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MDIC Expands EFS Program into the Neurovascular Space

MDIC is expanding its Early Feasibility Studies (EFS) efforts into the neurovascular space. With the launch of the Neurovascular EFS Initiative, MDIC will build on the successes of the Structural Heart EFS model where regulatory tools were developed by clinical research sites and industry sponsors with a goal to accelerate EFS timelines.

As part of the Neurovascular U.S. Early Feasibility Clinical Studies Initiative, sponsors, clinical research sites, and representatives of FDA will work together to:

- Identify the common ecosystem challenges for EFS neurovascular clinical research
- Develop new tools or adapt existing tools to facilitate increasing U.S. neurovascular EFS trials

“Industry partners and clinicians are interested in streamlining neurovascular EFS research in the U.S.,” says Chip Hance, MBA, co-chair of the Neurovascular U.S. Early Feasibility Clinical Studies Working Group. Hance is CEO of Regatta Medical and MDIC EFS Initiative Board Champion. He is co-chairing the Working Group with Adnan Siddiqui, MD, PhD, Professor of Neurosurgery at SUNY University at Buffalo and CEO of the Jacobs Institute.

An introductory meeting in July 2021 drew 28 individuals from industry and clinical research sites. The meeting established a common understanding of the approach MDIC intends to take to streamline neurovascular EFS trials in the U.S.

Volunteers are the backbone of all MDIC initiatives. As such, MDIC encourages volunteers from industry and clinical research sites working in the neurovascular space to join working groups that will focus on revisions to existing documents such as the clinical trial agreement template, an informed consent template, and budgets. MDIC will coordinate the collaboration of interested volunteers. To date, five clinical sites and eight industry sponsors have stepped up to join the Initiative. Volunteers representing industry sponsors include clinical and regulatory directors and attorneys, as well as principal investigators, clinical research coordinators, patient advocates, and attorneys from clinical research sites.

As a next step a meeting is being planned in spring 2022 where industry and clinical site representatives can gather and share resources and best practices.

Learn more about or join the Neurovascular U.S. Early Feasibility Clinical Studies Working Group:

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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.

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