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# Top Takeaways from FDA Draft Guidance on Software as Medical Device

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FDA's proposed adoption of an IMDRF document raises questions.

On October 14, the ***US Food and Drug Administration (FDA)*** releaseda new draft guidance document, Software as a Medical Device (SaMD): Clinical Evaluation (Draft Guidance).[1] The Draft Guidance was developed by the SaMD Working Group of the International Medical Device Regulators Forum (IMDRF),[2] a voluntary group of medical device regulators from around the world, including FDA. This is the first time that FDA has proposed issuing an IMDRF document as an official FDA guidance document.

The Draft Guidance discusses clinical evaluation recommendations for SaMD and focuses on the general principles of clinical evaluation, which include establishing scientific validity, clinical performance, and analytical validity for an SaMD. The Draft Guidance is available for public comment until December 13, 2016. We have highlighted below key takeaways.

**1. Cart Before the Horse?**

Over the years, FDA has issued several guidance documents attempting to clarify its position on software products. For instance, in 2015, the Agency issued its final guidance on Mobile Medical Applications, which describes when FDA will or will not actively regulate software that can be executed on a mobile platform.[3] However, the Mobile Medical Apps guidance is limited to the specific mobile app examples listed in that guidance, and FDA has yet to issue its long-promised draft guidance on clinical decision support software. Thus, there is no clear overarching policy on when software used for health- or medical-related purposes would be considered SaMD, subject to FDA regulation. In this context, issuing guidance on FDA's expectations for the clinical evaluation for SaMD seems premature. Software developers need to first understand where the proverbial line is before investing in clinical evaluation activities.

**2. New Unadopted Terminology and Reference Documents Used**

The Draft Guidance uses terminology defined in other IMDRF documents and also incorporates by

reference findings from other IMDRF documents; however, FDA has not officially adopted those other IMDRF documents as FDA guidances. Thus, it is not clear whether FDA intends for this Draft Guidance to be the first volley, followed up by formally issuing other IMDRF documents on SaMD as FDA guidances, or whether FDA would simply consider the terminology and principles in those other IMDRF documents to be adopted by proxy if and when it finalizes this current Draft Guidance. It also is not clear how the principles and terminology in these other IMDRF documents align with FDA's existing regulations and guidance documents. For instance, the Draft Guidance discusses a system of classifying SaMD based on its intended use and risk; however, it is not clear how this classification system would translate to FDA's existing device classification system (Class I, Class II, and Class III) and classification regulations. Such an understanding is important for SaMD developers to determine the premarket review standard that will apply (e.g., establishing substantial equivalence vs. safety and effectiveness), because this will inform the goals for SaMD clinical evaluation.

**3. Context Is Important**

Although this Draft Guidance's focus is SaMD clinical evaluation, a significant part of its 45 pages is used to provide definitions, general principles, context, and SaMD categorization principles (not to mention the references to other IMDRF documents, as described above). Only Section 6 directly addresses clinical evaluation. On that point, the new Draft Guidance describes clinical evaluation as the process for establishing the scientific validity, analytical validity, and clinical performance of an SaMD and provides recommendations for generating evidence in these three areas. The Draft Guidance further describes how to determine the required level of evidence based on the SaMD's categorization. With regard to categorization, the Draft Guidance proposes a SaMD categorization scheme based on: (1) how the information generated by the SaMD will be used (for nondiagnostic, diagnostic, or therapeutic purposes), and (2) the criticality of the healthcare situation or condition in which the SaMD is to be used. An SaMD intended to treat or diagnose critical healthcare situations or conditions is considered higher risk and thus would be subject to more rigorous clinical evaluation requirements.

**4. FDA Requests for Feedback**

In its Federal Register notice announcing the new Draft Guidance, FDA highlighted specific areas for which it would like feedback, including the following:

- Does the document appropriately translate and apply current clinical vocabulary for SaMD?
- Are there other types of SaMD beyond those intended for nondiagnostic, diagnostic, and therapeutic purposes that should be highlighted or considered in the document?
- Does the document adequately address the relevant clinical evaluation methods and processes for SaMD to generate clinical evidence?
- Given the uniqueness of SaMD and the proposed framework, is there any impact on currently regulated devices or any possible adverse consequences?

## Next Steps

The Draft Guidance document indicates that it is intended to provide globally harmonized principles of when and what type of clinical evaluation is appropriate based on the SaMD risk. However,

questions remain about how these principles translate to FDA regulatory requirements.

The Guidance Document is available for comment until December 13, 2016 (Docket No. FDA–2016–D–2483).

[1] 81 Fed. Reg. 71105 (Oct. 14, 2016), https://www.gpo.gov/fdsys/pkg/FR-2016-10-14/pdf/2016-24805.pdf.

[2] FDA,International Medical Device Regulators Forum (IMDRF) (last updated May 5, 2015), http://www.fda.gov/MedicalDevices/InternationalPrograms/IMDRF/default.htm.

[3] FDA, Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff, (Feb. 9, 2015), http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf.



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