

Health Care Technological Innovation from Idea to Commercialization In Memory of Dr. Benny Zeevi The 16th 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 10th-13th,2023 Sunday through Wednesday Tel Aviv, Israel

Program Founder

Benny Zeevi, M.D, Z"L

Managing General Partner Tel Aviv Venture Partners and Run Young Capital **Program Director**

Mike Berman

Medical Device Investor/Entrepreneur Venture Partner RiverVest Ventures **Program Director**

Susan Alpert, PhD, M.D

Principal SFADC LLC

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Dafna Gabbay

Founder and CEO, Curical Technologies





Course Syllabus

Day One: Sunday, December 10 th , 2023		
	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, Coller School of Management, TAU	
	Introduction to Program Structure, Faculty and Participants Introduction	
	Mike Berman, medical device investor/entrepreneur, past President of the Cardiology business of Boston Scientific	
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	
	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	
	Mike Berman, Medical device Investor/Entrepreneur, Past President Cardiology Business, Boston Scientific	
	Dafna Gabbay , Founder and CEO, Curical Technologies	
	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	





12:40 – 1:30 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.
	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
	Dafna Gabbay, Founder and CEO, Curical Technologies
1:30 - 2:20 PM	Networking Lunch
2:20 - 3:20 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. 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.
	Mike Berman, Medical device Investor/Entrepreneur, Past President Cardiology Business, Boston Scientific
	Dafna Gabbay, Founder and CEO, Curical Technologies



3:20 – 3:40 PM	Coffee Break
3:40 - 4:25 PM	Session 6:
	Innovation Lessons from the Birth of TAVI
	Stanton Rowe, Founder & CEO NTX Biomedical
4:25 - 6:00 PM	Session 7:
	What are key issues life sciences companies need to be thinking about - from the beginning!
	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





	Day Two: Monday, December 11th, 2023	
	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	
	<u>Companies</u>	
	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? Gila Tolub, Gila Tolub Ltd, Former Partner, McKinsey	
10:30 - 11:30 AM	Session 9:	
	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	
11:30 – 11:50 AM	Coffee Break	

11:50 - 1:20 PM	Session 10:
	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 & 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
1:20 - 2:00 PM	Networking Luncheon
2:00 - 3:15 PM	Session 11:
	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
3:15 - 4:15 PM	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
4:15 - 4:35 PM	Coffee break
4:35 - 5:10 PM	Session 13:
	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
5.10 - 5.50PM	Session 14: Elevance Health





Day Three: Tuesday, December 12 th , 2023		
	Day's Theme: Bringing the product to the market	
8:30 - 9:00 AM	Continental Breakfast	
9:00 - 10:30 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.	
	Mike Berman, medical device investor/entrepreneur, past President of the Cardiology business of Boston Scientific	
	Adi Gillat, PhD, Founding Partner at H-F & Co. and leads its IP, IT and Tech-Transactions Practice	
10:30 - 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.	
	Introduction: How you prepare yourself for fund raising	
	Mike Berman, medical device investor/entrepreneur, past President of the Cardiology of Boston Scientific	
11:30 - 11:50 AM	Coffee break	
11:50 - 12:40 PM	Session 17:	
	Capitalization of a life science Venture –Value inflection Points, Milestones and Capital Requirements,	
	Alternative financing, Terms etc. (Part 2)	
	Understand the Term Sheet	
	Dr. Ayal Shenhav , Head of Hi-Tech & Investment Funds Department, Gross & Co.	



12:40 - 1:30 PM	Session 18:
	My Path Through Medicine, Engineering & Innovation
	Prof. Elazer Edelman, Institute for Medical Engineering and Science, MIT, Cambridge, USA
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)
	Panel of VCs:
	Mike Berman, Medical Device Investor/Entrepreneur, past President of the Cardiology business of Boston Scientific
	Todd Sone, General Partner, aMoon
	Alon Maor, Partner at BRM
	Ittai Harel, Managing Partner, Pitango HealthTech
3:30 - 4:30 PM	Session 20:
	Lessons learned from our experience: A life science CEOs Panel
	Mike Berman, Medical Device Investor/Entrepreneur, past President of the Cardiology business of Boston Scientific
	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)
	Ori Hadomi, VP Strategic Initiatives & Partnerships at Medtronic. Former CEO, Mazor Robotics
4:30 – 4:50 PM	Coffee break
4:50 - 6:00 PM	Session 21:
	Resilience and adaptability of CEOs and Executives
	Interactive session
	Gila Tolub, Gila Tolub Ltd, Former Partner, McKinsey

Day Four: Wednesday, December 13 th , 2023	
	Day's Theme- Health Care IT / Digital Health
8:30 - 9:00 AM	Continental Breakfast
9:00 -10:15 AM	Session 22: GPT/AI and the impact on Healthcare Peter J. Fitzgerald, MD, PhD, FACC, Professor Emeritus, Medicine & Engineering, Director, Center for Cardiovascular Technology, Stanford University, Co-founder, Managing Partner, Triventures
10:15-11:15 AM	Session 23: Pharma Perspective on Technology & AI Innovation Tamara Mansfeld, Global Innovation Lead, Pfizer Karin Noy, Head Emerging Science & Innovation in Pfizer Israel
	AI technology to accelerate drug discovery Michal Rosen-Zvi, PhD, Director for Healthcare Informatics at IBM Research
11:15 - 11:30 AM	Coffee break
11:30 - 12:15 PM	Session 24: Healthcare IT and Health Tech Are Digital and Mobile Health Tools Medical Devices? Who's Opinion Counts? 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
12:15 – 1:00 PM	Establishing a US Entity 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: Whether to register in Delaware and navigating multiple state requirements Choosing the C Corporation from the get-go Implementing a 2-factor strategy for IP sourcing Best practices for cost-effective SEC registration Avoiding punitive pitfalls in talent management John Lieberman, Perelson Weiner LLP Carolyn Hochstadter, E. Carolyn Hochstadter Dicker LLC

1:00 - 2:00 PM	Networking Luncheon
2:00 - 4:00 PM	Session 26:
	Healthcare IT and Connected Health - Continue
	Opportunities and Challenges in Healthcare Big Data and AI
	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
4:00 - 5:30 PM	Session 27:
	The Persuasive Pitch, Part 3: Presentations Workshop
	Mike Berman, medical device investor/entrepreneur, past President of the Cardiology business of Boston Scientific
	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
5:30 - 6:00 PM	Session 28: 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 *