



Lahav Executive Education
Commemorating Daniel Recanati
Coller School of Management
Tel Aviv University

Health Care Technological Innovation from Idea to Commercialization The 15th Course

An Executive Program for
Biotechnology, Medical Device and Health IT Entrepreneurs and Managers

Offered by:

**The Coller School of Management, Tel Aviv University
Lahav Executive Education**

**December 4th-7th, 2022
Sunday through Wednesday
Tel Aviv, Israel**

Program Directors

Benny Zeevi, M.D.

Managing General Partner
Tel Aviv Venture Partners and Run Young
Capital

Mike Berman

Medical Device Investor/Entrepreneur
Venture Partner RiverVest Ventures

Susan Alpert, M.D., Ph.D.

Principal SFADC LLC
Chief Regulatory Officer, SynerFuse, Inc



Course Syllabus

Day One: Sunday, December 4th, 2022	
Day's Theme: The Creative Process and Technology Assessment	
8:30 - 9:00 AM	Registration/Administrative Continental Breakfast
9:00 – 9:20 AM	Welcome and Opening Remarks by Course Directors: Greetings – Prof. Dan Amiram, Dean, Collier School of Management, TAU Introduction to Program Structure, Faculty and Participants Introduction Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners and Run Young Capital
9:20 – 10:10 AM	Session 1: Keynote Lecture - The New "Kids" on the Block: Microbiome -Case study, what can we learn? Mike Berman, medical device investor/entrepreneur, past President of the Cardiology business of Boston Scientific
10:10 – 11:00 AM	Session 2: The Persuasive Pitch, Part 1: Introduction of course participants Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners, and Run Young Capital Susan Alpert M.D., PhD, Principal SFADC LLC, Chief Regulatory Officer, SynerFuse, Inc Mike Berman, Medical device Investor/Entrepreneur, Past President Cardiology Business, Boston Scientific In order to give participants a chance to learn more about their colleagues in the course, and as the first part of our focus on presentations, we are asking each participant to prepare and deliver a 3 minute presentation, using 4-5 power point slides, to introduce himself and his/her company to the group
11:00 - 11:20 AM	Coffee Break
11:20 - 12:40 PM	Session 3: The Persuasive Pitch, Part 2: Introduction of course participants



<p>12:40 – 1:30 PM</p>	<p>Session 4: <u>Project, Product or Company? Assessment and Qualification of Technologies as a Basis for a Startup</u> Healthcare (Medicine) must actively adopt Innovation in its teaching and culture, rather than letting it occur passively. Innovation is needed to overcome the many unmet needs that exist in Healthcare (Medicine) today The successful translation of discoveries from the lab to the market is the greatest challenge facing an entrepreneur. Many companies are formed on technologies emanating from university laboratories and spinouts from major corporations as well as new ideas originating by life science companies' ventures. One must define what is the objective vs. what is possible in the healthcare market. Many healthcare innovations fall because they neither integrate with existing clinical practice nor are successful in creating new ones. This session will provide tools and a contextual framework as to how technologies can be assessed by founders, corporations, and VCs so that they can orient and characterize their business for capitalization and partnering. Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners and Run Young Capital</p>
<p>1:30 - 2:20 PM</p>	<p>Networking Lunch</p>
<p>2:20 - 3:20 PM</p>	<p>Session 5: <u>Market Analysis and Competitive Analysis - Essentials of Marketing in life Sciences Companies</u> This session will focus on Market analysis, Clinical state of the art and product positioning: assessment of different applications for the same product (choosing the right application from commercial point of view), Determination of subgroup of patients most appropriate for the product, Competitive analysis, Importance of opinion leaders, patients groups, patients organization and Selling strategy: To build mutually satisfying long-term relationships with key customers in order to acquire and retain their business. Competitive analysis - product differentiation linked to improvements in efficiency and effectiveness – can help potential customers' better grasp the implication of economic value for their own businesses. Often, making these explicit links from the market and competitive data can lead to powerful insights as to the value of the offering to the customer, and help make a transformative difference in outcome. Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners and Run Young Capital</p>
<p>3:20 – 3:40 PM</p>	<p>Coffee Break</p>



3:40 – 4:25 PM	<u>Session 6:</u> <u>Innovation Lessons from the Birth of TAVI</u> Stanton Rowe, Founder & CEO NTX Biomedical
4:25 – 6:00 PM	<u>Session 7:</u> Lessons Learned for Medical Device Companies from the Renal Denervation Saga - Conducting Global Randomized Control Clinical Trials Mike Berman, medical device investor/entrepreneur, past President of the Cardiology business of Boston Scientific Andrew Weiss, ReCor, CEO Neil Barman, MD, ReCor, CSO Naomi Fisher, MD, Director of Hypertension Services at the Brigham and Women’s Hospital, Associate Professor of Medicine at Harvard Medical School Felix Mahfoud, Associate Prof. & senior physician of Internal Medicine and Cardiology at Saarland University Hospital, Germany and Affiliate/Visiting Prof. Harvard-MIT Biomedical Engineering, Institute of Medical Engineering and Science, Cambridge, US.



Day Two: Monday, December 5th, 2022

Day's Theme: Strategy and Execution

8:30 - 9:00 AM	Continental Breakfast
9:00 - 10:30 AM	<p><u>Session 8:</u> <u>The Healthy Way to Build Your Community – Interactive Master Class for Fast Growth Life Sciences Companies</u></p> <p>No one accomplishes much on his/her own; we all depend on others in some way. For many, networking means connecting on LinkedIn and distributing business cards at industry events. There's value in growing the network of people you know, but it's far more valuable when you build a community.</p> <p>When you reach out to people in service of what you want to create or achieve, you start to create a sense of community. Reaching out with a purpose makes it easier to network, and when you thoughtfully ask people for help, it builds a stronger connection between you. Your community becomes a network that shares a common aspiration or goal. Communities are so much more powerful because of this one important difference.</p> <p>In this session, we will ask you to reflect on your network – are you strategic about building your community? who is in it? who is missing? what can you do to strengthen it so it can help you reach your personal and professional ambitions?</p> <p><i>Gila Tolub, Partner, McKinsey, Tel Aviv</i></p>
10:30 - 11:30 AM	<p><u>Session 9:</u> <u>The Persuasive Pitch, Part 2: Presenting Your Idea—and Yourself—With Purpose, Clarity, and Power</u></p> <p>On the path from 'idea to commercialization' you will need to communicate persuasively about your product, your company, and yourself to a wide range of audiences—investors, regulators, partners, customers, and your own team. During this session we will focus on one of the most common—and, perhaps surprisingly, often one of the more difficult—types of presentations that entrepreneurs must deliver: the short introduction.</p> <p><i>Barry Katz, Founder and CEO, Barry Katz Communicating Success</i></p>
11:30 – 11:50 AM	Coffee Break



<p>11:50 - 1:20 PM</p>	<p>Session 10: <u>Biotechnology and Medical device Regulatory Planning, Clinical Development and the Implications for Strategy and Financing: From Proof of Concept to Marketing Success. Designing and conducting clinical trials</u> This session provides an abbreviated view of the overall process and specific insight into planning for FDA regulations in light of strategy, financial needs, and the concerns of prospective partners and investors. Entrepreneurs need to understand that there is an increasing need to perform clinical studies to support medical device safety and performance claims. They also need to have a basic understanding of the activities, resources and costs associated with the design and conduct of clinical studies. The failure to incorporate an effective clinical strategy into new project planning can lead to significant project and funding delays or, worse, the failure of the project. This session will provide an overview of the increasing need for device clinical study data; key activities, resource needs and costs; and planning for the successful design & conduct of medical device clinical studies for acceptance in the USA and Europe, even when these studies are conducted outside of these regulatory jurisdictions. Susan Alpert, PhD, MD, Principal, SFA Consulting LLC, Former Senior Vice President, Chief Regulatory Officer of Medtronic, Former Director, Office of Device Evaluation, CDRH at the FDA</p>
<p>1:20 - 2:00 PM</p>	<p>Networking Luncheon</p>
<p>2:00 - 3:15 PM</p>	<p>Session 11: <u>Incorporating Reimbursement in the Company Development Strategy</u> Stuart Kurlander, Healthcare and Life Sciences Partner at Latham & Watkins LLP Mike Berman, medical device investor/entrepreneur, past President of the Cardiology business of Boston Scientific</p>
<p>3:15 - 4:15 PM</p>	<p>Session 12: <u>Intellectual Capital Management</u> The goal of the session is to provide information and insight into the specific issues confronting investigators, entrepreneurs, investors, and their patent attorneys. The session will address the formation of specific IP strategy and execution and using intellectual capital for competitive advantage. Content includes major issues confronting companies with US and filings in other jurisdictions related to biotechnology, e.g., patent ownership, non-obviousness rulings, the scope of what can be patented. A VC will also provide an investor viewpoint. Brian Hopkins, Special Counsel, Cooley LLP</p>
<p>4:15 - 4:35 PM</p>	<p>Coffee break</p>



<p>4.35 – 5.10</p>	<p><u>Session 13:</u> Pharma Perspective on Technology & AI Innovation Karin Noy, Head Emerging Science & Innovation in Pfizer Israel Mati Gill, CEO of AION Labs</p>
<p>5.10 – 5.50PM</p>	<p><u>Session 14:</u> Elevance Health – Value Based Care, Data and payment models and how physicians are incentivized Ariel Bayewitz, Vice President Health Economics, Elevance Health</p>
<p>5:50 - 7:00 PM</p>	<p><u>Session 15:</u> Meet and Ask the Experts – Roundtables Mentoring Medical Devices: Andrew M. Weiss, President & CEO ReCor Medical Regulation: Susan Alpert, PhD, MD, Principal, SFA Consulting LLC, Former Senior Vice President, Chief Regulatory Officer of Medtronic, Former Director, Office of Device Evaluation, CDRH at the FDA Reimbursement: Stuart Kurlander, Healthcare and Life Sciences Partner at Latham & Watkins LLP Capitalization: Mike Berman, medical device investor/entrepreneur, past President of the Cardiology of Boston Scientific Gur Roshwalb, M.D., M.B.A., Partner at aMoon Jenny Barba, Founder and Managing Partner of Features Capital Dima Kuzmin, PhD, Managing Partner, 4BIO CAPITAL Health Tech: Allen Kamer, Managing Partner, OurCrowd Qure, Adam Dicker, MD, PhD, FASTRO, Enterprise Senior Vice President, Professor and Chair of Enterprise Radiation Oncology, Sidney Kimmel Cancer Center, Sidney Kimmel Medical College, Thomas Jefferson University US Healthcare System: Ariel Bayewitz, Vice President Health Economics, Elevance Health, Carolyn Hochstadter, E.Carolyn Hochstadter, Attorney at Law, Dicker, LLC, Audrey Horn, Product Innovation Director, Carelon Digital Platforms, Israel</p>
<p>7:00 PM</p>	<p>Drive to network dinner at Duplex Hertzlia (1 Ha'Etzel St., Herzliya Pituah, 2ng floor)</p>
<p>7:30 PM</p>	<p>Network Dinner for Faculty, Participants, and life sciences executives At Duplex Hertzlia Lecture: <u>Design Thinking in Life Sciences</u> Rebecca Sternberg, Megama Strategic Design, Co-Founder of Aquafit Intimate</p>



Day Three: Tuesday, December 6th, 2022

Day's Theme: Bringing the product to the market

8:30 - 9:00 AM	Continental Breakfast
9:00 - 10:30 AM	<p><u>Session 16:</u> <u>Biopharmaceutical and Medical Device Licensing, Partnering and Strategic Alliances</u></p> <p>Major practical issues in formulation of partnering goals and managing different types of strategic alliances, preparation for positioning for partnering, identifying and qualifying prospective partners, making the approach, negotiation, closing the deal, with special emphasis on how to design alliances and avoid many potential problems and complications in managing this relationship.</p> <p>Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners and Run Young Capital Adi Gillat, PhD, Founding Partner at H-F & Co. and leads its IP, IT and Tech-Transactions Practice</p>
10:30 - 11:30 AM	<p><u>Session 17:</u> <u>Capitalization of a life science Venture –Value inflection Points, Milestones and Capital Requirements, Alternative financing, Terms etc. (Part 1)</u></p> <p>Financing a life science venture is challenging. When meeting with investors and prospective strategic partners, entrepreneurs will often hear questions that ask: "Where are you in the value chain?" "How does your business model reflect this?" "How do you describe your milestones and how are you managing towards them?" "How do your milestones tie-in with your value inflection points?" This session will consist of a brief overview of typical value inflection points for each type of product, classical and alternative ways of financing, terms of financing rounds and more.</p> <p>Introduction: How you prepare yourself for fund raising Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners and Run Young Capital</p>
11:30 - 11:50 AM	Coffee break



<p>11:50 - 12:40 PM</p>	<p><u>Session 18:</u> <u>Capitalization of a life science Venture –Value inflection Points, Milestones and Capital Requirements, Alternative financing, Terms etc. (Part 2)</u> From Start to Finish – Everything Entrepreneurs Need to Know to Get Your Idea Funded All the Way Through Exit Allen Kamer, Managing Partner, OurCrowd Qure Hanan Brand, Vice President and Head of the Startup Division, Israel Innovation Authority</p>
<p>12:40 - 1:30 PM</p>	<p><u>Session 19:</u> <u>My Path Through Medicine, Engineering & Innovation</u> Prof. Elazer Edelman, Institute for Medical Engineering and Science, MIT, Cambridge, USA</p>
<p>1:30 - 2:20 PM</p>	<p>Networking Luncheon</p>
<p>2:20 - 4:00 PM</p>	<p><u>Session 20:</u> <u>Capitalization of a life science Venture –Value inflection Points, Milestones and Capital Requirements, Alternative financing, Terms etc. (Part 3)</u> Understand the Term Sheet Dr. Ayal Shenhav, Head of Hi-Tech & Investment Funds Department, GKH & Co. Panel of VCs: Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners, and Run Young Capital Mike Berman, Medical Device Investor/Entrepreneur, past President of the Cardiology business of Boston Scientific Allen Kamer, Managing Partner, OurCrowd Qure Jenny Barba, Founder and Managing Partner of Features Capital Dima Kuzmin, PhD, Managing Partner, 4BIO CAPITAL</p>
<p>4:00 – 5:00 PM</p>	<p><u>Session 21:</u> <u>Lessons learned from our experience: A life science CEOs Panel</u> Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners and Run Young Capital Jonathan Solomon, CEO BiomX David Golan, PhD Co-Founder and CTO, Viz.ai, Keren Leshem, CEO, OCON, Avner Halperin, CEO, Tel Hashomer Medical Research, Infrastructure and Services (THM)</p>



5:00 – 5:20 PM	Coffee break
5:20 - 6:00 PM	Session 22: <u>Healthcare 2030 – The Future Hospital, The Coming Transformation</u> Eyal Zimlichman, MD, MSc (MHCM), Deputy Director General, Chief Medical Officer and Chief Innovation and Commercialization Officer at Sheba Medical Center
6.00 – 7.20PM	Session 23: <u>Establishing a US Entity</u> The legal focus of this session will cover the key building blocks required for an Israeli company to successfully enter the U.S. market. It will also provide essential contract tips to help achieve these milestones. We will explore common concerns including: <ol style="list-style-type: none">1. Whether to register in Delaware and navigating multiple state requirements2. Choosing the C Corporation from the get-go3. Implementing a 2-factor strategy for IP sourcing4. Best practices for cost-effective SEC registration5. Avoiding punitive pitfalls in talent management John Lieberman, Perelson Weiner LLP Carolyn Hochstadter, E. Carolyn Hochstadter Dicker LLC



Day Four: Wednesday, December 7th, 2022

Day's Theme- Health Care IT / Digital Health

8:30 - 9:00 AM	Continental Breakfast
9:00 -10:15 AM	<p>Session 24: <u>"The consumerization of medicine...an epic change in care pathways"</u> Peter J. Fitzgerald, MD, PhD, FACC, Professor Emeritus, Medicine & Engineering, Director, Center for Cardiovascular Technology, Stanford University, Co-founder, Managing Partner, Triventures</p>
10:15 - 11:30 AM	<p>Session 25: <u>Health Tech - Healthcare IT and Digital Health- Part I</u> Health Tech - Healthcare IT and Digital health are integral technologies in healthcare and got a huge boost during the COVID-19 pandemic. For vast adoption, health tech must prove value, meaning a better outcome in a cost-effective way. Digital health technologies are facilitating fundamental shifts in healthcare; cultural and behavioral changes from all healthcare stakeholders, enhancing outcomes and quality of care and eventually will band the cost curve. As healthcare is becoming consumer centric and the post-pandemic reality "old" and "new" stakeholders are changing their business models and the role of potential applications of HCIT technologies and digital health and regulatory issues will be discussed. Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners, and Run Young Capital - The Opportunities and Challenges of Digital Health</p>
11:30 - 11:50 AM	Coffee break
11:50 - 1:30 PM	<p>Session 26: <u>Healthcare IT and Health Tech- Part 2</u> Are Digital and Mobile Health Tools Medical Devices? Who's Opinion Counts? Susan Alpert, PhD, MD, Former Senior Vice President, Chief Regulatory Officer of Medtronic, Former Vice President of Regulatory Sciences for C.R. Bard, Inc., previously worked at FDA</p>
1:30 - 2:30 PM	Networking Luncheon



2:30 - 4:30 PM	Session 27: <u>Healthcare IT and Connected Health - Part 3</u> Opportunities and Challenges in Healthcare Big Data and AI Michal Rosen-Zvi, Ph.D, Director for Healthcare Informatics at IBM Research Clinical validation in digital health and how to develop collaboration with health care systems and approaches of US healthcare technology buyers Adam Dicker, MD, PhD, FASTRO, Enterprise Senior Vice President, Professor and Chair of Enterprise Radiation Oncology, Sidney Kimmel Cancer Center, Sidney Kimmel Medical College, Thomas Jefferson University Partnership with a Startup- the Health Plan's Perspective Sigal Admony Ravid, Head of Strategic Partnerships at Carelon Digital Platforms, Israel
4:30 - 6:00 PM	Session 28: <u>The Persuasive Pitch, Part 3: Presentations Workshop</u> Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners and Run Young Capital Mike Berman, medical device investor/entrepreneur, past President of the Cardiology business of Boston Scientific Susan Alpert, PhD, MD, Former Senior Vice President, Chief Regulatory Officer of Medtronic, Former Vice President of Regulatory Sciences for C.R. Bard, Inc., previously worked at FDA
6:00 - 6:30 PM	Session 29: Program Adjournment <u>Teams gather for "Take-aways Exercise"</u> Each participant will receive at registration a worksheet to record for each session one major lesson or "take-away."

*** Changes in curriculum may occur ***