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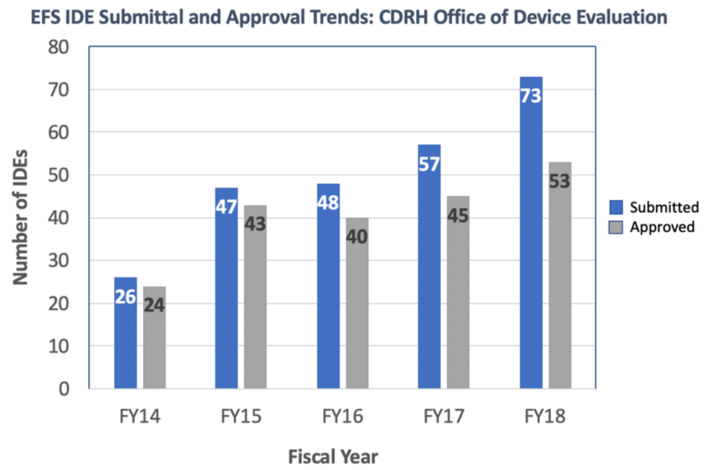
An Update from FDA on CDRH's EFS Program

By: Andrew Farm, M.D., Chief Medical Officer, Office of Cardiovascular Devices, U.S. FDA
Maureen L. Dreher, Ph.D., Office of Clinical Evidence & Analysis, U.S. FDA

CDRH's EFS Program facilitates conducting early feasibility studies in the United States to increase access for patients to potentially beneficial technologies and to support device innovation. The EFS Program also helps bring cutting-edge medical device research back to the U.S. The regulatory foundation for the EFS Program and recommendations for industry sponsors and investigators was published in FDA's guidance document (issued in October 2013), "Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical studies, Including Certain First in Human (FIH) Studies".

The growth of the EFS Program is shown in the graph below. Since the EFS guidance document was introduced, the number of EFS IDEs submitted and approved by FDA have increased progressively as more researchers and sponsors have elected to conduct their early feasibility studies in the U.S. Consequently, more U.S. patients now have the opportunity to participate in early clinical trials of innovative devices. The success of the EFS Program is the result of the efforts of many stakeholders including the FDA, industry sponsors, investigators, and clinical sites.



"Approved" represents FDA decisions of full approval or approved with conditions on EFS IDE applications within the same fiscal year of receipt.

Understanding that support during the earliest phases of medical device testing encourages medical device innovation and access for U.S. patients, MDIC supports CDRH's EFS program through the development of tools and best practices. These resources support the implementation and broad participation of the EFS program through MDIC's public-private partnership between FDA, industry, providers and other stakeholders.

Looking for more information?

Interested in participating as a sponsor or site? Visit our website for more information or email us today.

Our mailing address is:
1501 Wilson Blvd., Suite 910 Arlington, VA 22209