FDA Updates Supporting Materials for Expedited Access Program

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Medical Device Alert

FDA's Expedited Access Program (EAP) provides a process aimed at increasing efficiency and smoothing the path to market for medical devices that address unmet medical needs associated with life threatening or debilitating conditions. FDA has now released some additional resources meant to help companies considering whether to pursue EAP for their product. The sample Data Development Plans provide some insight into the type of information FDA expects to see during the application process and aligns well with our experience seeking EAP.

EAP was initially announced[1] in 2014 in draft form, though built on earlier pilot programs. FDA's guidance describing the program was finalized in April of 2015. EAP includes a number of key features which are attractive to device manufacturers, such as early and often interaction with FDA staff, involvement of senior FDA management, priority review, use of surrogate or intermediate endpoints, and a careful assessment of the balance between premarket and post market requirements. But one of the most important elements is a Data Development Plan, which forms the basis for an agreement with the agency as to the data that will support the future marketing plan. The Data Development Plan is submitted during the initial application for the EAP program and is further developed in consultation with the FDA review team. The original EAP guidance included information about what should be addressed by the draft Data Development Plan. In addition, FDA has now released two sample documents demonstrating what might be included in such a plan[2]. These two examples may be helpful to companies who are considering putting together and application for EAP. Reaching agreement with FDA on a Data Development plan is key to moving forward on an EAP pathway, though achieving agreement can sometimes prove to be challenging.

These Data Development Plan examples come as FDA celebrates the completion of the first year of EAP[3]. In a blog post the FDA disclosed that the Agency has accepted 17 of 29 EAP applications, yielding a fairly high acceptance rate given the relatively narrow focus of the program. Consistent with our own experience, the blog post also notes that companies tend to benefit most from the program when they have already established a preliminary proof of principle, but have yet started the final validation studies or any clinical studies. This allows industry and the agency to work together on the final plans.

Although EAP isn't right for every device, for the subset of devices focused on innovation for serious, life-threatening, or debilitating disease, it has provided a more efficient pathway in certain instances. We look forward to the next year as the agency continues to gain experience with the program.

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1 See Hogan Lovells commentary at https://www.hoganlovells.com/en/blogs/focus-on-regulation/fda-releases-draft-guidance-documents-on-new-expedited-access-program-for-premarket-approval-of-medical-devices-and-premarket-and-postmarket-data-collection

2 See http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/UCM522966.pdf and http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/UCM522967.pdf

3 See http://blogs.fda.gov/fdavoice/index.php/2016/05/celebrating-a-year-of-the-expedited-access-pathway-program-for-medical-devices/

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