



Edition 3 · April 30, 2019

Early Feasibility Studies (EFS) Resources & Tools

Did you know MDIC produces a number of resources and tools used to advance EFS? These resources assist stakeholders with gaining timely patient access, clinical trial contracting, IRB approval, and patient and institution education on EFS. A number of the resources can be found below or by visiting [MDIC's Resource Library](#) section of the website.

Contracting Resources

[EFS Contracting Resource: Negotiation Range Process and Language Libraries](#)

This Negotiation Range Process Resource begins by outlining a proactive EFS Negotiation Range process encouraging sponsors and sites to:

- Initiate EFS contracts from a reasonable starting point, and consider acceptable backup positions,
- Empower Contract negotiators to efficiently finalize contracts within acceptable negotiation ranges, and
- Engage Legal subject matter experts through a "right time, right scope" approach.

The Language Library tool contains several clause language examples which have proven acceptable to both the sponsors funding EFS trials and clinical sites conducting EFS trials. Importantly, in addition to language examples, these EFS Language Libraries provide commentary describing the considerations and negotiation points relative to each party during the EFS contract negotiation.

[EFS Master Clinical Trial Agreement \(MCTA\)](#)

With engagement of diverse stakeholders including industry, care provider organizations, and regulators, the EFS MCTA was developed to provide:

- A starting point for contract negotiations with a priori agreement of 90% or greater, and
- Allow both parties to focus remaining legal resources on the remaining 10% (or less) of the EFS MCTA requiring negotiation.

The EFS MCTA template and EFS Study Contract Language Library are provided by MDIC as educational tools. They are neither intended, nor should be considered, to be legal advice.

Patient Advocacy Tools

[MDIC 2016 Blueprint for Early Feasibility Study Success](#)

A best practices guide for navigating Early Feasibility Study (EFS) complexities, including regulatory, ethical and legal considerations. Developed as a supplement to the FDA's Guidance on EFS/FIH Investigational Devices, the EFS Blueprint addressed topics including FDA interactions, Ethics Committees and/or Institutional Review Boards (IRB)s, legal considerations, and patient perspectives.

[EFS Informed Consent Form Template](#)

A template of a patient Informed Consent Form (ICF) for adult patients considering participation in a study being conducted under an IDE through the FDA's EFS Program was developed as part of the 2016 Blueprint for Early Feasibility Study Success. An updated (JUN-2018) ICF template and editable version (MS Word) of that ICF template for EFS trials can be found [here](#).

[Patient Introduction to Consent for Early Feasibility Studies](#)

To aid with the education of patients who may be eligible for a specific EFS, a brief "Patient Introduction to Consent for Early Feasibility Studies" has been created. This document focuses specifically on what it means to the patient to participate in an EFS. The Patient Introduction is an educational aid provided to the patient prior to presentation of the ICF.

[Background Information on Early Feasibility Studies](#)

When hospital administration, research staff and IRB members have a good understanding of EFS, the time to complete study contracts, IRB approvals and patient screening and enrollment are likely to decrease. To aid with the education of these stakeholders, a brief "Background Information on Early Feasibility Studies" has been created. This document is directed to patient advocates and describes what it means for a patient to participate in an EFS.

EFS Network Pilot

With the availability of these EFS tools, MDIC has launched the EFS Network Pilot. The purpose of the Pilot is to demonstrate the impact of these tools on achieving the "60/60/60" goal.

- The Site Network Pilot is committed to creating a learning environment where best practices for efficient enrollment are shared to enable the entire EFS clinical ecosystem to improve.
- A "60/60/60" goal has been established and defined as the time to a) execute the EFS Clinical Trial Agreement, b) achieve IRB approval, and c) enroll the first patient. Experience shows that 60 days is achievable for all three components, and in fact is already obtained at some sites today.
- Please go [here](#) for a list of the sites currently enrolled in the network.

Looking for more information?

Interested in participating as a sponsor or site? Visit our [website](#) for more information or [email us](#) today.

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