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BIOMEDICAL INNOVATION AND ENTREPRENEURSHIP BOSTON CERTIFICATE PROGRAM

CONTENTS

BIOMEDICAL INNOVATION AND ENTREPRENEURSHIP CERTIFICATE PROGRAM

The Institute for Biomedical Entrepreneurship (IBE) develops and delivers a variety of formal and informal educational programs for researchers and other innovators which will:

- Provide an understanding of the execution processes involved in developing ideas into commercial successes, the major components of full-cycle development of an idea into a successful enterprise;
- Prepare participants to readily analyze and validate commercial potential of their research, and to intelligently evaluate potential startup opportunities for personal involvement;
- Leave participants capable of beginning the implementation process on ideas that merit development, and;
- Provide participants access to resources for developing their ideas and pursuing validated opportunities into commercial development.

CERTIFICATE PROGRAM

The IBE certificate program can be useful for anyone having an idea and much, little or no pre-existing entrepreneurial experience. The format is designed as a resource for multiple audiences including faculty, researchers, staff, and alumni with an interest in biomedical innovation and commercialization. Participants successfully completing the program requirements will have access to the business development and financing resources of the IBE's extensive network and project development company.

SCHEDULE

45 hours of class work and individual sessions with instructors and IBE network advisors, plus project time, and follow-on engagement with the IBE network.

ASSIGNMENTS

Because one of the core entrepreneurial skills is an ability to define opportunities, problems, and solutions when there is no pre-existing plan or structure, there is a prominent experiential component to this course. Assignments will be organized around a self-selected medical innovation business idea and will culminate in a business presentation to an experienced business and investor panel at the end of the program. The course will draw on lectures, discussions, group project presentations, sample presentations by successful startups, and guest lecturers with distinctive experience and expertise. There will be required and suggested readings. Students will not develop a full business plan, but will address, at a first-pass level, most of the early-stage development elements that appear in a plan. Final written deliverables for students taking the course for credit will be:

- An executive summary ("pitch sheet" format, 1-2 pages) suitable for wide distribution in promoting a startup idea;
- Written business case rationale for starting the company around the opportunity;
- A PowerPoint pitch presentation (15 pages or less) and;
- A due diligence analysis of another project presented in the class.

RECOMMENDED READING

Fairbrothers, Gregg, and Tessa M. Winter. *From Idea to Success: The Dartmouth Entrepreneurial Network's Guide for Startups*. New York: McGraw-Hill, 2012. Print.

- Introduction
- Chapters 1, 2 and 5
- Available on amazon.com in hard copy or kindle versions

Feguson, Steven M., and Uma S. Kaundinya. "14 - Licensing the Technology: Biotechnology Commercialization Strategies Using University and Federal Labs " Biotechnology Entrepreneurship: Starting, Managing, and Leading Biotech Companies. By Craig D. Shimasaki. N.p.: Academic, 2014. N. pag. Print.

https://www.ott.nih.gov/sites/default/files/documents/pdfs/Ferguson-Chapter14-BiotechEntrepreneur-2014.pdf

Ferguson, Steven M. "Partnering with the NIH: Now Part of the “Value Proposition” for Start-ups." Journal of Commercial Biotechnology. U.S. National Library of Medicine, 01 Apr. 2012. Web. 28 Feb. 2017.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3589979/

Rose, Don, and Cam Patterson. *Research to Revenue: A Practical Guide to University Startups*. Chapel Hill: U of North Carolina, 2016. Print.

- Introduction
- Chapter 1 and 2
- Chapter 3 pages 83-85, 87-95 and 121-126
- Available on amazon.com in hard copy or kindle versions

Sarasvathy, Saras D. "What Makes Entrepreneurs Entrepreneurial?" Effectuation: Society for Effectual Action. The Darden Graduate School of Business Administration, University of Virginia, n.d. Web. 01 Nov. 2016.

http://www.effectuation.org/sites/default/files/documents/what-makes-entrepreneurs-entrepreneurial-sarasvathy.pdf

Stevenson, Howard H., and David E. Gumpert. "The Heart of Entrepreneurship." Harvard Business Review. Harvard Business Review, 01 Aug. 2014. Web. 01 Nov. 2016.

https://hbr.org/1985/03/the-heart-of-entrepreneurship

REQUIRED MATERIALS

Participants will work in groups to develop an idea and present to reviewers on Sunday. Each participant should come with some ideas for projects to propose for group work. The IBE faculty will provide guidance on developing the final presentation. The more prepared each participant is prior to the program, the more time that is available to refine presentations for Sunday.

COURSE TOPICS

INTRODUCTION AND COMMERCIALIZATION OF RESEARCH

Session Objectives:

- Introduction to the course and speakers
- What is creativity and how does it lead to innovation and development?
- Role of entrepreneurship in moving ideas to reality
- Class format, schedule

ENTREPRENEURIAL EXECUTION AND TEAMS

Session Objectives:

- Definitions of key terms and concepts, the nature of entrepreneurial thinking
- Research and commercialization
- What is success? Setting goals, personal and company.
- Ideas and execution, challenges
- Better understand behavioral drivers and barriers to success
- Preparing yourself for continued personal and professional development relative to entrepreneurship

COMMERCIALIZING UNIVERSITY TECHNOLOGY AND THE ROLE OF STARTUP COMPANIES

Session Objectives:

- University Startup: characteristics and context
- Conflicts of interest and conflicts of commitment
- Use of students, confidentiality and open inquiry
- Consulting arrangements and policy
- Who owns the intellectual property? Factors and policy
- Use of space
- Working with tech transfer offices:
    - Disclosing to the university: Why disclose? When to disclose?
    - Licenses and options to license
    - Grants and restrictive provisions
    - Patent costs and prosecution

VALIDATION OF AN IDEA

Session Objectives:

- Development steps
- Timing of validation efforts
- Strategies and tactics

DEVELOPING PEOPLE AND THE TEAM

Session Objectives:

- The central importance of the people; teams
- Investors bet the team
- The founding team
- Beyond the founding team
- Hiring people and growth issues
- People needs change over time
- Advisors, directors and working with Boards
- Developing teamwork skills
- Team exercises

PARTNERING WITH YOUR "UNCLE SAM" -- NOW PART OF THE "VALUE PROPOSITION" FOR START-UPS

Session Objectives:

- In-licensing of NIH technology
- Research collaborations with intramural NIH
- Using pre-clinical / clinical NIH services
- Selling products / services to NIH
- Getting grants & contracts from NIH
- Utilizing NIH information sources

INTELLECTUAL PROPERTY

Session Objectives:

- Patents and patenting
- Copyrights
- Trade Secrets
- Protecting confidentiality
- Confidentiality agreements
- Working with attorneys

BUSINESS PLANS

Session Objectives:

- Purpose of plans and planning
- Uses of plans and presentations – as idea development tools, as selling tools
- Business planning outputs: "Elevator pitch", Executive summary, PowerPoint presentations, Written business plans, Additional diligence materials
- Sample pitches and summaries
- Effective plans - the needed elements, the "10-slide" sample content template
- Written plans and due diligence

REGULATORY PROCESS AND APPROVALS

Session Objectives:

- Regulatory agencies; their history and structure - US and other jurisdictions
- Relevant statutes and regulations
- FDA, international process and stages - advantages and disadvantages of different venues
- Filing and working with the agency
- Common pitfalls
- Outside resources and how to work with them

LICENSING – TERMS AND MECHANICS

Session Objectives:

- Strategies
- Types
- Territory/fields of use
- Exclusivity vs non-exclusivity
- Up-front fees
- Milestone payments
- Equity and anti-dilution
- Royalties
- Sub-licensing
- Relinquishment and other due-diligence provisions

MARKET ANALYSIS, SALES, REIMBURSEMENT

Session Objectives:

- Overview of Life Science Product Commercialization
- Identify Factors Critical to a Successful Product Launch
- Explain the Brand Planning Process
- Describe How Products are Priced
- Insight on the Reimbursement Process

FINANCING

Session Objectives:

- Private equity primer
- Alternatives for funding
- Strategic investors and collaborative agreements
- Angels and venture capital basics
- The venture capital process and structure
- Decision drivers for investors
- Valuations and basic deal terms

SCIENTIFIC VALIDATION, SCIENTIFIC REPLICATION AND THE COMMERCIAL PATHWAY

Session Objectives:

- Defining what investors and partners will look for and need.
- Defining key elements for success.
- Establishing, testing and documenting that the product, process or system meets its pre-determined specifications and quality attributes relative to standards required to achieve regulatory approval.
- Establishing, testing and documenting the process by-which a product can be replicated and scaled in accordance with manufacturing standards and regulatory requirements established for commercial products.
- The requirements and process of establishing, transitioning and documenting Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Manufacturing Process (GMP) in accordance with regulatory standards.

PRESENTATIONS AND COMMUNICATION

Session Objectives:

- Channels of communication
- Effective communication challenges, the “Curse of Knowledge”
- Heaths’ SUCCESS acronym –simple, unexpected, concrete, credible, emotional, stories
- Make it personal
- The power of images
- Emotions and decision-making
- Exercises by class - repeat pitches

LEGAL CONSIDERATIONS FOR STARTUPS

Session Objectives:

- Primer on considerations in setting up companies
- Deciding to incorporate
- Forms of incorporation and structuring
- Incorporation steps: commonly needed documents and agreements; key decisions
- Attorneys: their role; how to find and manage outside attorneys
- Agreements and written contracts:
- Business regulation: legal risks and potential litigation; factors to consider
- Credit law: creditors' rights and bankruptcy law; considerations in structuring finances

EXITS

Session Objectives:

- Planning for exits in biomedical companies
- Alternatives:
    - Licensing
    - Partnering and joint ventures
    - Acquisition
    - Public offering
- Factors to consider
- Positioning for exit: process and negotiation
- Resources and advisors

LEADERSHIP AND TEAMWORK

Session Objectives:

- Review of behavioral dynamics that impact effective leadership.
    - Motivation - theory
    - Listening - what disrupts your approach
    - Conflict Resolution - what is the hierarchy of behavior used to resolve conflict
    - Interpersonal Skills - more complicated than one thinks, "why are you viewed as introverted/extroverted".
    - Engagement - impact of stress and confidence
    - Acumen - the intersection on interpersonal and situational acumen

IBE BOARD OF DIRECTORS

GREGG FAIRBROTHERS, PRESIDENT – GROUPS-RECOVER TOGETHER

Fairbrothers is President of Groups-Recover Together, a for-profit medical startup that provides affordable treatment helping people to recover from opioid addiction, and is the founding executive chairman of therapeutic development company, Peroxyium, Inc. Fairbrothers is also a founder and board member or chair of currently active technology companies and two nonprofit organizations, The Institute for Biomedical Entrepreneurship and the Eleazar Wheelock Society.

Previously and for fourteen years, Mr. Fairbrothers was the founding director of the Dartmouth Entrepreneurial Network, Dartmouth College, and an adjunct professor of Business Administration in Regional Technology Center (DRTC), Inc. a free-standing New Hampshire non-profit corporation that operates a 55,000 sq. ft. technology incubator facility developing technology-based innovations with the potential for significant social impact, and in 2006-2009 co-founded the Apologia student journal at Dartmouth and the Eleazar Wheelock Society, where he still is a trustee. In 2016 he joined the Institute for Biomedical Entrepreneurship in Cambridge, MA as a co-founding board member.

Fairbrothers has more than 22 years of experience in almost all operational and investment-related aspects of the upstream oil and gas industry, including exploration, exploitation, production, marketing, acquisitions and divestment, joint ventures, and corporate finance through banks, multi-lateral institutions, limited partnerships and public markets (including IPOs and unsolicited purchases). Prior to returning to the Upper Valley in 1999, he was President and founder of a mid-sized international oil and gas producer, Samson International, Ltd., as well as President of Samson Resources, Inc., and a Director of the companies' parent holding company, Samson Investment Company.

Fairbrothers earned an MS in Geology from Rutgers University, and received his MBA from the University of Tulsa. He graduated magna cum laude with a BA in Earth Sciences from Dartmouth College.

ANTHONY MANNING, PHD, SENIOR VICE PRESIDENT, RESEARCH - MOMENTA PHARMACEUTICALS

A biomedical scientist by training, Tony has devoted the last 20 years to understanding the molecular basis of autoimmune disease and discovering novel therapeutic. He has held senior leadership positions within startup, mid-sized biopharma and global pharmaceutical companies. He has been responsible for the discovery of novel therapeutic targets and the advancement of large portfolios of both biologics and small molecules through pre-clinical and clinical development. He has worked with many exceptional and passionate scientists, who under his leadership discovered the key components of the NF-kB signal transduction pathway, and has delivered multiple novel biologics and small molecules into clinical development. At Roche Pharmaceuticals, he contributed to the development of Actemra and Rituxan for the treatment of rheumatoid arthritis. His experience as a senior leader in both the biotechnology and Pharma industries have provided him with unique insights into how to leverage innovation to build high value pipelines and companies. Manning has experience guiding external collaborations, venture investments, and incubator companies, and as a Board Observer for several biotechnology companies. He is a strong proponent for the role of education, and for the fostering the entrepreneurial approach to innovation.

CURTIS SPROUSE, PRESIDENT AND CEO - EUREKACONNECT

Curtis Sprouse brings more than 30 years of experience in the biotech, pharmaceutical, device and high-tech industries to his position as Founder, President and CEO of EurekaConnect, LLC a behavioral science company focused on personal and professional development. Curt is also a Founder and President of the Institute for Biomedical Entrepreneurship. As a founder of Boston Market Strategies, Inc, Curt worked with hundreds of organizations including many Fortune 500 companies. Curt has advised on business development, sales, marketing and clinical trial strategy for over 20 years. Curt founded iBall, Inc. a virtual core imaging lab focused in the clinical research market. Curt has also founded a publicly traded company focused on research and marine salvage. Prior to founding Boston Market Strategies Inc. and EurekaConnect, Curt served as Director of Special Projects for Mertech. He also served as Chief Financial Officer for OnDuty and Staff Support before assuming the role of President. Curt started his career as staff auditor at Ernst & Young (then Ernst & Whinney). Curt studied Business, Finance, Economics and Accounting at Westminster College in Wilmington, Pennsylvania where he also played football and ran track for all four years. In his spare time, Curt enjoys riding his motorcycle, golf, boating, down-hill skiing and most importantly spending time with his three kids and wife Stephenie in the North Shore town of Ipswich.

CHUCK YON, GENERAL COUNSEL - CHECKMATE PHARMACEUTICALS

Chuck is a transactional and licensing lawyer with extensive experience in funding and licensing technology for biotechnology and pharmaceutical companies. He has negotiated and closed more than 50 major (>$1 million) licensing, distribution and collaboration agreements with pharmaceutical, biotechnology, medical device and clean energy companies. Chuck has represented major research institutes and educational institutions and has licensed technology from leading research universities. He serves as outside General Counsel for several of his clients, providing licensing, regulatory and compliance advice, antitrust analysis, contract review and business strategies advice. As Senior Vice President, General Counsel and Secretary at Coley Pharmaceutical Group from 2001 through 2008, Chuck was responsible for all legal and regulatory matters, including patent prosecution and litigation strategy. He was the co-leader of the team that negotiated and completed the sale of Coley to Pfizer in 2008 for $250,000,000. Prior to Coley, Chuck was the Senior Vice President and General Counsel for Astra Pharmaceutical Products from 1989-1998.

He graduated with honors from Harvard College and Georgetown Law School. He also received an Executive MBA degree from the Kellogg School of Management at Northwestern University.