experience in technology development, business development, capital raising, and general management for companies ranging from start-ups to Fortune 500 entities. Most recently, he was President and CEO of BIOSAFE, Inc., an antimicrobial coatings company that was acquired by a leader in specialty chemicals. Prior to that, he was an Executive-in-Residence at the Pittsburgh Life Sciences Greenhouse, helping early stage portfolio companies to achieve initial capitalization and commercial launch. Max has also held senior leadership positions in other life science technology companies, including Vice President of Business Development for Bioimagene, Inc., a software solutions provider for diagnostic image analytics, Vice President of Development and Operations for TissueInformatics, Senior Program Manager for in-vitro diagnostic platforms at Alstom Automation Systems, Inc. (a prime contractor for Bayer Diagnostics), and President and Co-Founder of MedSelect Systems and Ergonics Corp. Max holds a bachelor's degree in Engineering and Applied Sciences from Harvard College and an MBA from the Tepper School of Business at Carnegie Mellon University.
- **F.J. Lucchino, JD**, has represented startups and other businesses for most of his two decades as a lawyer. In addition to being an entrepreneur who launched his own firm (through which he has represented dozens of tech clients), he worked for nearly three years as Vice President and General Counsel for a biotech with several dozen employees that ran multiple human clinical trials. In that role, he oversaw the company's myriad legal needs, including financing, partnership, IP, employment and regulatory matters. He also has large-firm experience, having worked for over three years at one of Pittsburgh's biggest firms. F.J. has assisted clients in-licensing technology from universities such as Pitt, CMU, Harvard and Virginia, and represented biotechs out-licensing technology to publicly traded industry leaders in major deals. More than anything else, F.J. enjoys working with entrepreneurs who are passionate about what they do, and he is inspired by their enthusiasm and willingness to make the sacrifices necessary for a successful entrepreneurial business. More than just a lawyer, clients often view him as a trusted member of their team.
- **Bob Marshall** is the Chief Editor of Med Device Online, a portal committed to advancing human health by connecting people, organizations, and ideas in the medical device industry. He creates content and manages contributed material for an audience of over 40,000 subscribers world-wide. Previously Bob gathered 25 years of experience in medical device product development, operations, manufacturing, quality assurance, and regulatory affairs through leadership roles with three medical device OEMS, two contract manufacturers, a startup company, and a consulting firm. He holds BS degrees in Electrical Engineering & Mathematics, and a MS degree in Organizational Leadership, all from Geneva College.

- **David Smith, JD**, is a Pepper Hamilton LLP corporate lawyer focusing on intellectual property transactions, licensing, venture financings, and regulatory matters for life sciences companies and investors. David is considered an authority on the legal issues surrounding the use of human biological materials. He is the co-founder and co-chair of the ETG Executive Forum, an annual workshop on the commercialization of engineered tissue products and regenerative therapies; he co-authors a column on FDA regulatory initiatives that appears monthly in *Genetic Engineering News*; he is founder and principal of Teregenics, which provides strategic product development analysis and consulting services to investors, research centers and companies involved in developing human tissue engineering and regeneration technologies. David received his AB from Hamilton College and his JD from American University.
- **Jenifer Slinsky Tarasi, JD**, is the Associate Director, Intellectual Property of the University of Pittsburgh's Office of Technology Management. Prior to joining the University, Jenifer was a practicing IP attorney with a mid-sized Pittsburgh law firm for more than 10 years. Her practice at the law firm spanned all areas of intellectual property law, including: patent, trademark and copyright prosecution; negotiating and drafting license agreements, assignments, confidentiality and non-compete agreements; and preparing patentability and non-infringement opinions. Additionally, Jenifer's transactional work has included drafting, reviewing and negotiating asset purchase agreements and joint developments agreements. She has participated in numerous due diligence projects and consulted in IP litigation matters. Jenifer's science background is based in chemistry. However, she has prosecuted patent applications that span the chemical, biotech and mechanical fields. She received a BS degree from Allegheny College, and her JD from the University of Dayton School of Law.
- **David Wehrle, CPA**, is the founding director of the University of Pittsburgh's Conflict of Interest (COI) Office in 2004, and, since 2006, has concurrently held the position of Associate Director of the Office for Investigator-Sponsored IND & IDE Support (O3IS).

B2B course schedule

Date	Topic	Instructors
#1 Jan 23	Welcome and introductions The B2B course Academic entrepreneurship: recognizing opportunity <ul style="list-style-type: none"> • The business of academic research • Overview of the Innovation Institute Exercise: science vs business Projects	Babs Carryer
#2 Jan 30	Pitt Translational canvas and Business basics Projects <ul style="list-style-type: none"> • Project review • Pitching of ideas for projects • Group selection 	Babs Carryer
#3 Feb 6	Entrepreneurial war story – Cohera Medical Group work on projects	Eric Beckman, PhD Dottie Clower, PhD Babs Carryer
#4 Feb 13	Guest speaker: Understanding intellectual property Presentation #1: Pitt Translational Canvas Feedback and discussion	Jenifer Tarasi, JD Babs Carryer
#5 Feb 20	Guest speaker: Regulatory & reimbursement Group work on projects	Bob Marshall Babs Carryer
#6 Feb 27	Presentation #2 The Art of the Pitch and Elevator pitches	Babs Carryer

	Spring break	
#7 Mar 13	Legal basics Group work on projects	F.J. Lucchino, JD Babs Carryer
#8 Mar 20	Presentation #3 Funding Building a team Blog post due 5pm today (for those taking B2B for credit)	Babs Carryer
#9 Mar 27	Guest speaker: Financial modeling Group work on projects	Max Fedor
#10 Apr 3	Guest panel: Scientist-entrepreneur: managing conflict of interest Presentation #4	David Wehrle, CPA Barbara Barnes, MD David Smith, JD Babs Carryer
#11 Apr 10	Marketing, sales and operations Practice presentations Interview with an Entrepreneur due 5pm today (for those taking B2B for credit)	Babs Carryer
#12 April 17	Final presentations Graduation Party!	Babs Carryer
April 24	Business plan due 5m today (for those taking B2B for credit)	