



EFS EXPRESS

Edition 23 · December 15, 2020

2020 Highlights of the EFS Program

In 2020, the MDIC EFS Program was able to continue its work and advance the program despite the COVID-19 pandemic. The MDIC EFS Program began work to streamline sponsor-site budget negotiations, developed a tool kit comprised of all EFS tools and resources, highlighted sponsors and sites that are improving the conduct of EFS, and began expanding into new therapeutic areas.

Identifying Best Practices in Budget Negotiations

Delays in budget negotiations are a key problem in EFS. With the goal of streamlining sponsor-site budget negotiations, MDIC held an EFS Budgeting Best Practices Workshop on February 26, 2020. Sponsors, sites, and representatives of FDA's CDRH and MDIC came together to share EFS budgeting best practices and discuss steps to streamline budget negotiations.

The workshop included presentations on best practices in budget negotiations from five sponsors and four sites. The presentations and other workshop materials are available on the [MDIC EFS Budgeting Best Practices Workshop](#) page.

MDIC then established an EFS budgeting working group comprised of interested participants to standardize and communicate budgeting approaches throughout the medical device clinical trial ecosystem. The working group will focus on communicating its recommendations in the first half of 2021.

Making Tools Easier to Find and Use

Recognizing that it was difficult for stakeholders to find many of the MDIC EFS tools, MDIC put all of its tools and resources together in the [MDIC EFS Tool Kit](#). The tools are helping sponsors and sites simplify and standardize the conduct of EFS in the U.S. Each tool was developed based on EFS metrics collected by MDIC and the needs of the sponsors, sites, and the FDA. Tools include:

- Success stories
- Best practices
- Master clinical trial agreement template
- Patient informed consent form template
- Contract language and negotiation tools
- Information tools for IRBs, site study staff, and patients.

Highlighting Successful Use of Tools

Some of the sponsors and sites who are successfully using these tools were highlighted in [MDIC EFS Success Stories](#). The six stories featured three sponsors and three sites. Each story highlights the tool(s) used and how the sponsor or site used the tool to improve the efficiency of one or more EFS.

Expanding into the Neuro Space

Over the last three years, the MDIC EFS Program has focused primarily on cardiovascular EFS, which served as a pilot for the program. The MDIC EFS Program is now turning its attention to other therapeutic areas beginning with the neurovascular space, where the number of innovative neurovascular devices under development is increasing. As a first step, MDIC has established an EFS neurovascular working group and begun recruiting participants. In 2021, MDIC will hold a meeting of the EFS neurovascular working group and begin to adapt its tools and resources for the neurovascular space.

What's Next for MDIC's EFS Program?

The MDIC EFS Program would like to thank stakeholders for their support in 2020. Strategic planning for the overall MDIC EFS Program in 2021 to continue streamlining the U.S. EFS ecosystem begins in January 2021. Look for details in a future issue of EFS Express.

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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