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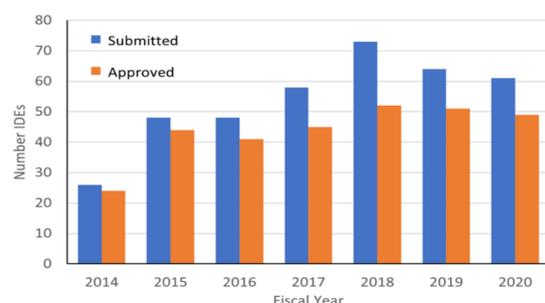
Early Feasibility Study Program During the COVID-19 Pandemic

By Maureen L. Dreher, Ouided Rouabhi, Andrew Farb

Since its inception in 2013, the Food and Drug Administration (FDA) Center for Devices and Radiological Health's Early Feasibility Study (EFS) Program has facilitated conducting early feasibility studies in the United States and has grown substantially throughout numerous clinical specialties. The 2020 fiscal year (FY) has been no exception with more than double the number of EFS Investigational Device Exemption (IDE) applications submitted and approved by the FDA since FY 2014 for the fourth year in a row (see figure 1 below). Consistent with this trend, FDA expects strong industry interest and support for the EFS Program to continue.

The interest in the EFS Program remained stable in 2020, even during the global COVID-19 pandemic. Furthermore, conducting an EFS continues to be an important way that sponsors, looking to advance the development of a device and obtain early human clinical data, can bring access to patients. However, the entire clinical trial ecosystem, including EFS, has been impacted by the unprecedented challenge of the COVID-19 pandemic. The FDA recognizes these challenges and the need for sponsors to make timely decisions regarding the assurance of subject safety, maintenance of compliance with good clinical practice, and ensuring data integrity. The FDA issued a guidance document to help sponsors navigate these challenges and recently updated the guidance as more information became available. The [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#) (issued March 2020, updated January 2021) includes general considerations for study sponsors when navigating the impacts of COVID-19 on their study execution. For example, the guidance describes how sponsors and Institutional Review Boards (IRB) can work together to assure that study subjects are protected during the pandemic. The guidance also includes frequently asked questions and answers for common topics such as monitoring studies remotely, documenting protocol deviations and modifications, and obtaining informed consent. The guidance applies to EFS of medical devices and to clinical investigations of all medical products. We encourage EFS sponsors to use this guidance as a resource to aid in the successful completion of their studies.

Figure 1. Early Feasibility Study Submission and Approval Trends



The y-axis shows the number of EFS IDEs submitted (in blue) and those fully approved or approved with conditions in the first review cycle between fiscal years 2014 – 2020 on the x-axis.

Join us April 21 for the 3D-EFS MDIC Symposium. In partnership with The Dartmouth Device Development Symposium Office, MDIC will host a 3.5-hour interactive virtual meeting focused on the Early Feasibility Study (EFS) Initiative to facilitate the first clinical use studies in the United States, providing updates and examining the current roadblocks. Learn more and register [here](#).

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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