Welcome back to the EFS Express with new Program Director Eileen Mihas, RN, MSN

Welcome to the first re-issue of *EFS Express*! It's been some time since the last one, and we are excited to be back! My name is Eileen Mihas, and I joined the Medical Device Innovation Consortium (MDIC) as the EFS Program Director in July of 2022. I am a registered nurse with more than 17 years of extensive experience in medical devices and clinical research. I am excited to play a part in our collective work and look forward to building on the EFS Working Group's success in partnership with key stakeholders to elevate further the practice of early feasibility studies in the United States.

In this quarterly newsletter, we will provide updates on MDIC's Early Feasibility Studies initiative, including successes and challenges, as well as share educational materials and tools produced through our combined efforts. In this issue, we provide a brief background on MDIC's EFS program and explore the significant progress that has been made in the Electrophysiology space.

We hope you find this information valuable, and we welcome your feedback. Please reach out to me (emihas@mdic.org) or Keondae Ervin (kervin@mdic.org) if you and/or a colleague are interested in participating in or learning more about this work.

Background on Early Feasibility Studies

About 10 years ago, multiple stakeholders and therapeutic disciplines in the medical device space identified areas where clinical needs were not being met. In 2013, the FDA issued an Early Feasibility Study (EFS) guidance document and established their EFS Program to help accelerate the clinical evaluation of novel medical devices in the US.

The vision is to drive overall efficiency for enrolling patients in an early feasibility study and accelerate access to potentially beneficial medical devices for patients in the US by shortening the overall approval timeline. Through MDIC's EFS Program, we helped advance those efforts, in part, by developing a clinical trial template, patient informed consent form, among other useful documents to streamline the contracting process. It is MDIC's hope to continue developing EFS resources and bring awareness to the tools that have already been developed in hopes of make US-based EFS more feasible and efficient.

EFS Electrophysiology Best Practices Workshop

MDIC hosted an EFS Electrophysiology (EP) Best Practices Workshop on February 1, 2023, in Boston, MA, in conjunction with the Atrial Fibrillation Symposium, which attracts a myriad of leaders in the medical device research ecosystem from across the globe. Attendees who joined the session learned about EFS trial operations and trends that can assist innovators, clinicians, and regulators collaboratively identify challenges and solutions. This type of interaction and engagement proved effective in the structural heart space by bringing first-in-world access to potentially beneficial medical devices to patients in the US. MDIC seeks to have a similar success in Electrophysiology.

Access the EP Workshop Key Insights Report

View the Slides Shared at the Workshop

Through didactic learning sessions and collaboration with the FDA, clinical sites, and industry, audience members learned best practices on promoting EFS in the US. Through the extraction of lessons learned, we can help to identify challenges to promote EFS. Attendees also learned how the FDA addresses regulatory challenges to reduce the overseas migration of clinical research for novel medical devices. MDIC seeks to address the administrative and operational challenges associated with conducting EFS trials by working with stakeholders to enhance and streamline the clinical trial process. Further opportunities for discussion will be forthcoming in 2023 including a session at the Heart Rhythm Society Annual Meeting this coming May.

“The EP EFS workshop successfully brought together key stakeholders in an effort to promote a shift in the early device development ecosystem. Representation by and discussion between leaders from the FDA, clinician investigators, clinical site research professionals, device industry strategic partners, device industry start-ups, and the financial community created a unique opportunity to move the initiative forward,” Pete Weiss, MD, MSc, Electrophysiology Steering Committee Chair said.

Have an EFS Success Story?

Have an EFS success story? In support of our 2020 Strategic Priorities, we want to publish success stories to help further the mission and vision of this project. If you would like to share, please send us an e-mail at efspilot@mdic.org with your contact information and 2-3 sentence summary of your project/story and we will contact you to set up a time to discuss further. Success stories may be written up and published in the EFS Express and across general MDIC channels and industry channels.

Electrophysiology Tools and Resources

There is also an ongoing effort to coordinate collaboration among all stakeholders to identify barriers and create tools and resources to help support EP EFS in the US. The recently released article, "Early feasibility studies in the United States: Focus on electrophysiology, published in the Journal of Cardiovascular Electrophysiology", published on behalf of MDIC’s EP Steering Committee is a testament to this program’s commitment to disseminating education and bringing awareness to key issues impacting EFS stakeholders. This review introduced key aspects of the discussion around early patient access to novel devices. It also addresses the unmet needs and efficient innovative technology development, to broaden awareness and encourage engagement by stakeholders to address central issues. This resource furthers a growing effort to shift Early Feasibility Studies to the United States for the benefit of all involved.

Closing Remarks

MDIC provides the space for stakeholders to convene and address barriers against opportunities for re-invigorating the clinical trial ecosystem in the United States to create a faster pathway to approval. Naturally beneficial relationships among stakeholders foster and accelerate the speed of innovation to enhance patient lives. All stakeholders have this mission in mind, but with differing levels of access to collaborative space. MDIC providing this neutral space allows for incremental changes to become transformative and disrupt the paradigm in which EFS trials have routinely been conducted.

Over the last few years, several groups have been engaged by MDIC’s EFS committees to address the fundamental issues of what defines an optimal early feasibility study clinical center, and what the barriers to success would be including contracts, institutional review board (IRB) involvement, indemnification, metrics of performance, site selection, and reimbursement for procedures. The goal is a robust medical care system which fosters the development of new technology to address unmet patient needs in an

efficient manner, to maintain strict assurance on safety and efficacy of such new technology, and to optimize processes for early approval so that patient outcomes can be measurably improved. Through vigorous engagement of vital EFS stakeholders, MDIC has furthered the discussion and identified approaches to resolution. To learn more about MDIC membership and how to join the network of collaborators to aid in creating solutions, tools, and resources that produce a pathway to more efficient EFS implementation in the United States, please reach out to me (emihas@mdic.org) or Keondae Ervin (kervin@mdic.org)

That's all for this edition of EFS Express. I look forward to continuing to bring awareness to EFS best practices and engaging with a wide array of industry collaborators to advance our shared objectives.