



University of Pittsburgh

Innovation Institute, School of Health Sciences

presents

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 7 – April 15, 2014
CLRES 2730 Section 1040

Offices of Enterprise Development and Technology Management

Marc Malandro, Ph.D., Associate Vice Chancellor and Director

Contact information:
Office of Enterprise Development
101 Gardner Steel Conference Center
Thackeray and O'Hara Streets
Pittsburgh, PA 15260
412-624-3160 Phone
412-624-3164 Fax

<http://www.oed.pitt.edu>

<http://www.otm.tt.pitt.edu>

Course instructor, Babs Carryer, bbc10@pitt.edu

From Benchtop to Bedside Course summary

This semester-long course is offered by the University of Pittsburgh's Offices of Enterprise Development and Technology Management, both of which are now combined under the new Innovation Institute. This course is designed to give research scientists, clinicians, and other interested parties the basic information necessary to assess the business potential of basic science research discoveries. The 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. The course 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 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, and plan for success within the regulatory and reimbursement guidelines. In addition, the course will clarify the scientist's expected role and responsibilities as the process moves forward through clinical and commercial development.

Goals

Upon completion of the course, 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 life science 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 instructors

This course is designed and hosted by the Offices of Enterprise Development and Technology Management (OED and OTM respectively), established to encourage and support entrepreneurial activities throughout the University of Pittsburgh Schools of Health Sciences through education and resource support. The instructors for this course include the following:

- **Babs Carryer** is a serial entrepreneur, writer and educator. She blogs about entrepreneurship on New Venturist. At Pitt, Babs teaches the Benchtop to Bedside technology commercialization course. For 2014, she is managing the Randall Family Big Idea competition, which is open to all

students and all schools/departments. Babs taught entrepreneurship at CMU for 15 years. She was Embedded Entrepreneur for CMU's Project Olympus for four years, and also Innovation Advisor for CMU's Institute for Social Innovation. She was director of training and faculty development at the National Collegiate Inventors and Innovators Alliance (NCIIA). Babs is President of Carryer Consulting and co-founder of LaunchCyte, with a portfolio of companies, almost all of which are in the life sciences. Babs has a Masters in Public Management (MPM) from Heinz College at CMU, and a BA from Mills College in CA.

- **Marc Malandro, PhD**, is the Associate Vice Chancellor of Technology Management and Commercialization, and the Director of the Office of Enterprise Development and the Office of Technology Management at Pitt. 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.
- **Paul Petrovich, CPA**, is the Assistant Director, Technology Commercialization, at the Office of Enterprise Development, where he works closely with Office of Technology Management and university researchers to promote spin-out and start-up companies that utilize University/UPMC discoveries. As a veteran consultant, Paul has provided management consulting services in all business sectors: service, retail, manufacturing and technology-based companies. He maintains an expertise in the federal Small Business Innovation Research (SBIR) program and has consulted with over 80 participant companies, with successful awards of over \$25 million. In 2006, he received the prestigious national Tibbetts Award recognizing his services connecting Western Pennsylvania's technology innovators with SBIR funding for product development. Paul holds a Bachelor of Science in Business Administration from Indiana University of Pennsylvania, and is a member of the Pennsylvania and American Institutes of Certified Public Accountants.

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 102 Benedum Hall from 5-8pm.

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.

Administrative support

Administrative support for this course is provided by Karen Zellars, who can be reached at the OED at 412-624-3160 or by email at zellars@pitt.edu.

Course instructor, Babs Carryer, can be reached by cell at 412-310-3502, or by email at babs@carryer.com or bbc10@pitt.edu.

Guest Speakers

In addition to the OTM/OED 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 Mascaró 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 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.

- **Greg Coticchia, MBA**, 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. In the past three years, Pitt has received over 65 invention disclosures and launched seven (33% of all startups) in software.
- **Patrick Daly** is President and CEO of Cohera Medical. Patrick has over 20 years of experience in medical device sales, marketing, international marketing and leadership positions throughout the Johnson & Johnson organization, including Ethicon Endo-Surgery, Ethicon Products, J&J Medical Australia/New Zealand, J&J Medical Asia Pacific.® For Cohera, Patrick has led three successful funding rounds of over \$57.8M in capital from private investors to facilitate the company's lead product, TissuGlu® Surgical Adhesive, through the FDA approval process for medical devices. Previously, Patrick spent over four years on active duty in the U.S. Army as a field artillery officer serving around the world. A native of New York, he is a graduate of the U.S. Military Academy at West Point where he received a B.S. in Engineering with a concentration in Latin American Studies. He played varsity lacrosse during his four years at West Point and was an All-American. Mr. Daly serves on several Boards, including the Emerging Growth Company Council (EGCC) for the Advanced Medical Technology Association (AdvaMed), the Pittsburgh Technology Council, and Girls Hope, a nonprofit that provides a well-balanced, nurturing home and quality education through college for academically capable girls. He is also a member of the Young Presidents Organization.
- **Carolyn Green** is 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. Atrean recently completed a \$20 million Series A financing to support the pre-clinical development of Atsttrin. 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.

- **Bob Marshall** is the Director of Growth for Regulatory & Quality Solutions (R&Q), a national professional services company serving the medical device industry. R&Q is headquartered in Murrysville, Pennsylvania and has an office in Cleveland, Ohio in addition to other resources across the US. Bob has over 20 years of experience in all aspects of medical device product development, manufacturing, quality assurance, and regulatory affairs. Bob previously held leadership positions with Renal Solutions (now Fresenius Medical Care), Siemens Medical Solutions, Medrad (now Bayer HealthCare), and Respironics (now Philips Healthcare). He holds a BS degree in Electrical Engineering and a Master of Science degree in Organizational Leadership, both from Geneva College.
- **Larry Miller, MBA**, is an Executive-in-Residence at Innovation Works, one of Pittsburgh's regional economic development organizations. Larry has more than 20 years experience in leading and managing medical device companies. Previously, Larry was President and CEO of Biomec, a privately held technology accelerator and investment company, which raised over \$20M in SBIR grants and provided contract engineering and manufacturing as well as business development consulting for radiology product manufacturers and distributors. Larry was President of the Healthcare Products group at Picker International and Philips Medical systems, a \$600M distributor of radiology supplies. He also managed the Asia/ Pacific region for sales and service of the diagnostic imaging product portfolio, and was president of the Picker Financial Group, a JV, captive leasing company. Larry earned his BS in Mechanical Engineering from the University of Pennsylvania and an MBA from the Wharton School.
- **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	Assignments
#1 Jan 7	<p>Welcome and introductions</p> <p>Academic entrepreneurship: recognizing opportunity</p> <ul style="list-style-type: none"> • The business of academic research • Overview of OTM <p>Overview of entrepreneurial ecosystem at Pitt</p> <p>Overview of B2B course Overview of projects Exercise: science vs business</p>	Marc Malandro Babs Carryer Paul Petrovich	Think about projects for next week
#2 Jan 14	<p>Introduction to entrepreneurship</p> <ul style="list-style-type: none"> • Lecture/discussion: problem, pain, solution, customers, key challenges to commercialization • Quick screen overview <p>Projects</p> <ul style="list-style-type: none"> • Projects overview • What projects are already here? • What projects Pitt has which can be used. • Groups (matching participants, MBA, law students to projects) • Group introductions • Quick Screen 	Babs Carryer	Quick screen project
#3 Jan 21	<p>Guest panel: Cohera</p> <p>Group work on quick screen Group meetings with Babs/Paul</p>	Eric Beckman Dottie Clower Patrick Daly Babs Carryer	Think of IP questions for next week Quick screen project
#4 Jan 28	<p>Understanding intellectual</p>	Jenifer Tarasi	Finish quick

	<p>property</p> <p>Group work for Quick screen presentations</p>	Babs Carryer	screen presentations for next week
#5 Feb 4	<p>Quick screen presentations Q&A, critique, discussion</p> <p>Market analysis/research, customers, competition, business model canvas, value proposition</p> <p>Exercise on value proposition Sharing and discussion</p>	Babs Carryer Paul Petrovich	
#6 Feb 11	<p>Building a team</p> <p>Exercise on team Sharing and discussion</p> <p>Group work on projects Team meetings with Babs/Paul</p>	Babs Carryer	
#7 Feb 18	<p>Primer on finance</p> <ul style="list-style-type: none"> • Revenues, expenses and projections • Supply chain • Business model <p>Exercise on revenue model Sharing and discussion</p>	Paul Petrovich Babs Carryer	
#8 Feb 25	<p>Financing: building the value chain</p> <ul style="list-style-type: none"> • Economic development funding • SBIR/STTR programs • Equity and debt financing <p>Exercise on funding Sharing and discussion</p>	Larry Miller Paul Petrovich Babs Carryer	
#9 March 4	<p>Regulatory & reimbursement, why these are Important</p> <ul style="list-style-type: none"> • Guest speaker on the regulatory and reimbursement pathways and potential hurdles 	Bob Marshall, R&QS Babs Carryer	

	Business plan basics		
Mar 11	SPRING BREAK PITT no class		
#10 Mar 18	Voice from the trenches: From Series A to Phase 2b Group time	Carolyn Green Babs Carryer	
#11 Mar 25	Scientist-entrepreneur: managing conflict of interest <ul style="list-style-type: none"> • Panel discussion Elevator pitches Project overview reminder Group time	David Wehrle Barbara Barnes David Smith, JD BabsCarryer	Prep elevator pitch for next week
#12 April 1	The art of pitching Elevator pitch presentations	Greg Coticchia Babs Carryer	Prepare final presentation and executive summary
#13 April 8	Group project time Practice pitches	Babs Carryer	Prepare final presentation and executive summary
#14 Apr 15	Final presentations Graduation Party!		Finish executive summary to hand in next week by email