TED Initiative Receives FDA Qualification of Medical Device Development Tool

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Dr. Esther Yuh and her TED Seed Project received FDA qualification today of the Medical Device Development Tool submitted on behalf of the TED Initiative.

The OsiriX CDE Software Module [1], is only the third qualification of a medical device development tool [2] (MDDT) by the FDA, the first of a biomarker test tool of any type, and the first such tool for TBI. A biomarker test is a lab test or instrument used to detect or measure an indicator of biologic processes or pharmacologic responses to a treatment (biomarker). This qualification provides a tool for more efficient development of devices in a critical area of medicine ? traumatic brain injury (TBI) treatment.

The MDDT program enables the FDA to qualify tools that medical device developers can use in the development of medical devices and the evaluation of their safety and effectiveness. Qualification means that the FDA has evaluated the tool and concurs with available supporting evidence that the tool produces scientifically and clinically meaningful measurements of data that can be used to help inform medical product development within the specified context of use. In this case, the OsiriX CDE, qualification means that the tool may be used to better identify eligible patients for enrollment in clinical trials.

The OsiriX CDE consists of a software module that assists health care providers, such as neuroradiologists, by providing a standardized way to mark and classify brain contusions using common criteria and to label abnormalities on magnetic resonance images for the purpose of enriching enrollment in clinical trials of therapeutic medical devices intended to improve outcomes of mild TBI patients.

?We?re committed to providing tools and policies to enable the efficient development of novel technologies that can address significant unmet patient needs. This is especially true when it comes to the development of treatments for traumatic brain injury, where few treatment options exist,? said FDA Commissioner Scott Gottlieb, M.D. ?Today?s qualification of the first biomarker test for brain injury may help innovators more efficiently enroll patients in clinical trials of therapeutic medical devices intended to be used to treat mild traumatic brain injury. A strategic goal of the FDA is to promote the creation and validation of biomarkers and development tools that can provide more efficient and accurate ways to evaluate the safety and effectiveness of products. Qualification of this tool demonstrates how the medical device development tools program advances the agency?s mission by modernizing regulatory approaches, reducing the time and resources needed to develop and assess new medical products, and ultimately accelerating patient access to safe, effective and innovative medical

devices.?

The FDA?s MDDT website has been updated to include the OsiriX CDE:

https://www.fda.gov/medicaldevices/scienceandresearch/medicaldevicedevelopmenttoolsmddt/ [3]

FDA News Brief:

https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm633239.htm [4]

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[1] https://www.fda.gov/downloads/MedicalDevices/ScienceandResearch/MedicalDeviceDevelopmentToolsMDDT/UCM
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