Video series highlights MDIC's work to streamline the startup of EFS in the U.S.

MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

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Video Series Raises Awareness about EFS Program

The FDA Early Feasibility Studies (EFS) program has enabled many Class III device companies to benefit from an accelerated review process, speeding the completion of EFS and making rapid gains towards device development and a pivotal trial. MDIC's video series, Emerging HealthTech: The MDIC Series | Early Feasibility Studies, explains why the FDA EFS program is so important and highlights MDIC's work to streamline the startup of EFS in the United States, including by developing tools for sites and sponsors. Created by The Mullings Group, the 14 videos feature MDIC leaders and device innovators Rick Geoffrion, MBA, and Chip Hance, BS, MBA.

"We want to raise awareness within the clinical community about the EFS program and the MDIC tools that are available and have been used with great success," says Geoffrion, President and CEO of Cyrano Therapeutics, Inc., and Vice Chair of The Mullings Group. In the videos, Geoffrion shares his past experience as founder of a cardiovascular device company that was able to shepherd a class III PMA structural heart device through the FDA EFS pathway. "If a company like mine did not have the opportunity to take advantage of the EFS program, we may have ceased to exist. And I think there are many companies that would have been in the same situation," he says.

MDIC's Role in the EFS Program

MDIC developed tools for sites and sponsors after device companies attempted to conduct EFS studies under the FDA EFS program and were stymied by long, costly administrative delays. "The ecosystem for first-in-man studies in the U.S. was not working well. IRB reviews, contracting, budgeting, and other activities could take up to a year," says Hance, CEO of Regatta Medical.

To measure EFS timelines and identify areas for improvement, MDIC gathered confidential data from industry sponsors. MDIC then brought leading U.S. institutions, sponsors (large and startups), and FDA together to streamline the EFS process. "MDIC provided a safe, collaborative environment for developing a healthy clinical trial ecosystem for EFS in the U.S.," says Hance.

One key MDIC tool is the EFS Master Clinical Trial Agreement (MCTA), which serves as the starting point for negotiations and contains common language for about 90% of any EFS contract. Ten major device company attorneys and 12 site attorneys collaborated to develop the MCTA, which is available in the MDIC EFS Tool Kit.

"MDIC has developed some incredible tools that small and large companies can use to effectively execute an EFS," says Geoffrion.

Both Geoffrion and Hance are active members of MDIC. Geoffrion is a member of MDIC's Board of Directors and Executive Committee and co-chair of the EFS Cardiology Steering Committee. Hance is the MDIC EFS Initiative Board Champion.

Watch the videos: Emerging HealthTech: The MDIC Series | Early Feasibility Studies

MDIC thanks Rick Geoffrion, MBA, President and CEO of Cyrano Therapeutics, Inc., and Chip Hance, CEO of Regatta Medical, for sharing their perspectives in the videos and in this EFS Express Story.

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.