



# EFS EXPRESS

Edition 19 · August 4, 2020

## Startup Accelerates Time to First Subject Enrolled in EFS by at least 50% by Using MDIC Tools

**Sponsor:** [preCardia](#)

**Company Size:** Startup

**Device Type:** Catheter-based system for acute decompensated heart failure

Using MDIC EFS tools and working with clinical research sites that are part of the MDIC-EFS Pilot Network let startup [preCARDIA](#) cut the amount of time needed to enroll the first subject in its EFS by at least 50%. "Time is money, especially if you're a small startup," says Sara Vidmar, the company's Senior Vice President of Clinical, Regulatory, and Strategic Affairs.

Vidmar and [preCARDIA](#) President and CEO Lisa Wipperman Heine had worked together on an EFS at another device company while the MDIC tools and resources were being developed. When the MDIC [EFS Background Information: IRBs and Site Study Staff](#) became available, the research leaders used this to help hospital administrators, research staff and IRB members understand EFSs. They were able to launch sites much faster.

So when preCARDIA launched an EFS for the company's catheter-based system for acute decompensated heart failure (the preCARDIA system), Vidmar and Wipperman Heine turned to MDIC to accelerate the process. The preCARDIA system treats patients with acute decompensated heart failure via intermittent superior vena cava occlusion.

"We began our study using the MDIC tools, and this made our lives so much easier," says Vidmar. By that time, MDIC had developed the [EFS Master Clinical Trial Agreement \(MCTA\) template](#) and the [EFS Patient Informed Consent Form Template](#). preCARDIA used these tools and [EFS Background Information: IRBs and Site Study Staff](#). Vidmar was part of the group that developed the MCTA.

Working with sites who are members of the MDIC EFS Pilot Network contributed to quicker study start-up times. For example, Northwestern Medical's contract approval time was only 43 days. "Northwestern had the fastest start-up of any site I've worked with in 27 years," says Vidmar, who attributes this to the medical center's familiarity with EFS studies, and their use of the MDIC MCTA and informed consent form templates.

Another rapid study start-up came from Tufts Medical Center, another network site. Their time to first patient enrollment was only 69 days. According to [metrics collected and presented by MDIC](#) at the 2019 MDIC Annual Public Forum, the average contract approval timeline is 164 days and the average timeline from IDE approval to 1st subject enrolled is 252 days.

preCARDIA also worked with other sites that had the necessary therapeutic expertise but were not members of the MDIC EFS Pilot Network. Use of [EFS Background Information: IRBs and Site Study Staff](#) and the [EFS Patient Informed Consent Form Template](#) shortened the usual IRB review process to one or two rounds of review. "The background document helped their IRBs understand and feel comfortable with an EFS study," says Vidmar.

By conducting the EFS in the U.S., Vidmar expects the FDA review process and clinical testing to be streamlined. "We'll carry forward the sites that have been good partners into the pivotal study and anticipate negotiations to be fairly easy," she says.

**MDIC Templates Used:** [EFS Master Clinical Trial Agreement](#), [EFS Patient Informed Consent Form Template](#), [EFS Background Information: IRBs and Site Study Staff](#)

*MDIC thanks Sara Vidmar, Senior Vice President of Clinical, Regulatory, and Strategic Affairs at preCARDIA, for sharing the company's 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](mailto: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.

**Looking for more information?** Consult our [list of EFS Resources and Tools](#)

**Interested in participating in the EFS Initiative as a sponsor or site?** [Email](#) us today for more information.

Follow on [Twitter](#). [Connect on LinkedIn](#). [Forward to Friend](#)

Copyright © All rights reserved.

Our mailing address is:  
1501 Wilson Blvd., Suite 910 Arlington, VA 22209

[update subscription preferences](#)