

## Health Care Technological Innovation from Idea to Commercialization <u>The 14<sup>th</sup> Course</u>

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

The Coller School of Business, Tel Aviv University
Lahav Executive Education

December 5<sup>th</sup>-8<sup>th</sup>, 2021 Sunday through Wednesday Tel Aviv, Israel

**Program Directors** 

**Dr. Benny Zeevi** 

Program Founder Managing General Partner Tel-Aviv Venture Partners **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 5 <sup>th</sup> , 2021	
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. Moshe Zviran, Dean, Coller School of Management, TAU
	Introduction to Program Structure, Faculty and Participants Introduction
	Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners & 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
	Moderators:
	Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners & 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 - 1:00 PM	Session 3:
	The Persuasive Pitch, Part 2: Introduction of course participants
1:00 - 2:00 PM	Networking Lunch



2:00 - 2:45 PM	Session 4: Project, Product or Company? Assessment and Qualification of Technologies as a Basis for a Startup 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.  Moderator: Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners & Run Young Capital Netta Levran, Director of Product Innovation, Anthem Israel
2:45 - 3:45 PM	Session 5: Market Analysis and Competitive Analysis - Essentials of Marketing in life Sciences Companies 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. Economic value to the customer analyses are calculated as cost savings, improvements in long-term client retention, decreased speed in client acquisition, increased average revenue/customer, and revenue associated with the opportunity/ability to establish entry barriers. Often times, 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.  Moderator: Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners & Run Young Capital Yael Nir, MD, Consulting, Spring Consulting
3:45 – 4:00 PM	Coffee Break

4:00 -5:00 PM	Session 6:
	Keynote Lecture – Status and Trends in the Biopharma Sector
	Alberto Loche, Associate Partner, McKinsey & Company Life Sciences
5:00 - 6:00 PM	Session 7:
	Intellectual Capital Management
	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.
	Lecture and Discussion: Brian Hopkins, Special Counsel, Cooley LLP

Day Two: Monday, December 6th, 2021		
	Day's Theme: Strategy and Execution	
8:30 - 9:00 AM	Continental Breakfast	
9:00 - 10:30 AM	Session 8: The Healthy Way to Build Your Community – Interactive Master Class for Fast Growth Life Sciences Companies. 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. 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. You community becomes a network that shares a common aspiration or goal. Communities are so much more powerful because of this one important difference. 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?  Moderator: Gila Tolub, Partner, McKinsey, Tel Aviv	
10:30 - 11:30 AM	Session 9:	
	Lessons learned from my experience: A life science CEO and Entrepreneur	
	Jonathan Solomon, CEO BiomX	
11:30 - 11:50 AM	Coffee Break	

11:50 - 1:20 PM	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  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 and conduct of medical device clinical studies for acceptance in the United States and Europe, even when these studies are conducted outside of these regulatory jurisdictions.  Faculty:  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
1:20 - 2:00 PM	Networking Luncheon
2:00 - 4:30 PM	Session 11:
	Meet and Ask the Experts – Roundtables Mentoring
	Medical Devices: Andrew M. Weiss, President & CEO ReCor Medical
	<b>Regulation:</b> 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
	<b>Reimbursement:</b> Stuart Kurlander, Healthcare and Life Sciences Partner at Latham & Watkins LLP
	<b>Capitalization:</b> Mike Berman, medical device investor/entrepreneur, past President of the Cardiology business of Boston
	Scientific; Dr. Morris Laster, Managing Partner, OurCrowd; Allen Kamer, Managing Partner, OurCrowd Qure
	Health Tech: Paul Browne, Senior Vice President and Chief Information Officer, Henry Ford Health System;
	Adam Dicker, MD, PhD, FASTRO, Enterprise Senior Vice President, Professor and Chair of Enterprise Radiation Oncology;
	David Golan, Co – Founder and CTO, Viz.ai
	US Healthcare System: Scott Dulchavsky MD PhD, CEO, Innovation Institute at Henry Ford Health System;
	Dr. Dan Siegal, Vice Chair of the Department of Radiology at Henry Ford Health System and Chief Medical Officer of Henry Ford Innovations Henry Ford Health System; Carolyn Hochstadter, E.Carolyn Hochstadter, Attorney at Law, Dicker, LLC, Audrey Horn, Product Innovation Director, Anthem Israel

4:30 - 5:00 PM	Coffee break
5:00 - 5:50 PM	Session 12: The Persuasive Pitch, Part 2: Presenting Your Idea—and Yourself—With Purpose, Clarity, and Power 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. Barry Katz, Founder and CEO, Barry Katz Communicating Success
5:50 - 7:15 PM	Session 13: Incorporating Reimbursement in the Company Development Strategy 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
7:15 PM	Drive to network dinner at the Mandarin Loft – Hotel Mandarin
7:30 PM	Session 14: Network Dinner for Faculty, Participants, and life sciences executives  At the Mandarin Loft – Hotel Mandarin, Yunitsman 21, Tel Aviv, Zuk Beach  Lecture: Keren Leshem, MBA, CEO OCON Healthcare "A new approach to Women's health thru the uterus"

Day Three: Tuesday, December 7 <sup>th</sup> , 2021	
Day's Theme: Bringing the product to the market	
8:30 - 9:00 AM	Continental Breakfast
9:00 - 10:20 AM	Session 15:
	Biopharmaceutical and Medical Device Licensing, Partnering and Strategic Alliances
	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.
	Moderator: Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners
10.20 11.20 11	Adi Gillat, PhD, Founding Partner at H-F & Co. and leads its IP, IT and Tech-Transactions Practice
10:20 - 11:30 AM	Session 16:
	Capitalization of a life science Venture –Value inflection Points, Milestones and Capital Requirements, Alternative financing, Terms etc. (Part 1)
	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.
	<b>Moderator:</b> Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners
	Dr. Morris Laster, Managing Partner, OurCrowd
11:30 - 11:40 AM	Coffee break
11:40 - 12:40 PM	Session 17:
	Capitalization of a life science Venture –Value inflection Points, Milestones and Capital Requirements,
	Alternative financing, Terms etc. (Part 2)
	Allen Kamer, Managing Partner, OurCrowd Qure - From Start to Finish – Everything Entrepreneurs Need to Know to Get
	Your Idea Funded All the Way Through Exit
	Karina Rubinstein, Sr. Director of BD Start-Up Division, Israel Innovation Authority

12:40 - 1:30 PM	Session 18:
	Keynote Lecture – Healthcare 2030 – The Future Hospital, The Coming Transformation
	Eyal Zimlichman, MD, MSc (MHCM), Deputy Director General, Chief Medical Officer and Chief Innovation and
	Commercialization Officer at Sheba Medical Center
1:30 - 2:20 PM	Networking Luncheon
2:20 - 3:30 PM	Session 19:
	Capitalization of a life science Venture –Value inflection Points, Milestones and Capital Requirements,
	Alternative financing, Terms etc. (Part 3)
	Moderator: Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners
	Dr. Morris Laster, Managing Partner, OurCrowd
	Dr. Ayal Shenhav, Head of Hi-Tech & Investment Funds Department, Gross, Kleinhendler, Hodak, Halevy, Greenberg,
	Shenhav & Co.
	Mike Berman, Medical Device Investor/Entrepreneur, past President of the Cardiology business of Boston Scientific
3:30 - 4:40 PM	Session 20:
	Establishing a US Entity
	John Lieberman, Perelson Weiner LLP
	Carolyn Hochstadter, E. Carolyn Hochstadter Dicker LLC
	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:
	1. Whether to register in Delaware and navigating multiple state requirements
	2. Choosing the C Corporation from the get-go
	3. Implementing a 2-factor strategy for IP sourcing
	4. Best practices for cost-effective SEC registration
	5. Avoiding punitive pitfalls in talent management
4:40 - 5:00 PM	Coffee break

5:00 - 6:00 PM	Session 21:
	Keynote Lecture - "Innovation Lessons from the Birth of TAVR"
	Stanton Rowe, Founder & CEO NTX Biomedical
6:00 - 7:00 PM	Session 22:
	Keynote Lecture: Macro trends in the USA healthcare system and their implications for inventors,
	entrepreneurs and investors.
	Ezekiel "Zeke" J. Emanuel, Vice Provost for Global Initiatives, the Diane v.S. Levy and Robert M. Levy University Professor,
	and Co-Director of the Healthcare Transformation Institute at the University of Pennsylvania

Day Four: Wednesday, December 8 <sup>th</sup> , 2021	
Day's Theme- Health Care IT / Digital Health	
8:30 - 9:00 AM	Continental Breakfast
9:00 -10:15 AM	Session 23:
	Keynote lecture – "Digital medicine, the revolution in health"
	Peter J. Fitzgerald, MD, PhD, FACC, Professor Emeritus, Medicine & Engineering, Director, Center for Cardiovascular
	Technology, Stanford University, Co-founder, Managing Partner, Triventures
10:15 - 11:30 AM	Session 24:
	Health Tech - Healthcare IT and Digital Health- Part I
	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 has to 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.
	The potential applications of HCIT technologies and digital health, it's role in global health, new business models, the use of
	social media by pharma and medical device companies as well as by healthcare providers and insurance companies and
	regulatory issues will be discussed.
	Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners - The Opportunities and Challenges of Digital Health
	Tamara Mansfeld, Global Innovation Lead, Pfizer Corporate Strategy & Innovation- Pharma perspectives on Digital Health
11:30 - 11:50 AM	Coffee break
11:50 - 1:30 PM	Session 24 (Continue):
	Healthcare IT and Health Tech- Part 2
	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 -
	Are Digital and Mobile Health Tools Medical Devices? Who's Opinion Counts?
1:30 - 2:30 PM	Networking Luncheon



2:30 - 4:30 PM	Session 24 (Continue): Healthcare IT and Connected Health - Part 3 2:30-3:00pm Opportunities and Challenges in Healthcare Big Data and AI Michal Rosen-Zvi, Ph.D, Director for Healthcare Informatics at IBM Research 3:00-3:30pm 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 3:30-4:00pm What technology investments are high priorities for US based healthcare systems and the key criteria used in making procurement decisions
	Paul Browne, Senior Vice President and Chief Information Officer, Henry Ford Health System  4:00-4:30pm  Real-World Application of Innovation in Digital Health – building the hospital of the future  Dr. Dan Siegal, Vice Chair of the Department of Radiology at Henry Ford Health System and Chief Medical Officer of Henry Ford Innovations Henry Ford Health System
4:30 - 4:45 PM	Coffee Break
4:30 - 6:00 PM	Session 25: The Persuasive Pitch, Part 3: Presentations Workshop Moderator: Benny Zeevi, M.D. Managing General Partner, Tel Aviv Venture Partners 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 26: Program Adjournment Teams gather for "Take-aways Exercise" Each participant will receive at registration a worksheet to record for each session one major lesson or "take-away."

\* Changes in curriculum may occur \*