FDA Moves Forward With Program for Medical Device Development Tools

On August 15, 2014, FDA announced that it is soliciting proposals to participate in a pilot program for Medical Device Development Tools (MDDTs). This action follows a draft guidance issued on November 14, 2013, in which FDA proposed an MDDT qualification process. MDDTs could speed device development and facilitate device review and evaluation by the Center for Devices and Radiological Health (CDRH). An MDDT must be accessible to the public, through sale, open source, etc., although FDA intends to protect proprietary information submitted in support of the MDDT. It is unclear how FDA will address the tension between its call for public access to MDDTs and the intellectual property concerns that could affect wide use of qualified tools.

MDDTs are “tools that manufacturers and FDA use to assess and measure the performance, safety, and effectiveness of medical devices.” Previously, if a manufacturer sought to use an MDDT for multiple products, a review team within CDRH would evaluate the appropriateness of the MDDT on a product-by-product basis. The MDDT qualification process aims to make MDDT evaluation more efficient by validating the use of MDDTs for particular purposes. After an MDDT is qualified, manufacturers may use the tool within its qualified “context of use” without the need for further detailed review of its suitability.

According to FDA, participants in the pilot program will have the opportunity “to work closely with FDA to determine the amount and type of evidence and other information needed to support qualification for a specific tool and context of use.” The pilot program is intended to provide valuable information for a final guidance on MDDTs.

FDA is limiting the pilot to 15 candidates and prioritizing proposals based on public health need or potential to impact multiple device programs. Appropriate candidates include tools that fit into these categories:

1. clinical outcome assessments (e.g., patient-reported outcomes or clinical outcomes based on clearly defined subjective clinical decision making as a measure of treatment benefit);
2. biomarker tests (e.g., instruments to measure blood pressure);
3. nonclinical assessment models (e.g., computer models to measure a parameter of interest).

According to the draft guidance, MDDT submitters must allow FDA to make public sufficient information to support use of the qualified MDDT. MDDT submitters must also consent to allow the general public to use the
MDDT and not restrict use to certain private entities. The pilot program does not, however, place any requirements on “licensing/cost/degree of access to intellectual property.”

FDA will begin accepting nominations for participation in the program on September 15, 2014. More information about the pilot program can be found here.

The draft guidance is available here.

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