



EFS EXPRESS

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Startup Finalizes EFS Contract with Brigham & Women's in Less Than 3 Months

Sponsor: [4C Medical Technologies, Inc.](#) (4C Medical)

Company Size: Startup

Device Type: Transcatheter Mitral Valve Replacement (TMVR)

Finalizing an EFS contract takes an average of 164 days, according to [metrics collected and presented by MDIC](#). But, by using the MDIC [EFS Master Clinical Trial Agreement \(MCTA\) template](#), medical device startup 4C Medical finalized their clinical trial agreement with Brigham and Women's hospital in less than three months (90 days).

"We only needed to make a few minor modifications to the template. Most of the legal language was fine with us because MDIC put so much effort into working with multiple stakeholders and legal departments to make sure that every stakeholder had an opportunity to comment," said Dr. Katherine Kumar, executive vice president of 4C Medical.

The company also used the MDIC [EFS Informed Consent Form \(ICF\) template](#) with Brigham and Women's Institutional Review Board (IRB). The IRB approval process was simple and took less than one month, Dr. Kumar said, because MDIC made sure the template fulfilled all the regulations and requirements.

As a small startup, 4C Medical often must prepare documents, such as an MCTA or ICF, from scratch for each site. Resources like the MDIC EFS MCTA and ICF are essential to companies like hers, Dr. Kumar said.

Brigham and Women's is also an MDIC site and it was the hospital's contracts team that sent the MDIC MCTA template.

"The PI was exceptionally pleased with how much quicker the process was. The fact that they could do everything almost seamlessly was very positive," said Dr. Kumar. "Anyone conducting an EFS absolutely must review the MDIC website and use the resources to save time and increase efficiency."

MDIC Templates Used: [Master Clinical Trial Agreement](#), [Informed Consent Form](#)

MDIC thanks Dr. Katherine Kumar, EVP of 4C 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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