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June 18, 2018

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-4301: Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program

To Whom It May Concern:

The Advanced Medical Technology Association ("AdvaMed") appreciates the opportunity to provide further input on the Food and Drug Administration's ("FDA" or "Agency") Digital Health Software Precertification ("Precert") Program Working Model v0.1.[1] AdvaMed represents manufacturers of digital health technologies, medical devices, and diagnostic products that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators and companies.

We commend FDA for its ongoing efforts to create a Pre-Cert Program. If properly developed and implemented, the Precert Program has the potential to reduce pre- and post-market burdens for both software developers and FDA, and enable streamlined changes and modifications to software. Moreover, patients and consumers will benefit under the Precert program as these important technologies will be available in a more timely manner.

AdvaMed is pleased to provide the following comments to the challenge questions contained in Section 1 of the Working Model. We note that these comments represent our current thinking on this topic. As the Working Model and the broader precertification program are further developed, explained, and analyzed, our views may change and/or evolve.

AdvaMed would like to thank the FDA for its consideration of these comments and looks forward to continuing to work with the Agency on this important issue. Please do not hesitate to contact me at 202-434-7224 or zrothstein@advamed.org if you have any questions.

[1] Developing a Software Precertification Program: A Working Model, v0.1 (April 2018), *available at* https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/ucm605685.pdf.

Respectfully submitted,

/s/

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Associate Vice President
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Attachment

AdvaMed Responses to Working Model v0.1

June 18, 2018

1.1. How might an existing excellence or maturity appraisal framework used by a SaMD manufacturer be leveraged to demonstrate an organization's performance and success as outlined by the five excellence principles?

Existing excellence or maturity appraisal frameworks (*e.g.*, standards and certifications) should be considered as evidence to support excellence. Depending on the type of appraisal framework (*e.g.*, if the standard or certification is related or equivalent to quality, clinical responsibility, cybersecurity, etc.), it could be counted as an objective indicator for one or more of the key attributes associated with the excellence principles. Organizations should be able to easily map their existing frameworks to attributes identified as being associated with the excellence principles.

1.2. How might the appraisal process consider the track record demonstrated through an organization's objective Key Performance Indicators (KPIs) as part of the evaluation?

It is unclear if this question is referring to the process of obtaining certification or the level of certification. It is our understanding the FDA intends that all requirements must be met in order to become certified, and that experience with medical products would allow for a higher level of certification (level 2). While a retrospective review of KPIs may be helpful in demonstrating that all requirements are met, this should not be required. As companies decide to apply for certification, they may develop new KPIs, or different ways of trending their existing KPIs. Requiring historical review of KPIs could artificially limit access to the program, with a potentially unfair bias against smaller companies.

1.3. Does it matter if the track record is in medical device products or in consumer products and why? How long, and how detailed of a track record would be needed to demonstrate an organization's sustainable performance? Why?

Medical device products are similar to consumer products, but different with respect to patient safety. It is critical for a precertified organization to demonstrate handling product complaints and adverse events from a safety perspective. If an organization can demonstrate a track record that establishes the effectiveness of the postmarket surveillance process, including ongoing monitoring of patient safety, risk management, issue identification and resolution, etc., then either medical device or consumer product experience would be sufficient.

The length of track record could be based on a combination of length of time on the market and number of products.

1.4. When looking at past performance, how should negative events be evaluated to provide an accurate assessment of responsiveness, responsibility, and improvement?

It is unclear if FDA is defining a "negative event" as a complaint or an adverse event that is identified as part of postmarket surveillance activities. As part of the evaluation of customer complaints, FDA could consider whether the complaint is considered an adverse event, should the adverse event have been identified and mitigated during risk management. More broad concepts may be considered for all complaints, including how complaints are triaged;

how quickly/transparently they are addressed; whether there have been repeat complaints for the same issue/cause; and what improvements and learnings were implemented. Of primary importance is that adverse events are evaluated in a timely fashion. It is also important that the process for evaluating both internal and external sources of information, bugs, vulnerabilities and latent faults be identified. These types of issues should be evaluated with respect to their criticality, as well as logged and tracked. However, it will not be possible, nor is it necessary, to resolve all of these items.

1.5. FDA is anticipating establishing two levels of precertification. Please advise whether and why the same appraisal model should be used to assess all organizations applying for precertification, or whether separate appraisal models should be used for each level of precertification and why?

The appraisal model should be the same, and should be based on demonstrating organizational excellence and quality. Both well-developed as well as start-up companies are equally well positioned to demonstrate excellence. To obtain level 2 certification, the applicant must be able to demonstrate a history of meeting the regulatory requirements associated with medical products. The achievement of level 2 certification will provide additional benefits, such as a more streamlined regulatory review.

Accordingly, the appraisal model should begin first with assessing the organization's commitment to excellence. If the firm is able to demonstrate this element of the appraisal model, the organization should qualify for level 1 status. Once level 1 status is achieved, then consideration of the firm's history of meeting the regulatory requirements while demonstrating a commitment toward excellence associated with medical products should be considered to determine whether the firm is eligible for level 2 status.

1.6. How might an appraisal framework reconcile the requirement for precertified organizations to demonstrate a consistent threshold of excellence with the recognition that different organizations are likely to use performance measures specific to their operations and product lines?

FDA could ask applicants to map their specific measures to the attributes associated with the excellence principles and provide justification as to why the company-specific measures are equivalent. To facilitate this process, FDA could develop a guideline to describe the specific acceptable measure or the general intent of what they would be looking for. For example, in terms of cybersecurity, FDA could identify a few categories to measure excellence from the NIST Cybersecurity Framework that enable organizations to map back to KPIs for those specific categories.

Alternatively, if there are critical KPIs/appraisal questions that have been identified, then they should be listed and companies should justify how the measurement of the KPI is appropriate.

1.7. How might an excellence or maturity assessment balance the FDA's "least burdensome" approach with the obligation to assure stakeholders that SaMD are safe and effective?

From the perspective of other stakeholders besides the SaMD developer, it may appear that less effort is taken from a regulatory approval perspective. This is a misinterpretation, as the

evidentiary standard has not changed. Real-time review could serve as an alternative pathway to point-in-time approval. Real-time review could be augmented with continuous monitoring, where the amount of required monitoring is commensurate with the risk of the product, and as agreed to with the FDA. Communication channels that allow for FDA's continuous monitoring must be designed to prevent intrusions.

1.8. When considering large organizations that are multinational or include multiple business units, what defines a "unit" for purposes of FDA precertification? If FDA precertifies a "unit" within a corporation or multinational, how should FDA factor in corporate processes during appraisal?

A unit should be defined by the manufacturer. The important issue is that the applicant demonstrates that the unit, or each unit, or central function collectively meet the key attributes associated with the excellence principles.

1.9. Should there be two levels of Pre-Cert? What should be the differentiating factors between Pre-Cert levels?

Yes, there should be 2 levels based on track record as currently proposed in the Working Model. However, FDA would need to clarify the requirements for track record and definition of "limited" experience delivering SaMD.

1.10. Are there specific approaches to developing SaMD, such as machine learning and artificial intelligence, that raise different considerations with respect to the excellence principles, e.g., such that the appraisal would be different and/or precertification for the company based on processes/culture using one technology should not apply to other SaMD development methods? Why or why not?

Machine learning, artificial intelligence, and similar applications are technological approaches that can be incorporated into the software development process. They do not raise unique concerns outside of the excellence principles. The model should be the same as for other software where the focus is on demonstrating that the process meets key attributes of the essential principles, and the product meets the appropriate aspects of continuous monitoring.