MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

EARLY FEASIBILITY STUDIES

In 2013, Early Feasibility Studies were becoming increasing difficult to complete in the United States. With lengthy approval processes for the Investigational Device Exemption and Institutional Review Board, many organizations were going overseas to complete these studies. In-country early feasibility studies can facilitate direct and interactive collaboration between FDA, sponsors, and innovators in early product lifecycle stages.

Medical Device Innovation Consortium's Early Feasibility Studies program has been diligently working toward making innovation more accessible in the United States by producing study toolkits, budgeting templates, and legal templates addressing site contracting and informed consent. Identifying other means to make these studies more accessible, program volunteer leadership identified nuanced needs in the area of electrophysiology and neurovascular, which are a focus of current working groups.

MDIC's Clinical Science Initiative

The Early Feasibility Studies Program falls under MDIC's Clinical Science Initiative. MDIC's Clinical Science Initiative addresses the biggest barriers to collecting adequate clinical evidence in support of new medical technology. Clinical Science stakeholders work together to create blueprints for innovative clinical trials techniques, develop standards and metrics for effective clinical trial designs, and encourage the collection of adequate and appropriate clinical and patient preference data.

Resources

- Blueprint for Early Feasibility Study Success is a best practices roadmap for navigating complexities.
- FDA Guidance on Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies

If you are interested in learning more, please contact MDIC today.

ABOUT MDIC

The Medical Device Innovation Consortium (MDIC) is a public-private partnership that brings together representatives of the FDA, NIH, CMS, NIST, and other agencies, industry, non-profits, and patient advocacy organizations to improve the processes for development, assessment, and review of new medical technologies.

MDIC coordinates the development of methods, tools, and resources used in managing the total product life cycle of a medical device to improve patient access to cutting-edge medical technology.

We are driving faster, safer, and more cost-effective innovation for patient benefit.

LEARN MORE ABOUT MDIC'S EARLY FEASIBILITY STUDIES PROGRAM

Learn more about MDIC's Early Feasibility Studies by visiting **www.mdic.org.**