



offers the acclaimed course for scientists:

“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 basic research discoveries to the patient**

Course Syllabus
January 25 – April 19, 2017
CLRES 2730 Section 1040

Babs Carryer, Director Education & Outreach, Innovation Institute

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From Benchtop to Bedside

Course summary

This 12-week course is offered by the University of Pittsburgh's Innovation Institute., which encourages and supports innovation and entrepreneurship across campus to all 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 basic science research discoveries. The B2B course will help scientists develop additional focused information, including proof of concept and validation experiments, that increase the value of the technology and reduce the investment risk. B2B will also give scientists insight into how intellectual property and other differentiators can create a barrier to entry for the competition. The course will cover 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.

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 a potentially important therapy or diagnostic towards clinical trials, or an equally important device through the regulatory pathway;
- The University and regional resources available to clinicians and researchers to help them in the process of getting an innovative therapy, diagnostic, or device 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

Innovation Institute instructors for this course include the following:

Babs Carryer, MPM, Director of Education & Outreach for the [Innovation Institute](#), is an entrepreneur and educator with many years' experience. Her role at the university encompasses programs to

encourage and support innovation & entrepreneurship across campus to all students, faculty, researchers and clinicians. Babs teaches Pitt's [Benchtop to Bedside](#) and [Concept to Commercialization](#) technology commercialization course to researchers, clinicians and graduate students. Babs is a serial entrepreneur, writer and educator. She blogs about entrepreneurship on [NewVenturist](#). For 15 years, Babs helped to build the entrepreneurial ecosystem at CMU, teaching entrepreneurship, 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 also 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](#). Babs has recently completed her first novel, a murder mystery that takes place in a startup, called "HD66 – search for a cure, or a killer?" which will be published in 2016.

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 and exercises leading up to the final presentation. Course attendees are encouraged to invite guests to the final presentations.

Logistics

The course is held in Benedum 102 Wednesday evenings from 5-8pm from January 25 until April 19, excluding March 8, which is spring break.

Course instructor, Babs Carryer, can be reached by cell at 412-310-3502, office 4-3172, or by email at 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. They will be uploaded 24hours in advance.

Guest Speakers

In addition to the Innovation Institute faculty, 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 Vice President of Research and Development and 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 TissueGlu® 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.
- **Greg Coticchia, MBA**, is Director of the Blast Furnace, the Pitt student accelerator. He is also Entrepreneur-in-Residence at the Innovation Institute. Greg is an award-winning technology executive with over 25 years' experience in high tech products and services. He is considered by many to be one of the best strategic minds and marketing executives in the technology business. He was major contributor in two of the largest and most successful software companies in the world, LEGENT (now CA) and AXENT (now Symantec). Recently, as CEO and co-founder of eBillingHub, he grew the company from inception to a leading market position that led to its sale to Thomson Reuters. Greg has participated in raising over \$63M in venture capital, and over 17 mergers and acquisitions at the company or product level. Greg has served as CEO (three times) and has been involved with launching over 100 products and solutions. A graduate of Pitt in Industrial Engineering, where he also received his MBA, he currently teaches business-to-business marketing at Katz and acts as Executive in Residence (EIR) for Pitt in the areas of software and IT. As EIR, Greg's job is to facilitate the licensing of Pitt-developed software to startups and corporations.
- **Maria Fagan** is President and Co-Founder of Regulatory and Quality Solutions (R&Q) which provides industry-leading regulatory and quality engineering services throughout the entire medical device product lifecycle, including remediation. Maria and partner Lisa Casavant launched R&Q in July of 2008 and the firm has now serviced more than 175 clients. In 2015 R&Q ranked #1,440 on the Inc. 5000: a list of the fastest-growing private companies in America. This bettered the ranking of #1,651 in 2014. Maria has worked in regulated industry for over 30 years, and in

the last 25 years she has focused on medical device quality and regulatory. Prior to founding R&Q, she held positions of increasing responsibility at MEDRAD Inc. (now owned by Bayer), a medical device manufacturer in both quality and regulatory arenas. MEDRAD is a two-time winner of the Malcolm Baldrige quality award. She received a B.S. degree in Mechanical Engineering from the University of Pittsburgh and holds a certificate in Business Management from Carnegie Mellon University. Her international experience includes Regulatory Director of Europe, Middle East, and Africa for MEDRAD which included regulatory submissions, post-surveillance activities, and more.

- **Carolyn Green** is Executive Director of Pfizer's R&D Innovate, ERDI, a new Pfizer Worldwide R&D program that makes equity investments in companies that are of strategic interest to Pfizer. Previously, Carolyn was President of Atrean, Inc., a privately held biopharmaceutical company developing a novel engineered protein called Atsttrin, for the treatment of inflammatory diseases such as Rheumatoid Arthritis. Prior to joining Atrean, Carolyn was President, Chief Operating Officer and co-founder of Logical Therapeutics, Inc., a clinical stage biopharmaceutical company developing bio-activated non-steroidal anti-inflammatory prodrugs for arthritis and chronic pain. For Logical, Carolyn helped to raise \$45 million in venture financing from a syndicate of highly regarded venture capital funds. Carolyn was the founding Director of the OED at Pitt, and in this role facilitated numerous spin-outs. She has held various leadership and sales positions, including CEO of Mobot, Inc., which specialized in artificial intelligence software and hardware for human-computer interactions, Director of North American Marketing and Sales for publicly-traded AEA Technology plc, in the computer-aided engineering software sector, and Business Manager for Algor, Inc., where she was responsible for the business development, sales and customer service sectors. Carolyn has a BS in Chemistry from the University of Pittsburgh.
- **Marc Malandro, PhD**, is the Vice Chancellor of Technology Management and Commercialization at Pitt, and Founding Director of the Innovation Institute. Prior to joining the University, Dr. Malandro co-founded Sagres Discovery, a functional biology company focused on understanding the molecular basis of cancer, where he served as Vice President of Technology and Strategic Alliances. His responsibilities included developing and implementing high-throughput gene identification and gene expression analysis platforms, managing company intellectual property, technology licensing and overseeing scientific collaborations. Sagres Discovery was acquired by the Chiron Corporation, now a part of Novartis. Prior to Sagres, Marc served as Director of Genomics and Applications Development at Celera Agricultural Genomics (Celera AgGen), a division of Celera Genomics, and as Director of Research at PE Agricultural Genomics (PE AgGen), a division of Applied Biosystems. At Celera and Applied Biosystems, Marc was responsible for developing and implementing high-throughput molecular marker technologies and products in plants and animals. He also developed a high-throughput platform for expression-based gene discovery in agriculture that led to the development of several large research collaborations with leading agrochemical and biotechnology companies. Marc received his PhD in Biochemistry and Molecular Biology from the University of Florida, College of Medicine, and completed his postdoctoral fellowship in the Department of Human Molecular Genetics at Case Western Reserve University. He is the co-inventor on 15 issued patents and patent applications.
- **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 Slinskey 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 25	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, licensing, startups, and intellectual property Exercise: science vs business Projects Entrepreneurship @ Pitt	Babs Carryer
#2 Feb 1	Cohera Medical Panel Projects <ul style="list-style-type: none"> • Project overview • Pitching • Groups 	Eric Beckman Dottie Clower Babs Carryer
#3 Feb 8	Business basics <ul style="list-style-type: none"> • Market focus • Business Model Canvas #1 Business Model Canvas presentations	Babs Carryer
#4 Feb 15	Finish #1 Business Model Canvas presentations Customer discovery <ul style="list-style-type: none"> • Market research • Interviewing customers & stakeholders • Competition Value proposition	Babs Carryer
#5 Feb 22	Voice from the trenches: Getting from the bench to the bedside	Carolyn Green Babs Carryer
#6 March 1	Understanding intellectual property Group work on projects	Jenifer Tarasi Babs Carryer

	Spring break	
#7 Mar 15	Art of the Pitch Group work on projects	Greg Coticchia Babs Carryer
#8 Mar 22	Primer on finance Building a team	Babs Carryer
#9 Mar 29	Scientist-entrepreneur: managing Conflict of interest: panel #2 Business Model Canvas presentations	David Wehrle Barbara Barnes David Smith, JD Babs Carryer
#10 Apr 5	Financing: building the value chain Finish #2 Business Model Canvas presentations	Babs Carryer
#11 Apr 12	Regulatory & reimbursement, why these are Important Guest speaker on the regulatory and reimbursement pathways Elevator pitches Group work on projects	Maria Fagan, R&Q Solutions Babs Carryer
#12 April 19	Final presentations Graduation Party!	Babs Carryer
April 26	Final submission of executive summaries for those taking B2B for credit	