



EFS EXPRESS

Edition 18 · July 7, 2020

Startup Launches EFS at One Site in 26 Days by Using MDIC's MCTA

Sponsor: [Conformal Medical](#)

Company Size: Startup

Device Type: Left atrial appendage closure device

Once a startup company finalizes a product design, speed to entry in the clinical setting is essential. Conformal Medical experienced an unexpected delay when a late change in clinical trial reimbursement for its left atrial appendage closure device required renegotiation of contracts for its EFS.

Despite having to re-negotiate the contract, by using the MDIC [EFS Master Clinical Trial Agreement \(MCTA\) template](#) and working with an EFS experienced clinical research site, the company was able to launch the study at this site in 26 days. Finalizing an EFS contract takes an average of 164 days, according to [metrics collected and presented by MDIC](#).

"This was my first EFS (first-in-human) in the U.S. Going in I was a bit skeptical; I didn't think things could move so quickly," says Chris Cain, VP of Clinical & Regulatory Affairs at Conformal Medical. "I usually dread contract negotiations, but this one went really fast."

Working with a site that had EFS experience and an internal champion were key factors, says Cain. The clinical research staff and their IRB were familiar with the EFS process. The project lead, who had worked with MDIC to develop the MTCA, served as a champion for the Conformal Medical EFS.

Along with using the MTCA, access to MDIC members who have conducted EFSs in the U.S. and meeting FDA staff have been key benefits of being involved with MDIC for Cain. "MDIC is the center-post that brings all of these different stakeholders together and creates platforms where you can interact. It's a guiding light in the EFS space," he says. Cain expects Conformal Medical to be able to move more efficiently from the first-in-human trial to the pivotal trial due to the company's involvement with MDIC and consistency in the sites and the FDA reviewer in both phases. "The transition from EFS to the pivotal trial should be smoother because the sites already know the technology and FDA already knows the product and data," says Cain. "This will save us time and money."

MDIC Templates Used: [EFS Master Clinical Trial Agreement](#)

MDIC thanks Chris Cain, VP of Clinical & Regulatory Affairs at Conformal Medical, 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 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.

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