



3D | **EFS** | **MDIC**
 MEDICAL DEVICE
 INNOVATION CONSORTIUM

SYMPOSIUM

Meeting Outline

3D EFS MDIC:

April 21, 2021

12:00-3:30 PM Eastern Standard Time

3.5-hour event

What Makes EFS Different?

Symposium Co-Chairs

Aaron Kaplan, MD

David Holmes, MD

3D EFS MDIC Group Executive Committee

Andrew Farb, MD, Rick Geoffrion, Pamela Goldberg

David Holmes, MD, Jon Hunt, PhD, Chip Hance

Aaron Kaplan, MD, Martin Leon, MD

Michael Mack, MD, Adnan Siddiqui, MD PhD

Jaime Walkowiak, JD, Bram Zuckerman, MD

Noon:	Welcome Pamela Goldberg	President & CEO Medical Device Innovation Consortium
12:05 PM	Welcome Jeff Shuren, MD JD	Director, Center for Devices & Radiological Health Food and Drug Administration
12:10 PM	Framing Comments Aaron Kaplan, MD	Professor of Medicine & Director 3D Symposium, Dartmouth-Hitchcock Med Ctr.
12:20 PM	Interview-What Makes EFS Different? Clinical Site Perspective Interview with:	Jaime Walkowiak, JD Baylor, Scott & White Health InstilBio
12:35 PM	What Makes EFS Different- Key Issues & Stumbling Blocks Indemnification, Reimbursement, Patient Recruitment	
Moderator	Chip Hance	Regatta Medical
Presenter	Examining the Metrics Jon Hunt, PhD	Medical Device Innovation Consortium
	Steven A. Farmer, MD PhD Lynne Goodreau, RN Jill Trekell Tamim Nazif, MD Michael Zapien	Centers for Medicare & Medicaid Services Northwestern Memorial Edwards Lifesciences Columbia University Ancora Heart

1:15 PM	What Makes EFS Different? A Large Company & Investigator Perspective Interview with:	Ian Meredith, MD PhD Global Chief Medical Officer Boston Scientific
1:30 PM	EFS Case Study- A Large Company Experience Interview with:	Jeffery J. Popma, MD Chief Medical Officer (Coronary & Structural Heart) Medtronic
1:45 PM Moderator	Expanding EFS beyond Structural Heart- Learnings for other Disciplines Andrew Farb, MD	Centers for Devices & Radiological Health Food and Drug Administration
	Lauren Baker, PhD Katherine Kumar, PhD Adnan Siddiqui, MD PhD Paul Sorajja, MD Vivek Reddy, MD	Insight Medical Consulting 4C Medical Technologies U Buffalo/Jacobs Institute Minneapolis Heart Mount Sinai Medical Center
2:25 PM	What Makes EFS Different FDA Perspective Interview with	Andrew Farb, MD Chief Medical Officer/Cardiovascular Devices Centers for Devices & Radiological Health Food and Drug Administration
2:40 PM Moderator	EFS/EU MDD to MDR Transition-Implications Rick Geoffrion	Cyrano Therapeutics
	Lisa Becker Olivier Delporte Hanson Gifford Daniel O'Mahony, PhD Nitin Mehta	Abbott Structural Heart Miracor The Foundry & Lightstone Ventures Seroba Lifescience TUV-Sud
3:10 PM	Closing Comments David Holmes, MD	Scripps Professor in Cardiovascular Medicine Mayo Clinic
3:30 PM	ADJOURN	

Symposium Description

3D-EFS MDIC Symposium is a 3.5-hour interactive virtual meeting focused on the Early Feasibility Study (EFS) Initiative to facilitate the first clinical use studies in the United States, providing updates and examining the current roadblocks.

Symposium Outline:

- EFS – Key Issues, Stumbling Blocks, Reimbursement, Contract Negotiation, Indemnification
- Structured interviews with EFS experts from: industry (large market leaders and start-ups), clinical sites, clinical investigators
- Expanding EFS Cardiovascular experience to other disciplines
- EFS compared with EU MDD-MDR transition – perspectives from thought leaders

Who Should Attend?

- Clinical research personnel in medical device companies and investigational sites
- Clinical investigators
- Regulatory affairs personnel
- Investors

The Symposium is co-sponsored by MDIC and The Dartmouth Device Development Symposium Office.