ON THE EVE OF

AF SYMPOSIUM 2023

Early Feasibility Studies Best Practices Workshop

1 FEBRUARY, 2023 | 1:00–5:00 PM

BOSTON, MA | THE OMNI HOTEL

TO REGISTER

Program Information

This conference has attracted an international community of leaders in the medical device research ecosystem. Attendees at this session will learn about EFS trial operational trends, to assist innovators, clinicians and regulators interactively to identify challenges and solutions to bringing first-in-world access to potentially beneficial medical devices to patients in the US. The audience will also learn about best practices from clinical sites and industry to represent how collaboration can help to identify challenges and to share lessons learned to promote EFS in the US. The audience will also learn how the FDA has addressed the regulatory challenges and successfully reduced the out migration and how MDIC is working on addressing the administrative and operational challenges by working with the FDA, industry and clinical sites.

FDA's Vision:
Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

Early Feasibility Studies (EFS) Background

- The FDA issued an Early Feasibility Study (EFS) guidance document and established an EFS Program in 2013 to help facilitate the clinical evaluation of innovative medical devices in the US.
- Application of EFS principles as outlined in the guidance has shortened the approval of EFS investigational Device Exemption (IDE) application to less than 60 days in most cases.
- Industry Sponsors and Investigators have used the EFS Program to greatly increase the number of EFS performed in the US.
- After IDE approval by FDA, research performed by MDIC showed that there were delays in EFS initiation primarily due to prolonged contracting and budget negotiations between the clinical sites and sponsors.
- To help address delays in EFS start-up, the MDIC EFS initiative has created a toolkit to meet a 60/60/60 target corresponding to 60 days for FDA IDE approval and IRD approval, in parallel with finalizing contracting and budgeting, plus 60 days for first patient enrolled.

Check out the MDIC EFS Toolkit – Master Clinical Trial Agreement and Informed Consent Form

Program Overview and Faculty

Program Overview

This workshop is intended to bring together the FDA, CMS, Industry, and clinical site partners to discuss how to implement EFS trials. It will provide a half day of presentations delivered by recognized thought leaders in the medical device ecosystem. The agenda will consist of lectures and engage in high level panel discussions focused on EFS in Electrophysiology.

Co-Chairs

Justin Klein, MD, JD
Vensana Capital

Pete Weiss, MD, MSC
Banner University of Arizona

MDIC Board Champion

Chip Hance

FDA Early Feasibility Study Program Co-Leader

Andrew Farb, MD

MDIC Staff

Keondae Ervin

Eileen Mihas

External Faculty

Amin Al-Ahmad, MD
Texas Cardiac Arrhythmia Institute at St. David's Medical Center

Samuel Asirvatham, MD
Professor of Medicine, Professor of Pediatrics Mayo Clinic College of Medicine and Science

Ken Coffey
CEO, Atrian Medical

Kate Dalton, MS, RD, CCRC
Director, Cardiology Research, New York-Presbyterian/Columbia University Medical Center

David Hazlewood, PhD
Biomedical Engineer, Office of Cardiovascular Devices, FDA

Avi Fischer, MD
Senior Vice President, Medical Affairs & Innovation, Orchestra BioMed, Inc.

Holger Friedrich, MD
CEO, Aquaheart

Lynne Goodreau, RN, MS
Administrative Director, Bluhm Cardiovascular Institute Clinical Trials Unit, Northwestern University

Anthony Hong, MD
VP, Preclinical & Clinical Research and Medical Affairs, Biosense Webster

Brad Horst
Global Vice President, Clinical Management, Rhythm Management Division at Boston Scientific

Jerome Kalifa, MD, PhD
Co-Founder, Volta Medical

Aaron Kaplan, MD
Founder & Chief Medical Officer, Conformal Medical & Director, Clinical Research, Heart & Vascular Center Dartmouth-Hitchcock Medical Center

Moussa Mansour, MD
Director of the Cardiac Electrophysiology Laboratory and Director of the Atrial Fibrillation Program at Massachusetts General

Devi Nair, MD
St. Bernard's Medical Center

Andrea Natale, MD
Executive Medical Director, Texas Cardiac Arrhythmia Institute at St. David's Medical Center

Vivek Reddy, MD
Director of Cardiac Arrhythmia Services, Mount Sinai

Kit Schneider
Sr. Director of Clinical and Preclinical, Engineering, FARAPULSE, Inc, Boston Scientific

Ken Stein, MD
Senior VP and CMO, Rhythm Management and Global Health Policy, Boston Scientific

George Van Hare, MD
Medical Officer, Implantable Electrophysiology Devices Team, Division of Cardiac Electro-physiology, Diagnostics, and Monitoring Devices

Jaime Walkowiak, JD

Bram Zuckerman, MD
Director, Office of Cardiovascular Devices Center for Devices & Radiological Health (CDRH) at FDA

Rejuvenating the U.S. Electrophysiology Clinical Trial Ecosystem: EP Early Feasibility Studies Best Practices Workshop

1:00 PM **Welcome**
Pete Weiss, MD and Justin Klein, MD, JD

1:10 PM **History of the Early Feasibility Pathway for Novel Medical Devices**
Andrew Farb, MD (FDA)

1:15 PM **MDIC led Transformation of the Structural Heart Regulatory Pathway: The Return of Early Feasibility Studies to the U.S.**
Chip Hance

1:20 PM **Session I: The Evolving Regulatory Pathways for Novel EP Devices**

Session Leaders
Ken Stein, MD and Vivek Reddy, MD

Speakers
Vivek Reddy, MD – "Trends in Electrophysiology Clinical Studies and the Need for an Effective Clinical Trial Ecosystem"

Kit Schneider – "Farapulse: Clinical and Regulatory Journey"

Ken Coffey – "An EP Startup's Perspective on the Clinical Pathway"

George VanHare, MD – "FDA Perspectives on Electrophysiology Clinical Studies"

Jerome Kalifa, MD, PhD – "Early Feasibility Clinical Evidence: Using the US-EU Regulatory Paradigms to Advance Innovative Technologies: The Volta Medical Experience"

1:55 PM **Open Discussion / Q&A**

2:30 PM **Break**

2:45 PM **Session II: EFS and the Bridge to Pivotal – Clinical Site Experience**

Session Leaders
Tony Hong, MD and Devi Nair, MD

Speakers
Site Learnings: Devi Nair, MD – "Conducting Early EP Clinical Research in the U.S.: A Clinical Site Success Story"

Samuel Asirvatham, MD (Mayo Clinic) "Promoting Innovation through EFS"

Site Learnings: Moussa Mansour, MD (Mass Gen) – "Ambitions and challenges in conducting early research in the U.S."

Site Learnings: Amin Al-Ahmad, MD – "Ambitions and challenges in conducting early research in the U.S."

Aaron Kaplan, MD – "A Sponsor's Perspective: Utilizing the EFS Pathway for a Novel Electrophysiology Device"

Avi Fischer, MD – "Considerations as a Study Sponsor Bringing an EFS to the U.S."

Holger Friedrich, MD – "Quality Enrollment is Essential, But Time is Money"

3:20 PM **Open Discussion / Q&A**

3:50 PM **Break**

4:05 PM **Session 3: Shortening Time to First Patient In: Timely and Effective Contracting**

Session Leaders
Jaime Walkowiak, JD

Speakers
Jaime Walkowiak, JD – "Yes We Can Negotiate Contracts in 60 Days!"

Kate Dalton (Columbia) – "Institutional Alignment in a Teaching Hospital for Early Feasibility Studies"

Lynne Goodreau (NMH) – "10 Successful EFS Studies and Counting at a Leading Clinical Site – It can be Done"

Brad Horst (Boston Scientific) – "Tips and Tricks of Contract Negotiation from a Sponsor's Point of View"

David Hazlewood, FDA – "FDA Categorization of IDE Applications to Assist CMS Coverage Decisions"

4:35 PM **Open Discussion / Q&A**

5:05 PM **Wrap Up and Closing Remarks**
Pete Weiss, MD and Justin Klein, MD, JD

Summary of Next Steps
Eileen Mihas

5:30 PM **Cocktail Networking Reception**

6:30 PM **Special Dinner Event**
Keynote Speaker
Bram Zuckerman, MD