



# **EFS Symposium: Implementation Strategies for Early Feasibility Studies**

*Sponsored by MDIC in collaboration with CRF*

Event Materials

**June 12, 2019**

**Chicago Ballroom X  
Sheraton Grand**

**301 E North Water St., Chicago, IL 60611**



**EFS Symposium:  
Implementation Strategies for  
Early Feasibility Studies**

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**Wednesday, June 12<sup>th</sup>, 7:00-9:30 pm**

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## **AGENDA**

- 7:00 – 7:10 p.m.: David Holmes – Welcome and Introductions
- 7:10 – 7:20 p.m.: Pamela Goldberg and Chip Hance – Introduction to MDIC and Update of the Initiative
- 7:20 – 7:50 p.m.: Topic # 1: Identification of relevant patient population/Patient screening
- Scott Chadderdon – OHSU (10 min)
  - Blessie Concepcion – Boston Scientific (5 min)
  - Panel discussion (15 min)
- 7:50 – 8:20 p.m.: Topic # 2: Patient consent issues
- Charlie Davidson – Northwestern (10 min)
  - Jill Trekell – Edwards (5 min)
  - Panel discussion (15 min)
- 8:20 – 8:50 p.m.: Topic # 3: Procedural and clinical follow-up issues
- Tamim Nazif – Columbia (10 min)
  - Chris Cain – Conformal Medical (5 min)
  - Panel discussion (15 min)
- 8:50 – 9:20 pm: Aaron Kaplan - Round table discussion focused on audience participation
- 9:20 – 9:30 p.m.: David Holmes and Michael Mack - Wrap up and Next Steps

### **Panelists:**

- Howard Herrmann – Penn Medicine
- Vinod Thourani – Medstar Heart and Vascular Institute
- Michael Mack – Baylor Scott & White
- Scott Lim – University of Virginia
- Bernard Vasseur – FDA

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## Attendees

|     |                           |  |   |
|-----|---------------------------|--|---|
| 1.  | <b>Helen Scotch</b>       | VP Clinical & Regulatory   | Abbott  |
| 2.  | <b>Neil Moat</b>          | Chief Medical Officer, Structural Heart  | Abbott  |
| 3.  | <b>Josh Schumacher</b>    | Sr. Clinical Project Manager   | Abbott  |
| 4.  | <b>Stefano Osta</b>       | Researcher   | Aortic Lab                                    |
| 5.  | <b>David Heimansohn</b>   | Cardiac Surgeon  | Ascension Indianapolis                        |
| 6.  | <b>Melanie Glover</b>     | Executive Director, CV Research  | Ascension Indianapolis                        |
| 7.  | <b>Jaime Walkowiak</b>    | COO, SVP   | Baylor Scott & White                          |
| 8.  | <b>Michael Mack</b>       | Cardiac Surgeon  | Baylor Scott & White                          |
| 9.  | <b>Necole Kell</b>        | Clinical Research Supervisor   | Baylor Scott & White                          |
| 10. | <b>Laoti Bussone</b>      | Senior Clinical Trial Manager  | Boston Scientific                             |
| 11. | <b>Blessie Concepcion</b> | Director Global Clinical Trials  | Boston Scientific                             |
| 12. | <b>Yoshi Kaneko</b>       | Assistant Professor of Surgery, Cardiac Surgeon  | Partners Healthcare (B&W Health)              |
| 13. | <b>Ilia Hariton</b>       | VP of R&D  | CardioValve                                   |
| 14. | <b>Nitza Shoham</b>       | VP CA & RA   | CardioValve                                   |
| 15. | <b>Tamim Nazif</b>        | Assistant Professor of Medicine  | Columbia UMC                                  |
| 16. | <b>Martin Leon</b>        | Mallah Family Professor of Cardiology  | Columbia UMC                                  |
| 17. | <b>Chris Cain</b>         | VP, Clinical & Regulatory Affairs  | Conformal Medical, Inc.                       |
| 18. | <b>Ori Ben-Yehuda</b>     | Executive Director, CRF Clinical Trials Center   | Cardiac Implants                              |
| 19. | <b>Martin Quinn</b>       | Cardiologist   | CroiValve                                     |
| 20. | <b>Aaron Kaplan</b>       | Director, Device Development, Cardiovascular Medicine  | Dartmouth-Hitchcock Heart and Vascular Center |
| 21. | <b>Jill Trekell</b>       | Director, Office of Product Evaluation and Quality<br>Office of Neurological and Physical Medicine Devices | Edwards Lifesciences                          |
| 22. | <b>Bernard Vasseur</b>    | Medical Officer, Structural Heart Device Branch  | FDA   |
| 23. | <b>Ryan Wright</b>        | President  | Flow-FX                                       |
| 24. | <b>Patrick Sweeney</b>    | CEO / Medical Director   | Flow-FX                                       |
| 25. | <b>Patrick Brady</b>      | VP of Sales  | Hawthorne Effect, Inc.                        |

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|-----|--------------------------------|---|------------------------------|
| 26. | <b>Neil Kleinman</b>           | Preventative & Interventional Cardiology                | Houston Methodist            |
| 27. | <b>William Gray</b>            | Systems Chief   | Lankenau Heart Institute     |
| 28. | <b>David Holmes</b>            | Interventional Cardiologist                             | Mayo Clinic                  |
| 29. | <b>Lisa Beck</b>               | Director Clinical Affairs                               | MCRA                         |
| 30. | <b>Liliana Rincon-Gonzalez</b> | Program Director Clinical Science                       | MDIC                         |
| 31. | <b>Pamela Goldberg</b>         | President & CEO   | MDIC                         |
| 32. | <b>Chip Hance</b>              | Board of Directors                                      | MDIC                         |
| 33. | <b>Charles Davidson</b>        | Vice Chair for Clinical Affairs, Department of Medicine | Northwestern University      |
| 34. | <b>Scott Chadderdon</b>        | Assistant Professor of Medicine                         | OHSU                         |
| 35. | <b>Yael Kislev</b>             | Senior Clinical Manager                                 | Pi-Cardia                    |
| 36. | <b>Raghu Basude</b>            | VP of R&D   | SynerZ Medical               |
| 37. | <b>Mano Thubrikar</b>          | President   | Thubrikar Aortic Valve, Inc. |
| 38. | <b>Steven Bolling</b>          | Professor of Medicine                                   | University of Maryland       |
| 39. | <b>Marissa Donatelle</b>       | Program Coordinator                                     | University of Virginia       |
| 40. | <b>Scott Lim</b>               | Professor   | University of Virginia       |
| 41. | <b>Howard Hermann</b>          | Cardiology  | University of Pennsylvania   |