

The Biotechnology Innovation Organization Presents:

The Fifteenth Annual Biotechnology Entrepreneurship Boot Camp

Sunday, June 2 and Monday, June 3, 2019

Room 108A, Level 100

Pennsylvania Convention Center

Boot Camp Co-Chairs

National Co-Chair

Dennis Gross, MS, PhD
CEO, Pennsylvania Drug
Discovery Institute at the
Pennsylvania Biotechnology
Center

National Co-Chair

**James F. Jordan, MBA,
CHT**
President & CEO, Pittsburgh
Life Sciences Greenhouse
Distinguished Service
Professor in Healthcare &
Biotechnology Management,
Carnegie Mellon University

Local Co-Chairs

Wendy DiCicco
Board Member, Carmell
Therapeutics

Kathryn Doyle PhD, JD
Partner, Saul Ewing Arnstein &
Lehr

**Harold Safferstein, PhD, JD,
MBA**
Senior Vice President, Corporate
Development, Cognition
Therapeutics

National Co-Chair Emeritus

Arthur A. Boni, PhD
John R. Thorne Distinguished
Career Professor of
Entrepreneurship Emeritus,
Tepper School of Business,
Carnegie Mellon University
Editor in Chief, Journal of
Commercial Biotechnology

National Co-Chair Emeritus

Stephen M. Sammut, MBA
Senior Fellow, Health Care
Management and Lecturer,
Entrepreneurship, Wharton
School, University of
Pennsylvania

BIO Coordinators

Sarah Arth, CAE
Vice President, Education
Biotechnology Innovation
Organization

Sarah Maki
Manger, Education
Biotechnology Innovation
Organization

Jocelyn Moratzka
Coordinator, Education
Biotechnology Innovation
Organization

History: The 2005 to 2019 Boot Camps

The Biotechnology Entrepreneurship Boot Camp was founded by Professors Arthur Boni of the Tepper School of Business at Carnegie Mellon, and Steve Sammut of the Wharton School, and by Jeffrey Libson, Partner, Pepper Hamilton LLP and Lecturer at Wharton School Health Care Management Program. The first Boot Camp was launched at the 2005 BIO Industry Organization's Annual Meeting in Philadelphia. The Boot Camp was originally designed as a program for CSOs but is now expanded in scope and design to address a broad range of issues for entrepreneurs more generally. The Boot Camp was created in response to the growing need in the managerial, scientific and academic community to learn about the necessary elements and skills to transform technology and invention into a viable company. The Biotechnology Innovation Organization through its BIO 2005 Academic-Industry Committee ("AI") worked with the founders to develop this unique program to fill this knowledge gap. The insight and energy required for entrepreneurial success can be developed by anyone motivated to think strategically, select projects and plan for expeditious and cost-effective management, understand the requirements of all the involved stakeholders, and oversee the essential components of the commercialization process.

The Boot Camp concept is Philadelphia's legacy gift to BIO and future annual meetings. The intention is that the Boot Camp will travel from year to year to each of the BIO International Convention venues – a veritable "moveable feast." Now in its fourteenth year, the Boot Camp was offered at BIO International Convention's in Chicago in 2006, 2010, and 2013, Boston in 2007 and 2012, Philadelphia in 2005 and 2015. San Diego in 2008, 2014 and 2017, Atlanta in 2009 and Washington, DC in 2011. The creation of the syllabus, the recruitment of faculty, and the faculty's extensive preparation suggested that wherever possible there should be core faculty, i.e., a portion of the faculty from the Philadelphia Boot Camp who would volunteer from year to year. This approach has the added benefit of improving the presentations and the material from year to year as the faculty themselves identify what works, as well as how to teach together. Most of the faculty (and presenting companies), however, is recruited from the host region.

To facilitate and incorporate local participation, local co-chairs are recruited each year. In previous years, Local Co-Chairs were:

Chicago, IL, 2006:

- Panayiotis P. Constantinides, Ph.D, Principal, Biopharmaceutical & Drug Delivery Consulting
- Elsie Quait-Randall, Ph.D., MBA Executive Director of the Office of Research Contracts and IP, McMaster University, formerly of Office of Technology Transfer, Argonne National Laboratory

Boston, MA, 2007:

- Robert Creeden, Partners HealthCare Systems, Inc., Managing Director, Center for Innovative Ventures

San Diego, CA, 2008

- Kurt A. May, MBA, Assistant Dean, Executive Development Center, Rady School of Management, University of California, San Diego
- Duane J. Roth, Chief Executive Officer and Member of the Board of CONNECT.
- Steve Flaim, PhD, FACC, FAHA, Chairman Emeritus, Tech Coast Angels, Director Angel Capital Association

Atlanta, GA, 2009

- Frank R. Hunt, MS MBA, President, SE bioStrategies, Inc., CEO, PNP Therapeutics, Inc.
- Dennis P. Schafer, CEO, Life Science Management

Chicago, IL, 2010

- Patrick G. Morand, Managing Director, SWMF Life Science Fund
- Charles B. Hoslet, Managing Director, UW-Madison Office of Corporate Relations

- Allen J. Dines, Assistant Director, Office of Corporate Relations, University of Wisconsin

Washington, DC, 2011

- Elana Fine, Director of Venture Investments, Dingman Center for Entrepreneurship, Robert H. Smith School of Business, University of Maryland
- Toby Gordon, Sc.D., Associate Professor, The Johns Hopkins Carey Business School
- Martha J. Connolly, Ph.D., Director, Maryland Industrial Partnerships, University of Maryland

Boston, MA, 2012

- Ashley J. Stevens, D.Phil. (Oxon), CLP, President, Focus IP Group, LLC and Lecturer, Strategy and Innovation Department, School of Management, Boston University
- Rekha Paleyanda, PhD, Sr. Business Strategy and Licensing Manager, Partners Healthcare

Chicago, IL, 2013

- Patrick G. Morand, Managing Partner, Open Prairie Ventures
- Allen J. Dines, Assistant Director, Office of Corporate Relations & Venture Designer Hybrid Zone X, University of Wisconsin-Madison

San Diego, CA, 2014

- Kurt A. May, MBA, Co-founder and Chairman, Psynomics Incorporated
- Larry Stambaugh, Founding Principal, Aperçu Partners
- Justin Chakma, Associate Director, Auspex Pharmaceuticals and Thomas, McNerney & Partners, LLC

Philadelphia, PA, 2015

- Dennis Gross, M.S., Ph.D., CEO, Pennsylvania Drug Discovery Institute at The Pennsylvania Biotechnology Center
- James Jordan, MBA, CHT, Chief Investment Officer, Pittsburgh Life Sciences Greenhouse, Distinguished Service Professor in Healthcare & Biotechnology Management, Carnegie Mellon University
- Alex B. Reitz, PhD., CEO, Fox Chase Chemical Diversity Center, Inc., The Pennsylvania Biotechnology Center

San Francisco, CA 2016

- Benjamin Chen, Ph.D. Managing Director, Ignatius Transaction Partners
- Moira Gunn, Ph.D. Host, NPR - BioTech Nation, Director, Business of Biotechnology Program, Professor, School of Management University of San Francisco

San Diego, CA 2017

- Steve Flaim, PhD, FACC, FAHA, Chairman Emeritus, Tech Coast Angels, Director Angel Capital Association
- Larry Stambaugh, Founding Principal, Aperçu Partners, Founding Principal, Aperçu Partners, Chairman, Molecular Assemblies, Inc., Chairman, MindXSciences, Inc., LifeTime Director, BioCom, Chairman, ParaNetics

Boston, MA 2018

- Edward Ross, Jr., MBA, President & CEO, ReadyDock, Inc., Member, MassMedical Angels and Launchpad Venture Group
- Amy Siegel, MA, Co-founder and President, S2N Health

Philadelphia, PA 2019

- Harold Safferstein, PhD, JD, MBA, Senior Vice President, Corporate Development, Cognition Therapeutics
- Kathryn Doyle PhD, JD, Partner, Saul Ewing Arnstein & Lehr
- Wendy DiCicco, Board Member, Carmell Therapeutics

Convention Registration opens at 1:00 PM on Saturday, June 1. Participants in the Boot Camp should obtain their Convention Badges prior to the Boot Camp.

Sunday, June 2, 2019 Program Schedule

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| 8:00 AM - 8:30 AM | Registration & Continental Breakfast | |
| 8:30 AM - 9:00 AM | Opening Remarks, Program Overview of Program and Sponsor Acknowledgments | National Co-Chair Emeritus: Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania |
| 9:00 AM - 9:45 AM | SESSION 1: Keynote Speaker Jeffrey D. Marrazzo, MBA, MPA Chief Executive Officer, Spark Therapeutics, Inc. | Introduced by: Kathryn Doyle, PhD, JD Partner, Saul Ewing Arnstein & Lehr |
| 9:45 AM - 10:45 AM | SESSION 2: Project, Product or Platform: Assessment and Qualification of Technologies as a Basis for a Business Startup Forming a company around a technology is relatively easy. Staffing and capitalizing it is another story. Savvy employees, astute venture capitalists, and selective prospective strategic partners know that companies without technological “critical mass” sufficient to bring a series of products to the market are unsustainable. This session will provide tools and a contextual framework (the metaphor of a “project, product, or platform”) as to how technologies can be assessed for capitalization and partnering. The session includes a real-time review of the technology of a new company with intent of recommending commercialization and risk reduction strategies. | Moderator and Lecturer: Arthur A. Boni, PhD John R. Thorne Distinguished Career Professor of Entrepreneurship Emeritus, Tepper School of Business, Carnegie Mellon University Editor in Chief, Journal of Commercial Biotechnology Presenter: D. Kacy Cullen, PhD Founder, Innervace, LLC Associate Professor of Neurosurgery & Bioengineering, University of Pennsylvania School of Medicine Sponsor: Kathryn Doyle, PhD, JD Partner, Saul Ewing Arnstein & Lehr Commentators: Wendy DiCicco Board Member, Carmell Therapeutics Dennis Gross, MS, PhD CEO, Pennsylvania Drug Discovery Institute at the Pennsylvania Biotechnology Center Vivian Lee Managing Director, Aqua Partners LLC Harold Safferstein, PhD, JD, MBA Senior Vice President, Corporate Development, Cognition Therapeutics |

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| | | John S. Swartley, MBA, PhD Associate Vice Provost for Research, Managing Director, Penn Center for Innovation |
| 10:45 AM - 11:00 AM | Break-out with refreshments for case discussion followed by group recommendations | Reconvene for group recommendations |
| 11:00 AM - 11:45 AM | Session 3: Reimbursement & Pricing Strategies It is never too early to assess how the market will respond to products, especially as it relates to pricing and reimbursement. Many companies do not address this issue and then run into problems (and potentially failures). This session will address the fundamentals of pharmaceutical pricing and reimbursement strategies. | Moderator: Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania Faculty: Robert Wanerman, JD, MPH Partner, Epstein Becker & Green, PC |
| 11:45 AM - 12:45 PM | SESSION 4: What Every Investigator Must Know about IP in Biotechnology Startups The goal of the session is to provide information and insight into the specific issues confronting investigators, entrepreneurs, investors, and their patent attorneys. Additionally, the speakers will describe the prevailing treatment by the PTO and the courts of specific issues and implications. | Moderator: Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania Faculty: Kathryn Doyle, PhD, JD Partner, Saul Ewing Arnstein & Lehr LLP Raymond A. Miller, JD Partner, Pepper Hamilton LLP |
| 12:45 PM - 1:15 PM | Lunch | |
| 1:15 PM – 2:15 PM | SESSION 5: Regulatory Planning for the U.S. & Global Market - Implications for Strategy and Financing This session provides the specific insight into planning for U.S. and global regulations and clinical trials. What are the considerations and the challenges that sponsors might encounter? | Moderator: Dennis Gross, MS, PhD CEO, Pennsylvania Drug Discovery Institute at the Pennsylvania Biotechnology Center Faculty: David T. Lin, PhD, MBA President, TS Pharma Experts |
| 2:15 PM – 3:00 PM | SESSION 6: The R&D - Marketing Interface By expanding upon a strategic development tool based upon FDA Guidance called the <i>target product profile</i> (TPP), alignment of R&D, reimbursement, pricing, regulatory, label claim, | Moderator and Speaker: James Jordan, MBA, CHT President & CEO, Pittsburgh Life Sciences Greenhouse Distinguished Service Professor in Healthcare & Biotechnology Management, Carnegie Mellon University |

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| | <p>IP, marketing, and sales strategies are aided.</p> <p>The TPP ensures product strategy and commercialization plan details do not disconnect as resource and technical constraints avail themselves during implementation.</p> | <p>Faculty: Thanigavelan Jambulingam, PhD Professor, Pfizer Fellow, Arrupe Research Fellow, Department of Pharmaceutical and Healthcare Marketing, Haub School of Business, Saint Joseph's University</p> |
| 3:00 PM - 3:15 PM | Bio-Break | |
| 3:15 PM - 4:00 PM | <p>SESSION 7: Building an IP Pyramid impervious to competitive advancement</p> <p>A patent excludes others from replicating an approach, however that may not equate to an exclusive market position. True exclusivity is creating a competitive position impervious to competitive advancement.</p> <p>The goal of the Intellectual Property Pyramid™ is to understand the exclusivity a patent provides matched with the desired result. What you are trying to understand is the reason the patent exists (the problem it's solving), and then ask yourself if your patent is the only path to achieving that goal.</p> | <p>Presenter/Faculty: James F. Jordan, MBA, CHT President & CEO, Pittsburgh Life Sciences Greenhouse Distinguished Service Professor in Healthcare & Biotechnology Management, Carnegie Mellon University</p> |
| 4:00 PM – 4:45 PM | <p>SESSION 8: Building and working with the Board</p> <p>Building and working with a board is a key element for success in entrepreneurial companies. Better boards make better companies. We will cover the best practices and successful principles of a great board and sound corporate governance processes.</p> | <p>Presenter/Faculty: James F. Jordan, MBA, CHT President & CEO, Pittsburgh Life Sciences Greenhouse Distinguished Service Professor in Healthcare & Biotechnology Management, Carnegie Mellon University</p> |
| 4:45 PM - 5:30 PM | <p>SESSION 9: Building an Entrepreneurial Management Team</p> <p>Team building in biotechnology companies is the most challenging task for entrepreneurs, and the backbone of venture capitalists' decision to invest or not to invest. The session provides exploration of the issues in forming an entrepreneurial team of a start-up or early stage company and approaches to successful team formation and management of the team.</p> <p>The panelists represent the perspective of a CEO and a venture capitalist who built the management team of local company.</p> | <p>Lecturer and Moderator: Arthur A. Boni, PhD John R. Thorne Distinguished Career Professor of Entrepreneurship Emeritus, Tepper School of Business, Carnegie Mellon University</p> <p>Presenters: Steve Nichtberger, MD Co-Founder, Chairman, and CEO, Cabaletta Bio</p> <p>Sponsor: Kathryn Doyle, PhD, JD Partner, Saul Ewing Arnstein & Lehr LLP</p> <p>Faculty:</p> |

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| | | <p>Wendy DiCicco Board Member, Carmell Therapeutics</p> <p>Vivian Lee Managing Director, Aqua Partners LLC</p> <p>Harold Safferstein, PhD, JD, MBA Senior Vice President, Corporate Development, Cognition Therapeutics</p> <p>David Smith, JD Of Counsel, Pepper Hamilton LLP</p> |
| 5:30 PM - 7:00 PM | Networking Reception | |

Monday, June 3, 2019 Program Schedule

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| 8:30 AM - 9:00 AM | Registration & Continental Breakfast | |
| 9:00 AM - 9:40 AM | <p>SESSION 10: The Business Plan and Pitch in the Fund-Raising Process</p> <p>Experienced entrepreneurs and their investors openly recognize that within a year of operating, few companies resemble their original business plan. Business plans and the accompanying pitch, however, provide the starting point of a shared vision and evidence that the founding team can reach a consensus in the business and technology development planning process and the resources required to meet critical milestones. The session provides a framework for developing a pitch to investors/partners, and the essentials of a business plan.</p> | <p>Moderator and Lecturer: Arthur A. Boni, PhD John R. Thorne Distinguished Career Professor of Entrepreneurship Emeritus, Tepper School of Business, Carnegie Mellon University</p> |
| 9:40 AM – 10:00 AM | <p>SESSION 11: Leveraging Resources of Partners to Optimize Value Creation and Capture</p> <p>The Business Model contains all elements required by a firm to create, deliver, and capture value. In developing and validating the business model elements, the firm can leverage the resources and channels of partners across the value chain and share the value created and delivered with others. Creative partnering can be used to reduce the risk profile and also reduce capital requirements for the firm as it evolves through the commercialization, testing, and go-to-market phases. In the last decade or so, this open innovation approach has been used extensively in the biopharma and medtech community to commercialize using both internal and external resources. In effect, the firm “rents” elements of the business model from others. This session is designed to introduce and rationalize “Open Innovation 101” for early-stage companies and complements the Lean Startup model to more efficiently validate product/market fit via creative partnering.</p> | <p>Moderator and Lecturer: Arthur A. Boni, PhD John R. Thorne Distinguished Career Professor of Entrepreneurship Emeritus, Tepper School of Business, Carnegie Mellon University</p> |
| 10:00 AM- 10:15 AM | Break-out with refreshments for Group Discussions | |

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| <p>10:15 AM - 10:45 AM</p> | <p>SESSION 12: Group & Presentations</p> <p>Utilizing the worksheet provided, students will discuss and identify the areas where partnerships could either accelerate, de-risk, or deepen domain relationships. Utilizing group discussions, gather potential partners and introductions.</p> <p>Two volunteers will take 15 minutes each to discuss their strategies.</p> | <p>Moderator: Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania</p> |
| <p>10:45 AM - 11:45 AM</p> | <p>SESSION 13: Building Your Capitalization Strategy</p> <p>A start-up requires the continuous alignment of customer, investor, and acquirer's objectives and concerns. Investors fund the journey, and a poorly planned and ill-provisioned journey increases the probability of failure.</p> <p>This discussion will center around the customer (who in this case is the investor) so students can understand their needs, timing, and investment criteria.</p> <ul style="list-style-type: none"> - Non-Dilutive Funding – NIH - Angels - Corporate Venture Capital - Venture Capital - Corporate Partners | <p>Moderator: Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania</p> <p>Faculty: Steven M. Ferguson, MBA, CLP Deputy Director, Licensing and Entrepreneurship, National Institutes of Health</p> <p>James Foley, PhD CEO, Aqua Partners Former head of Business Development, Bristol Myers Squibb</p> <p>David Smith, JD Of Counsel, Pepper Hamilton LLP</p> <p>Wei Wu, PhD Healthcare Investment Director, BOE Ventures</p> |
| <p>11:45 AM - 12:30 PM</p> | <p>Lunch Box in Room</p> | |
| <p>12:30 PM – 1:30 PM</p> | <p>SESSION 14: Pre-seed/Seed Funding Pitch</p> <p>The facilitator will give a brief introduction on the phases of private equity funding.</p> <p>Companies need to be aware of the expectations of investors for each phase and also learn to handle objections. For example, if a pre-seed funder is asking you for human data, they either aren't a pre-seed funder, or they are using the objection to avoid investing or providing feedback.</p> <p>In this segment, two companies will present their investor pitch and receive feedback appropriate to their investment phase.</p> | <p>Moderator: Harold Safferstein, PhD, JD, MBA Senior Vice President, Corporate Development, Cognition Therapeutics</p> <p>Presenters: Mahesh Narayanan President and CEO, PepVax, Inc.</p> <p>Michael Nelson, JD Chief Executive Officer and Co-Founder, Intrommune Therapeutics</p> <p>Sponsor: Wendy DiCicco Board Member, Carmell Therapeutics</p> |

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| | | <p>Faculty: Wendy DiCicco Board Member, Carmell Therapeutics</p> <p>James Foley, PhD CEO Aqua Partners Former head of Business Development, Bristol Myers Squibb</p> <p>Wei Wu, PhD Healthcare Investment Director, BOE Ventures</p> |
| 1:30 PM – 2:00 PM | <p>SESSION 15: Defining your Exit Triggers</p> <p>Running out of cash can be caused by a poorly planned and ill-provisioned journey. Startups frequently run out of cash when they mis-plan their exit. This discussion will offer you a tool to aid in your planning.</p> | <p>Lecturer: James F. Jordan, MBA, CHT President & CEO, Pittsburgh Life Sciences Greenhouse Distinguished Service Professor in Healthcare & Biotechnology Management, Carnegie Mellon University</p> |
| 2:00 PM – 2:45 PM | <p>SESSION 16: Early-Stage Funding Pitch</p> <p>Early-stage valuation points are frequently aligned with Phase II clinical trial inflection points from an investor perspective. Additionally, the probability of strategic investors and a milestone-based exit are available. This requires a pitch that satisfies a broader audience.</p> <p>In this segment, a company will present its investor pitch and receive feedback appropriate to their investment phase.</p> | <p>Moderator: Kathryn Doyle, PhD, JD Partner, Saul Ewing Arnstein & Lehr LLP</p> <p>Presenter: Jessica M. Gibson, MBA CEO and Co-Founder, Ariel Precision Medicine</p> <p>Sponsor: Harold Safferstein, PhD, JD, MBA Senior Vice President, Corporate Development, Cognition Therapeutics</p> <p>Faculty: Wendy DiCicco Board Member, Carmell Therapeutics</p> <p>James Foley, PhD CEO Aqua Partners Former head of Business Development, Bristol Myers Squibb</p> <p>Wei Wu, PhD Healthcare Investment Director, BOE Ventures</p> |
| 2:45 PM - 3:00 PM | Break-out with refreshment for Group Discussions | |
| 3:00 PM – 3:45 PM | <p>SESSION 17: Group & Presentations</p> <p>Utilizing the feedback given during the two investor pitches, students will discuss and identify areas of improvement in their pitches. Two volunteers will take 15 minutes each to discuss their strategies.</p> | <p>Moderator: Kathryn Doyle, PhD, JD Partner, Saul Ewing Arnstein & Lehr LLP</p> |

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| 3:45 PM – 4:30 PM | SESSION 18: Working with the Media: Thoughts for Bio-Entrepreneurs | Lecturer: Moira A Gunn, PhD Host, NPR - BioTech Nation Director, Business of Biotechnology Program Professor, School of Management, University of San Francisco |
| 4:30 PM – 6:00 PM | SESSION 19: Capitalization of the Venture - Mechanics CEOs and CSOs of biotechnology companies spend as much time raising capital as managing their company. An attorney specializing in company formation and capitalization will join the panel to provide legal models. | Moderator: Dennis Gross, MS, PhD CEO, Pennsylvania Drug Discovery Institute at the Pennsylvania Biotechnology Center Faculty: David Smith, JD Of Counsel, Pepper Hamilton, LLP |
| 6:00 PM | SESSION 20: Boot Camp Wrap-up, Acknowledgements, & Adjournment | National and Local Co-Chairs |