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ESTABLISHED 1988
NEWSLETTER FROM **DELPHI CONSULTING GROUP** (**DCG**)
An Internet Based Medical Device Regulatory Service,
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Vol. 27, Issue 6 June 2021

FDA Plans Oversight for AI Medical Devices, Addressing Bias

The FDA has introduced a new plan to improve transparency and reduce bias in artificial intelligence software. How will this impact healthcare organizations?
By: Nathan Eddy

As artificial intelligence and machine learning are included in an expanding array of medical devices, concerns about the algorithms' lack of transparency and potential bias driving patient outcomes have led the Food and Drug Administration to tackle the issue with a multipronged approach.

The FDA announced an initial plan in January, outlining five actions the agency aims to take. These include a transparent, patient-centered approach, the establishment of new pilot programs to enable real-world performance monitoring and the development of a regulatory framework.

Among the greatest benefits of AI/ML in software are its ability to learn from real-world use and experience, and to improve its performance. But as an October 2020 study from Harvard's T.H. Chan School of Public Health pointed out, there are still concerns regarding transparency related to how data is collected, the overall quality of the data and how it's being validated.

patient-centered care
Part of the FDA's action plan includes support for the development of machine learning best practices to evaluate and improve ML algorithms for topics such as data management, interpretability and documentation, as well as advancing real-world performance monitoring pilots.

The FDA also noted that the action plan would continue to evolve to stay current with developments in the field of AI/ML-based software as a medical device (SaMD).

As the agency pointed out in an April 2019 discussion paper, the potential power of AI/ML-based SaMD lies within its ability to continuously learn, where the adaptation or change to the algorithm is realized after the SaMD is distributed for use and has learned from real-world experience.

READ MORE: AI can increase efficiency in healthcare, even in a pandemic.

In turn, the autonomous and adaptive nature of these tools requires a new, total product lifecycle regulatory approach that supports a rapid cycle of product improvement, allowing SaMD to continually improve.

To address this, premarket submissions to the FDA for AI/ML-based SaMD would include a "predetermined change control plan," which would describe the types of anticipated modifications that the AI/ML would generate.

By comparison, traditional software solves problems by being explicitly programmed by the development team. The team knows how to solve the problem, or consults an expert with domain knowledge, and creates the software algorithm accordingly, says Pat Baird, senior regulatory specialist and head of global software standards at Philips.

"However, for many types of AI applications, the development team doesn't know how to solve the problem. Instead, they make a problem-solving engine that learns from data that is provided to it," Baird says.

This opaqueness raises concerns for stakeholders, including users and patients, so building trust and being able to explain the data used to train the system and the quality processes that are in place will be key factors in the adoption of AI in healthcare.

RELATED: Find out why nurses are essential to AI integration in healthcare.

'Responsible and Explainable AI Is Essential'
Medical AI already has a bias problem because it's not always easy for researchers to obtain large, sufficiently varied data sets, which can then lead to those biases being baked into algorithms from the start.

"I think the first step in reducing bias is to raise awareness about different kinds of bias that can occur, remind people to challenge the assumptions that they have, share techniques on how to detect and manage bias, share examples and so on," Baird says. "To improve machine learning, we need to be better at sharing our collective learning."

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Delphi Consulting Group, Houston, Texas 77071-3404
Contact: J. Harvey Knauss, +(832) 675-9281 voice, info@delphiconsulting.com or www.delphiconsulting.com

Dr. Kaveh Saf(avi, senior managing director of global health for Accenture, says the FDA should be applauded for seeking a way to allow AI to be approved so that patients can get the full benefit of devices that can continuously improve.
But transparency is critical to adoption, he adds, pointing to research that shows people will not use technology that contains AI if they don't understand it.

"That goes for employees using technology as part of their work and end consumers," Safavi says. "Responsible and explainable AI is essential to our ability to recognize the promise of the technology entirely."

The US Food and Drug Administration (FDA) on 17 May revised its question-and-answer guidance on inspections during the COVID-19 pandemic to clarify the regulatory actions it plans to take when it cannot conduct an onsite inspection of a facility.

FDA announced that while the pandemic continues to restrict onsite inspections, the agency "intends to continue using alternative tools to evaluate facilities." FDA continues to conduct onsite inspections for those products deemed "mission critical."

The newly revised guidance updates an earlier version issued in August 2020 and follows a recent guidance on the agency's use of alternative tools, such as remote interactive evaluations, during the pandemic. (RELATED: *FDA issues pandemic inspections FAQ guidance, Regulatory Focus* 19 August 2020; *FDA issues long-awaited pandemic remote inspections guidance*, *Regulatory Focus* 14 April 2021).

The agency states that the document is "intended to provide information regarding common queries related to inspections for facilities manufacturing pharmaceutical products and sites involved in the conduct of clinical, analytical, and nonclinical studies."

FDA's ability to conduct inspections and its use of alternative tools in place of onsite inspections have been topics of concern for both industry and those overseeing the agency. Despite efforts to mitigate the impact of conducting fewer inspections and resorting to document reviews where possible, the Government Accountability Office (GAO) has warned that FDA faces a looming inspection backlog, which the agency plans to address via a resiliency roadmap released earlier this month. (RELATED: *FDA's inspection backlog: GAO raises concerns as delays mount*, *Regulatory Focus* 9 March 2021; *FDA tallies pandemic inspection toll, issues new 'resiliency roadmap'*, *Regulatory Focus* 5 May 2021).

The Q&A addresses how inspections have been impacted by COVID-19, the types of inspections FDA deems "mission critical," and its criteria for issuing complete response (CR) letters following an inspection.

The new updates to the guidance document clarify which actions FDA may take when it cannot conduct a physical inspection.

When the available information supports the adequacy of the facilities and sites named in a pending application, and no deficiencies have been identified, FDA may approve the application.

FDA may issue a CR letter for facility- or site-related deficiencies in cases where the available information from a prior inspection or other source identifies facility or site deficiencies, but an inspection cannot be completed due to travel restrictions. In this case, the CR letter may include additional deficiencies identified by the assessment team.

If an inspection is necessary because there is insufficient information currently available to make a determination on the acceptability of a site, FDA may issue a CR letter without facility or site deficiencies. Any facility or site issue will be referred to in a comment in the CR letter; the CR letter will contain other deficiencies that were identified by the assessment team.

FDA may also defer action in cases where an inspection is deemed necessary but there is a lack of information about the facility or site. This action is taken in those case where no deficiencies have been identified and the application otherwise satisfies the requirements for approval; the revised guidance acknowledges that this action means that FDA has missed its goal date for action on the application

FDA states in the guidance that it would "not automatically" issue a CR letter if it cannot conduct an inspection because of travel restrictions and that "decisions regarding applications will be based on the totality of the information available to FDA, including information obtained from use of the alternative tools."

The agency also says that manufacturers may submit applications for a sites located in areas impacted by COVID-19: "Reference in an application to a facility in a region impacted by COVID-19 travel restrictions does not preclude submission to FDA."

The revised guidance will be in effect for the duration of the public health emergency.

To be remembered.

Texas native invented the adhesive used in one of the best inventions of the twentieth century - the **3M Post-it-Notes**. ***Spencer Silver*** 1941 - 2021, passed away at home. *Is there anyone that has not used Post-it-Notes, do not think so.*