Medical Device Development Tools

Medical Device Development Tools (MDDT)

The FDA's Medical Device Development Tools (MDDT) program is a way for the FDA to qualify tools that medical device sponsors can use in the development and evaluation of medical devices. Qualification means that the FDA has evaluated the tool and concurs with available supporting evidence that the tool produces scientifically-plausible measurements and works as intended within the specified context of use. The context of use depends on the product area, the stage of medical device development, and the role of the tool in device evaluation. The program promotes innovation in medical device development and regulatory science [1] to help bridge the gap between research of medical devices and the delivery of devices to patients.

TED Neuroimaging EWG MDDT Proposal Advances to Qualification Stage

The Neuroimaging EWG has been engaged with FDA Center for Devices and Radiological Health (CDRH) for over a year in the MDDT program. Submitted in June 2016, the TED proposal nominates using Magnetic Resonance Imaging as an enrichment neuroimaging biomarker for TBI clinical trials. The proposal was soon after accepted into the Pilot Phase of the MDDT Program. Through intense collaboration under the guidance of CDRH, the proposal has been fine tuned and has progressed through the pre-qualification stage. In April 2017, the proposal was advanced to the Qualification Stage and TED was invited by CDRH to submit a Qualification Package complete with a detailed study design and analytic plan.

Links
[1] https://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm2022362.htm