



EFS EXPRESS

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Sponsors and Sites Accelerate Clinical Research with MDIC EFS Master Clinical Trial Agreement

Making innovative devices available sooner is essential to startup device manufacturers, clinical research sites, and patients. Using the MDIC [EFS Master Clinical Trial Agreement \(MCTA\)](#), three sponsors developing cardiovascular devices and three sites have been able to complete EFS contract negotiations in 26 to 90 days.

That's far shorter than the 164 days (on average) usually required to finalize a CTA for an EFS, according to metrics collected and presented by MDIC. The MDIC EFS MCTA covers more than 90% of the contract process.

Faster Enrollment

"Time is money, especially if you're a small startup," says Sara Vidmar, Senior Vice President of Clinical, Regulatory, and Strategic Affairs at [preCardia](#), one of the startups that accelerated its EFS by using the MDIC EFS MCTA. preCardia cut the amount of time needed to enroll the first EFS subject by at least 50% and shortened contract approval with the Bluhm Cardiovascular Institute at Northwestern Medicine to 43 days.

Read the EFS Express Success Story on [preCardia](#).

Since the [Bluhm Cardiovascular Institute](#) started using the MDIC EFS MCTA with startups like preCardia, research managers have been completing contract negotiations 43 days or less. "The MCTA template has become a go-to resource to streamline CTA negotiations, says Lynne Goodreau, Administrative Director of the Bluhm Cardiovascular Institute Clinical Trials Unit.

Read the EFS Express Success Story on [Northwestern Medicine](#).

Efficient Contract Negotiations

[Conformal Medical](#) and [Baylor Scott & White Research Institute, Heart and Vascular Research](#) used the MDIC EFS MCTA to reduce contract negotiations to 26 days. "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.

With 13 EFS completed since 2014, the Baylor, Scott & White Research Institute already knew that collaboration with MDIC and use of tools like the MDIC EFS MCTA would increase efficiencies.

Read the EFS Express Success Story on [Conformal Medical](#).

Read the EFS Express Success Story on [Baylor Scott & White Research Institute, Heart and Vascular Research](#).

Using the MDIC EFS MCTA, leaders in cardiology research at [Columbia University Irving Medical Center](#) cut the amount of time needed to finalize an EFS contract to about 30 days. [4C Medical Technologies, Inc.](#) finalized its CTA with Brigham and Women's Hospital in less than 90 days.

- Read the EFS Express Success Story on [Cardiology Research at Columbia University Irving Medical Center](#).
- Read the EFS Express Success Story on [4C Medical Technologies, Inc.](#)

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

Join us April 21 for the 3D-EFS MDIC Symposium. In partnership with The Dartmouth Device Development Symposium Office, MDIC will host a 3.5-hour interactive virtual meeting focused on the Early Feasibility Study (EFS) Initiative to facilitate the first clinical use studies in the United States, providing updates and examining the current roadblocks. Learn more and register [here](#).

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.

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