MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

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Academic Medical Center Cuts CTA Process to Less than 6 Weeks

Site: Northwestern Medicine
Site Type: Academic medical center
Device Type: Cardiovascular devices

Negotiating a clinical trial agreement (CTA) for an EFS could take the Bluhm Cardiovascular Institute at Northwestern Medicine up to six months if a master service agreement was not previously established with an industry sponsor, delaying early patient access to life-saving cardiovascular devices. The academic medical center's usual CTA timeline was similar to the average of 164 days, according to metrics collected and presented by MDIC at the 2019 MDIC Annual Public Forum.

Since the Bluhm Cardiovascular Institute started using the MDIC EFS Master Clinical Trial Agreement (MCTA) template with startup companies, research managers have been able to complete contract negotiations in four to six weeks.

"In the EFS space, we work with quite a few startup companies that may be limited in their clinical trial infrastructure. The MCTA template has become a go-to resource to streamline CTA negotiations," says Lynne Goodreau, Administrative Director of the Bluhm Cardiovascular Institute's Clinical Trials Unit.

preCARDIA, Inc. is one of the startups where the Bluhm Cardiovascular Institute was able to accelerate CTA negotiations using the MCTA. This EFS uses preCARDIA's proprietary balloon catheter and pump controller device to treat patients with acute decompensated heart failure. The device is designed to address this condition via intermittent superior vena cava occlusion.

The EFS MCTA template is especially helpful in the challenging indemnification and publication sections. "Having language that multiple institutions have agreed upon makes executing CTAs much easier and faster," says Anna Huskin, program manager at the Clinical Trials Unit.

Sean Perry, director of research contracts in Northwestern Medicine's Office for Sponsored Research, was part of the MDIC working group that developed the EFS MCTA template. The working group included staff from other academic medical centers, the FDA, and medical device sponsors of all sizes.

Goodreau and Huskin appreciate MDIC's collaborative approach to solving EFS challenges and the opportunity to learn from other academic medical centers. "There are many unknowns in the EFS space," says Goodreau. "It's a new area and we are learning as we go." Relationships with other academic medical centers formed through MDIC enable Goodreau and Huskin to better navigate the EFS clinical trial environment.

"We know we're going to see many EFSs in the pipeline. For future projects with smaller companies, we will guide them to the MDIC site and promote use of the EFS MCTA template," says Goodreau.

MDIC Template Used: EFS Master Clinical Trial Agreement

MDIC thanks Lynne Goodreau and Anna Huskin for sharing the site'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** 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

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