MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

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New Director Liz Mino, PhD, is Expanding EFS Program

Liz Mino, PhD, joined MDIC in June 2021 as Program Director of the EFS Initiative. Liz has 17 years of extensive experience in the medical device industry, primarily in the start-up space.

“I am first and foremost a patient advocate so being able to bring novel technology to individuals in need has always been important to me,” says Liz. “In some medical device sectors, technological advances in the U.S. lag behind other countries because early clinical trials are done outside the U.S. Outsourcing clinical trials to other countries often results in the delayed introduction of novel devices in the U.S. Bringing EFS trials back to the U.S. has the potential to accelerate time to market of novel technologies in the U.S. At MDIC, we strive to improve regulatory efficiencies in EFS trials.”

Expanding into the Neurovascular and Electrophysiology Spaces

Liz is overseeing the expansion of MDIC’s EFS Program into the neurovascular and electrophysiology spaces. The Neurovascular U.S. Early Feasibility Clinical Studies Initiative held its first meeting in July 2021, with 28 invitees from industry and clinical research sites participating. Member recruitment is underway and working group meetings will be held in early fall. In parallel, planning is underway for the Electrophysiology (EP) EFS Clinical Studies Initiative, which Liz expects MDIC to launch in the winter of 2021.

As part of the EFS Initiative, MDIC looks to identify centers of excellence, clinical research sites that can conduct EFS for structural heart, neurovascular, and EP devices, or at least two of the three specialties. This will lead to further regulatory efficiencies and faster study startup.

Promoting Current Work

Along with the expanded activities, Liz will continue to promote:

- U.S. EFS through partnerships between FDA, CMS, industry sponsors, and clinical research sites
- The MDIC EFS toolkit and other educational materials.

Tools include success stories, best practices, templates for a Master Clinical Trial Agreement and a Patient Informed Consent Form, contract language and negotiation tools, and information tools for IRBs, site study staff, and patients. Each tool was developed based on EFS metrics collected by MDIC and the needs of the medical device industry, sites, and FDA.

“A considerable amount of work has gone into the contents of the EFS toolkit. These tools are content rich and thoroughly vetted, but unfortunately very few companies know that these tools exist,” says Liz. “It’s important to get the message out to large and small sponsors, as well as clinical sites, as these tools can reduce inefficiencies and speed time to study approval."

Read more about the tools in our toolkit.

Access the toolkit.

Bringing Extensive Device Experience to MDIC

Before joining MDIC, Liz was a Principal Scientist for Acutus Medical, Inc. She has worked for several other medical device manufacturers in the roles of clinical director, field clinical engineer, and field scientist. Liz has a PhD in applied physiology from the University of Utah and she completed a Post-Doctoral Fellowship at New Mexico Resonance.

Have an EFS success story? In support of our 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 a 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.

Looking for more information? Consult our EFS Tool Kit.

Interested in participating in the EFS Initiative as a sponsor or site? Email us today for more information.

Our mailing address is:
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