On October 14, 2016, FDA released draft guidance entitled Software as a Medical Device (SaMD): Clinical Evaluation (the “SaMD Draft Guidance”). The draft guidance was prepared by the SaMD Working Group of the International Medical Device Regulators Forum (IMDRF), chaired by Bakul Patel, Associate Director for Digital Health at CDRH, and was endorsed by the IMDRF Management Committee in September 2016. Simultaneous with the release of the SaMD Draft Guidance, FDA announced the opening of a 60-day comment period to give the public a chance to react to the content of the draft guidance.

The SaMD Clinical Evaluation Draft Guidance

The proposed guidance describes standards for determining the clinical validity, which includes scientific validity and clinical performance, and analytical validity of a software medical device. The standards and the amount of evidence required increase relative to the clinical significance of the software, as determined by the intended use of the information (to treat, diagnose, or drive/inform clinical management) and the criticality of the healthcare situation. The SaMD Draft Guidance also indicates when independent clinical evaluation data should be reviewed by an independent party.

Although the clinical evaluation standards proposed in the SaMD Draft Guidance will be important for preparing premarket applications, the draft guidance goes further, stating that continuous clinical evaluation should be incorporated into the lifecycle of all software devices, regardless of clinical significance.

The Effect of the SaMD Draft Guidance on FDA

The SaMD Draft Guidance is a continuation of the global effort to harmonize general standards for regulated products among regions, without significantly interfering with specific regulations of national or regional jurisdictions. In fact, the draft guidance explicitly states that its recommendations are “not meant to replace or conflict with premarket or postmarket regulatory requirements related to the regulatory classification of SaMD in different jurisdictions.”

However, the effect of releasing the SaMD Draft Guidance under FDA’s auspices is that once the Agency finalizes the guidance, it will become part of FDA’s “current thinking” on performance of clinical evaluations to support premarket applications for software medical devices and manufacturer compliance will be expected. This could be a good thing because it will increase the level of detail available to industry stakeholders about the type and amount of evidence that should be included with premarket notifications and applications for each class of software medical devices. While FDA’s PMA guidance has copious information on clinical evaluation standards, the 510(k) guidance describes vague and discretionary standards for clinical or non-clinical data needed to support substantial equivalence. The effect of the SaMD Draft Guidance cuts both ways, though, because the new standards could impose significantly higher burdens on manufacturers to generate supporting data for 510(k)s,
especially when clinical evaluation is expected to extend into the product’s entire lifecycle.

**Comment Period on SaMD Draft Guidance is Open**

FDA has announced that it will accept comments on the SaMD Draft Guidance from October 14 to December 13. FDA and IMDRF are requesting comments on the guidance in general and on the following specific issues:

1. Does the document address the intention captured in the introduction/scope or vice versa?
2. Does the document appropriately translate and apply current clinical vocabulary for SaMD?
3. Are there other types of SaMD beyond those intended for non-diagnostic, diagnostic and therapeutic purposes that should be highlighted/considered in the document?
4. Does the document adequately address the relevant clinical evaluation methods and processes for SaMD to generate clinical evidence?
5. Are there other appropriate methods for generating clinical evaluation evidence that are relevant for SaMD beyond those described in the document?
6. Are the recommendations identified in section 7.2 related to the “importance of clinical evidence and expectations” appropriate as outlined for the different SaMD categories?
7. Are the recommendations identified in section 7.3 related to the “importance of independent review” appropriate as outlined for the different SaMD categories?
8. Given the uniqueness of SaMD and the proposed framework—is there any impact on currently regulated devices or any possible adverse consequences?

To comment, go to [docket number FDA-2016-D-2483 at Regulations.gov](https://www.regulations.gov/docketComment) and click Comment Now.

©1994-2019 Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. All Rights Reserved.