

Opening Comments

Aaron V. Kaplan, M.D.

Professor of Medicine (Cardiology)

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Heart & Vascular Center

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3D13: Who is Attending? Again!

*Not Adjudicated

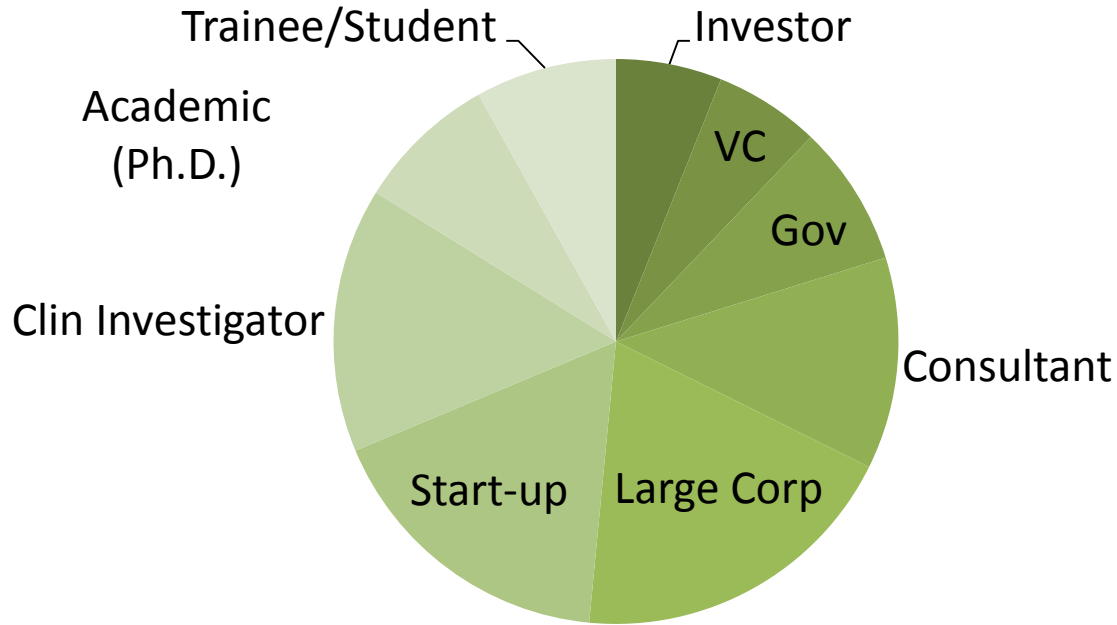
3D13: Who is Attending?

- M.D. 43 (35%)
- Active Clinicians 21 (17%)
- Trainees & Students: 10 (8%)
- CEO (Current or Emeritus) 17 (14%)

Non-Hierarchical

3D13: Who is Attending?

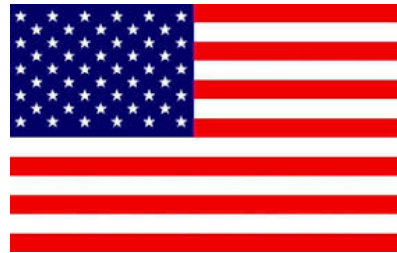
A wide spectrum of stakeholders



Hierarchical

3D13: Who is Attending?

Seven Countries Represented



3D13: Who is Attending?

20 Companies

Abbott Vascular

Abiomed

Boston Scientific

Cardiac Implants

Corvia

Corindus

Creganna Medical

Direct Flow Medical

Edwards Lifesciences

genae

GenoSpace

Hawthorne Medical

Hilbert Paradox

IBM-Watson

JenaValve

Medtronic

Milestone Medical

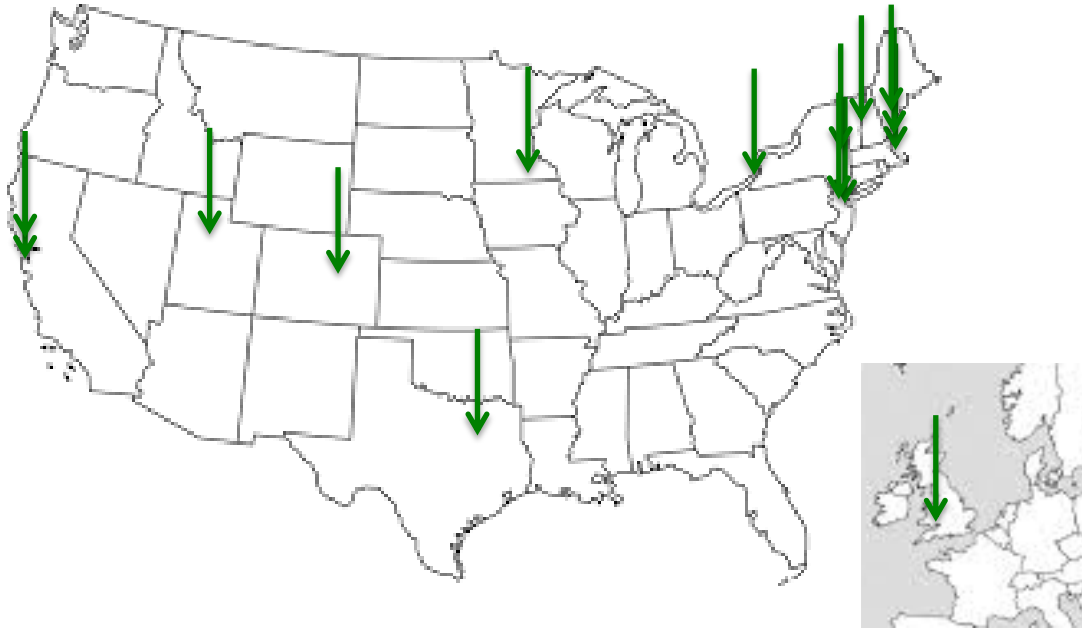
Mitralign

Simbex

Tryton Medical

3D12: Who is Attending

16 Medical Centers (US 15 & UK 1)



Albany Medical Center/Albany
Stratton VA Med Ctr, Beth Israel
Deaconess Medical Center, Brigham
and Women's Hospital, Mass
General, Dartmouth-Hitchcock,
Columbia U Med Ctr, Mount Sinai,
University of Buffalo Neurosurgery,
Mayo Clinic,, The Heart Hospital
Baylor Plano University of Colorado,
InterMountain Health, Stanford-
Palo Alto VA Medical Center

University Hospital Wales

3D13: Thursday Morning

8:00 AM	Welcome	Ross A. Jaffe, M.D. <i>Chair, Board of Overseers/Geisel School of Medicine</i>
8:10 AM	Welcome & Opening Comments	Aaron V. Kaplan, M.D. <i>Symposium Chair</i>
8:30 AM	The Wide Lens: What Successful Innovators See that Others Miss	Ron Adner, Ph.D. <i>Tuck School of Business</i>
9:15 AM	Looking Through a Wide Lens: Seeing the 'Uberization' of Health Care	Peter J. Fitzgerald, M.D., Ph.D. Stanford University
9:45 AM	Q&A Dialog with Ron and Peter	
10:00 AM	Break	

Session 1: Early Medical Device Investing: *Do We Need a Wider Lens?*

Forces Driving Risk Capital Away From Series A Medical Device Investments: U.S. & World Wide Perspectives

10:30 AM Overview:

Aaron V. Kaplan, M.D.

10:40 AM Round Table Conversation

Clinician-US Venture Fund: *Biostar Ventures*

Louis Cannon, M.D.

A US-Irish Venture Fund: *Lightstone Ventures*

Michael Carusi

Large Strategic Investor: *Abbott Ventures*

Mark Gent

US-Israeli Venture Fund: *TriVentures*

Michal Geva

Incubator: *The Foundry*

Jeff Grainger, J.D.

Entrepreneur-University Incubator: *Wyss Institute at Harvard*

Andy Levine

Serial Entrepreneur-US Venture Fund: *New Enterprise Associates* Josh Makower, M.D.

Session 2: Early Feasibility Testing: Moving into the Clinic

- 1:15 PM Early Feasibility Testing in the U.S.: An Update Andrew Farb, M.D.
Center for Devices and Radiological Health/FDA
- 1:30 PM How Changes in the Regulatory Environment (US/OUS) Impact My Decisions?
Moderator: Michael J. Mack, M.D.
- Clinician-Entrepreneur: *Stanford University* Todd Brinton, M.D.
Start-up CEO: *Mitralign* Rick Geoffrion
Regulator: *Center for Devices and Radiological Health/FDA* Nicole Ibrahim Ph.D.
Vascular Center Director: *Mass General Hospital* Michael Jaff, D.O.
An Investigator's Perspective: *Columbia Univ Med Center* Martin B. Leon, M.D.
Established Device Manufacturer: *Edwards Lifesciences* Stanton Rowe
Payor: *Centers for Medicare & Medicaid Services* Tamara Syrek Jensen, J.D.

3D13: Session 3

Post Approval Integrated Medical Device Evaluation System

2:15 PM	21 st Century Cures: An Overview and Perspective	Josh Rising, M.D.
2:30 PM	An Overview	Greg W. Daniel, Ph.D.
2:50 PM	Round Table Conversation	Josh Rising, M.D.
	<i>STS Registry/Univ Colorado Medical Center</i>	John D. Carroll, M.D.
	<i>Centers for Medicare & Medicaid Services</i>	Joseph Chin, M.D.
	<i>NICE/University Hospital Wales</i>	Peter Groves, M.D.
	<i>Kaiser Permanente</i>	Jo Carol Hiatt, M.D.
	<i>ADVI</i>	Louis Jacques, M.D.
	<i>Center for Devices and Radiological Health/FDA</i>	John Laschinger, M.D.
	<i>King & Spalding</i>	Beverly Lorell, M.D.
	<i>Brigham & Women's Hospital</i>	David O. Williams, M.D.

Session 4: Study Design.2015 *Applying New Strategies to Device Approval*

3:45 PM 'If I Were King of The Forest': What I Would Require For Device Approval

Moderator

Martin B. Leon, M.D.

Left Atrial Appendage Closure – Next Gen Device

Brian Whisenant, M.D.

Left Atrial Appendage Closure – Expanding Indication

David Holmes, M.D.

Percutaneous MVR for Functional MR/Class III CHF

William Gray, M.D.

Inter-Atrial Shunt Device to Treat Heart Failure

Vivek Y. Reddy, M.D.

Round Table Conversation

Payor: *Centers for Medicare & Medicaid Services*

Joseph Chin, M.D.

Clinician-Trialist: *BI-Deaconess Med Center*

Donald Cutlip, M.D.

Medical Device Manufacturer: *Boston Scientific*

Keith Dawkins, M.D.

Regulator: *Center for Devices and Radiological Health/FDA*

Andrew Farb, M.D.

Medical Device Start-up: *Corvia*

George Fazio

Regulator & Consultant: *NDA Partners*

David Feigal, M.D.

Clinician-Payor: *NICE/University Hospital Wales*

Peter Groves, M.D.

Clinician-Trialist: *Gates Vascular Institute*

Nick Hopkins, M.D.

Regulator: *Center for Devices and Radiological Health/FDA*

John Laschinger, M.D.

Friday Morning

- 8:15 AM Welcome Aaron V. Kaplan, M.D.
- 8:20 AM Medical Innovation Post Health Care Reform/New Payment Models
John D. Birkmeyer, M.D. *Dartmouth-Hitchcock Medical Center*
- 8:50 AM New Payment Models: Impact on Payors and Medical Device Sector Chris A. Simon
McKinsey & Company
- 9:10 AM Health Care Reform & New Payment Models: Medical Device Manufacturers
The Impact on Thinking Within the 'C Suite'

Michael A. Mussallem Chris Simon
Chairman & CEO: *Edwards Lifesciences* *McKinsey & Company*
- 9:45 AM Break

Session 5 Digital Health, Value-Based Care and New Payment Models: Predicting the Future: *What will be different in 10 years?*

10:00 AM	A Medical Device Analyst Perspective	Robert Hopkins
10:10 AM	An FDA Perspective	Bakul Patel
10:20 AM	Consumerization of Healthcare	Chaitanya Dhagam, M.D.
10:30 AM	Moderator	Ross A. Jaffe, M.D.
	Large Medical Center: <i>Brigham & Women's Hospital</i>	Dale Adler, M.D.
	Clinician: <i>NICE/University Hospital Wales</i>	Peter Groves, M.D.
	Closed Panel HMO: <i>Kaiser Permanente</i>	Jo Carol Hiatt, M.D.
	Large Medical Device Manufacturer/ <i>Abbott Vascular</i>	John Hernandez, Ph.D.
	Clinician Investigator: <i>Massachusetts General Hospital</i>	Ken Rosenfeld, M.D.
	Reimbursement & Regulatory Consultant: <i>Richner Consultants</i>	Randel Richner
	Multi-National CRO: <i>genae associates/Hilbert Paradox</i>	Bart Segers
11:45 AM		Closing Comments
Noon:		Adjourn

This Symposium is Supported By:

Gifts (Restricted & Unrestricted)

- Abbott Vascular
- Edwards Lifesciences
- Medtronic, Inc.
- Boston Scientific Corporation
- Abiomed
- Creganna Medical

Registration Fees

3D13: Logistics

- Presentations will be Posted on the 3D Website
www.3D-Dartmouthsymposium.org
- No Direct Quotes
- No Press
- No Tweets (Please)

3D13: Logistics

- Dinner: Please RSVP
- Check Out
 - Please Check Out Before the Start of the Meeting
 - Bags Storage Available
- Feedback: Survey Monkey

Thank You