EFS EXPRESS

Edition 1 • February 21, 2019

Welcome to the EFS Express

Welcome to the first edition of MDIC's EFS Express! This publication was created to provide updates on the EFS Site Network Pilot along with educational materials. In this edition, learn more about the pilot and read about the evolution of interest in EFS from Dr. David R. Holmes, Jr. of the Mayo Clinic. We hope you find this information helpful and we welcome your feedback.

EFS Site Network Pilot

MDIC has made progress in several areas important to advancing EFS and timely patient access, including clinical trial contracting, IRB approval, and patient and institution education on EFS. A Master Clinical Trial Agreement, an Informed Consent Form template that conforms to the FDA EFS guidance, and educational aids for patients, hospital staff and IRBs are now available for use online. 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 time to patient enrollment.

- 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.

Interest in Early Feasibility Studies

By David R. Holmes, Jr, MD I Mayo Clinic

Interest in Early Feasibility Studies developed as a result of concerns by multiple stakeholders involved in the process of delivering care to address unmet clinical needs. The multiple stakeholders included regulatory agencies, industry, professional societies, physicians, patients, and entrepreneurs. Multiple disciplines were involved including cardiology, cardiovascular surgery, gastroenterology, orthopedics, neurology, and neurological surgery. In each of those fields, practices identified patients who had identified clinical needs that were not able to be met. This coincided with an interest in the development of new technology that could be adapted to address these needs. The medical technology ecosystem continued to creatively design new approaches; however, the regulatory processes to test this new technology, or make it available to US patients, lead to multiple areas of conflict. The result was outmigration of technology, which was often developed in the US, to other areas of the world. Technology outmigration, particularly to Europe and Asia, was accompanied by the outmigration of funding by entrepreneurs and medical companies, and the inability to treat patients in the United States with US-developed technology early in the product life cycle. During the period of 2004-2009, there was an 85% reduction in funds in the US related to approaches to meet clinical problems.

With increasing interest and concern from multiple stakeholders as well as information in the lay press highlighting medical conditions that were not being treated in the US, but were being treated in patients in Europe and other parts of the world, the FDA began consideration of, and the implementation of a Guidance for Early Feasibility Studies. This fundamentally important program laid the groundwork and structure for the interactions needed by Industry in the development and testing of new technology. The Guidance was ecumenical and focused on the approaches that would be required no matter which medical or surgical discipline was involved.

Although this Guidance established the framework of procedures to optimize the interaction between Industry and FDA, it did not address some other central issues, namely the hospital sites in which such studies might be performed, or the reimbursement for such studies. Without a focus on those issues, the process of optimizing approaches to treating unmet clinical needs would be severely limited. Over the last several years, there has been the engagement of several groups to address the fundamental issues of what defines an optimal early feasibility study clinical center, and what the barriers to success would be including contracts, IRB involvement, indemnification, metrics of performance, site selection, and reimbursement for procedures. Robust engagement of MDIC has furthered the discussion and identified approaches to resolution.

The eventual goal is a robust medical care system which fosters the development new technology to address unmet patient needs in an efficient manner, to maintain strict assurance of safety and efficacy of such new technology, and to optimize processes for early approval so that patient outcomes can be measurably improved.

Looking for more information?

For more information about MDIC's EFS Program visit our website or email us today.