

Learn about MDIC's EFS Tool Kit for sponsors and clinical research sites.

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EFS EXPRESS

Edition 22 • November 3, 2020

The Complete MDIC EFS Tool Kit Now Available for Sponsors and Clinical Research Sites

Since its inception, the MDIC EFS initiative has focused on working with sites, sponsors and FDA to develop tools and resources to simplify and standardize the conduct of EFSs in the U.S. This year, we put them together in the [MDIC EFS Tool Kit](#).

“We wanted to make it easier for sponsors and clinical research sites to access our EFS tools so that they can more efficiently navigate EFSs in the U.S.,” says Chip Hance, BS, MBA, industry veteran and MDIC EFS Initiative Board Champion.

The tools include success stories, best practices, templates for a master clinical trial agreement and patient informed consent form, contract language and negotiation tools, and information tools for IRBs, site study staff, and patients. Each tool has been developed based on EFS metrics collected by MDIC and the needs of the medical device industry, sites, and FDA.

Here are brief descriptions of, and links to, our tools.

EFS Success Stories

This year, MDIC began highlighting how sponsors and sites are using the EFS tools in EFS Success Stories.

The 6 stories feature 3 sponsors and 3 sites.

Sponsors:

- [4C Medical Technologies, Inc.](#)
- [Conformal Medical](#)
- [preCardia](#)

Sites:

- [Northwestern Medicine](#)
- [Cardiology Research at Columbia University Irving Medical Center](#)
- [Baylor Scott & White Research Institute, Heart and Vascular Research](#)

MDIC EFS Best Practices Workshops

Best practices workshops bring together stakeholders to share best practices and improve the conduct of EFSs in the U.S.

In 2020, MDIC held an EFS Budgeting Best Practices Workshop, focused on improving the efficiency of sponsor-site budget negotiations.

Workshop presentations and other materials are available on the [MDIC EFS Budgeting Best Practices Workshop](#) page.

Other best practices workshops and related presentations were:

- [MDIC EFS Site Best Practices Workshop](#)
- [MDIC EFS Symposium at TVT 2019](#)

- Presentation at [TCT 2019](#) (Transcatheter Cardiovascular Therapeutics)

MDIC EFS Master Clinical Trial Agreement (MCTA)

This tool facilitates efficiencies in the EFS contracting process with a template that covers more than 90% of the contract process.

All of the sponsors and sites featured in [EFS Success Stories in 2020](#) used this tool.

Get the [MDIC EFS Master Clinical Trial Agreement \(MCTA\)](#).

MDIC EFS Contract Language Library & Negotiation Tool

This tool drives efficient and consistent contracting processes among clinical sites and sponsors. It outlines a proactive EFS Negotiation Range process and includes EFS Contract Clause Language Libraries with examples of language that both sponsors and sites have accepted.

EFS Success Story featuring this tool:

- [Baylor Scott & White Research Institute, Heart and Vascular Research](#)

Get the [MDIC EFS Contract Language Library & Negotiation Tool](#).

MDIC EFS Patient Informed Consent Form (ICF) Template

The MDIC EFS Patient Informed Consent Form (ICF) Template is based on the FDA guidance document [Investigational Device Exemptions \(IDEs\) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human \(FIH\) Studies](#). It should be adapted for each EFS device and procedure and the relevant medical condition.

EFS Success Stories featuring this tool:

- [4C Medical Technologies, Inc.](#)
- [preCardia](#)

Get the [MDIC EFS Patient Informed Consent Form Template](#).

MDIC EFS Background Information: IRBs and Site Study Staff

This tool facilitates the contract and IRB approval process for EFSs, and patient screening and enrollment, by helping hospital administrators, research staff, and IRB members understand EFSs.

EFS Success Story featuring this tool:

- [preCardia](#)

Get the [MDIC EFS Background Information: IRBs and Site Study Staff](#).

MDIC Patient Introduction to Consent for Early Feasibility Studies

Focused on common questions patients ask about EFSs, this tool helps educate patients about these studies.

Get the [MDIC Patient Introduction to Consent for Early Feasibility Studies](#).

MDIC EFS Blueprint

Considered a best practices roadmap for navigating EFS regulatory, ethical, and legal considerations, the blueprint supplements the FDA's guidance document [Investigational Device Exemptions \(IDEs\) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human \(FIH\) Studies](#).

Get the [MDIC EFS Blueprint](#).

Screening Consent Form: Informed Consent and HIPAA Authorization

Cardiology Research at Columbia University Irving Medical Center developed a screening consent form for interventional vascular studies that allows researchers to send standard of care CT scans and laboratory results to the sponsor for eligibility evaluation.

Read the [EFS Success Story](#) about Columbia University.

Get the [Screening Consent Form: Informed Consent and HIPAA Authorization](#).

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.

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.

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