Site Grows EFS Program and Helps Create EFS Ecosystem through MDIC

Site: Baylor Scott & White Research Institute, Heart and Vascular Research
Site Type: Academic medical center
Device Type: Primarily mitral valve and tricuspid valve devices

The Baylor Scott & White Research Institute has conducted 13 EFSs since 2014, with 9 of these studies in the last two years. Most of the site’s EFSs involve mitral valve and tricuspid valve devices, with a few involving other cardiology and vascular devices. Research leaders attribute the growth of the EFS program to two things: the site’s world-class surgeons who lead these studies and collaboration with MDIC.

“Building trust and a collaborative network helps us grow in the EFS arena and helps the industry,” says Kristen Chionh, MS, RD, CCRC, Director of Clinical Research at the Baylor Scott & White Research Institute.

Since the start of the EFS initiative at MDIC, leaders of the Baylor Scott & White Research Institute have worked closely with MDIC. “We’ve worked on creating efficiencies around the EFS process and developing the EFS ecosystem,” says Jaime Walkowiak, Former COO of Baylor Scott & White Research Institute and SVP at Baylor Scott & White Health.

The research institute led and hosted MDIC EFS working groups on contracts and IRBs. These working groups developed the MDIC EFS Contract Resource and the MDIC EFS Patient Informed Consent Form Template. Walkowiak and Chionh have also participated in site and budgeting best practices workshops.

The MDIC EFS Contract Resource MDIC EFS Master Clinical Trial Agreement (CTA) template have been especially helpful to Walkowiak and Chionh when working with startup device companies. In an EFS for Conformal Medical, the research institute was able to launch the study in 26 days. Finalizing an EFS contract takes an average of 164 days, according to metrics collected and presented by MDIC.

Learning how other sites conduct EFSs and what happens behind the scenes at sponsors, FDA, and CMS has been “eye-opening,” says Walkowiak. “We have learned so much from each other.”

Sponsors who know Walkowiak and Chionh through MDIC now invite the Baylor Scott & White Research Institute to participate in their EFSs. Some sponsors even ask for input when designing EFSs. “This evolves EFSs and makes all sites better,” says Chionh.

MDIC Resources Used: MDIC EFS Contract Resource and MDIC EFS Master Clinical Trial Agreement (CTA) template.
MDIC thanks Jaime Walkowiak, Former COO of Baylor Scott & White Research Institute and VP of Baylor Scott & White Health, and Kristen Chionh, Director of Clinical Research at Baylor Scott & White Research Institute, 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 efspliot@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.