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Latest Data Shows Improvement in Some EFS Administrative Processes

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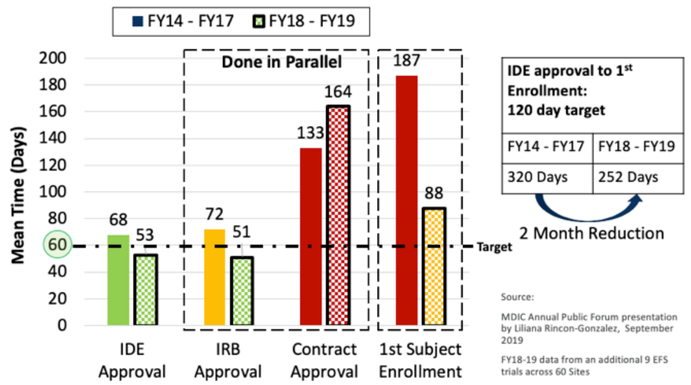
Recognizing the importance of timely patient access to innovative medical technologies, the FDA published a guidance document for EFS in 2013. This EFS Guidance successfully improved average EFS IDE approval times. In 2017 MDIC collected metrics in the first ever collaborative sharing of Sponsor administrative data. Thirteen study sponsors provided data to MDIC to compile EFS Performance Metrics. Analysis of the metrics demonstrated that although most EFS IDEs were approved in the first 30-day review cycle, administrative challenges were the largest barriers to clinical trial operations. Times to IRB approval, contract approval, and first subject enrollment were all higher than 60 days each. The average time from the site packet received at the site to first patient enrolled was 320 days.

This summer, MDIC repeated the exercise of gathering EFS performance metrics from sponsors to see how the landscape had evolved (see graph below). Sponsors provided data from nine Early Feasibility Studies conducted at 60 sites. The recent data shows some improvement in time to IRB approval and first patient enrollment, resulting in a reduction of 2 months from when the site gets the packet to first patient enrollment. However, the total average time of approximately eight months greatly exceeds MDIC's target of four months. Additionally, contract and budget negotiations between sites and sponsors are still a challenge and need improvement.



The data above was presented at the Annual Public Forum on September 5, 2019. The full presentation and an audio recording of the session are available on the MDIC website by clicking here.

These metrics provide valuable insights into other opportunities to improve patient access. For example, a Master Clinical Trial Agreement template has been developed in collaboration with industry, clinicians, and institutions, and is now posted on the MDIC website and available for use in EFS trials. Also, an informed consent template that conforms to the FDA EFS guidance is posted on the MDIC website and available for use in EFS trials. There are also education aids for patients, hospital staff and IRBs available for download.

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:
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