U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Virtual

FDA DISCUSSION QUESTIONS

OCTOBER 22, 2020

DIVERSITY IN TRAINING AND VALIDATION DATASETS

1) Artificial Intelligence (AI) and Machine Learning (ML) medical devices are often developed using training and validation data sets that represent or capture patient outcomes. If the data used to train these devices are not representative across various demographic subgroups or across the disease spectrum (for a specific intended use), it would be unclear how well the devices will perform across the entire population of patients living with the condition. Research shows that multiple medical conditions show differences in outcomes by sex, gender, age, race, and ethnicity. In addition to demographic factors, there are multiple aspects of the dataset (e.g., types of diseases, severity of disease, comorbidities, duration of disease) that may impact the accuracy and applicability of the AI/ML device. Please address the following questions:
    a. What do you believe is the best approach for a developer to clearly convey the demographic composition of the training and validation datasets?
    b. What approaches do you think the FDA and industry should consider to help assure diverse groups of patients are reflected in training and validation data sets for the proposed intended use?
    c. Should the description of the data used to inform the algorithms be made publicly available or made available only to the users?
    d. What assurances do you think the FDA and industry could provide that would encourage patients to share their data to be used in these algorithms? In datasets that could be used for any algorithms?

2) AI/ML device manufacturers update their programming for a variety of reasons. Some of these changes are submitted to FDA prior to implementation for marketing authorization while other updates can be implemented and documented for later review by the FDA. The different types of modifications include:

- *Modifications related to device performance, with no change to the intended use or type of input signals*. This type of modification includes re-training with new data sets of the same input signals and a change in the AI/ML architecture.
- *Modifications related to inputs, with no change to the intended use*. This type of modification includes changes to the algorithm for use with new types of input signals but does not change the intended use of the device.
- *Modifications related to the device's intended use*. These types of modifications include those that change how the device is used. For example, a device that was previously used to aid in the diagnosis of a condition would instead provide a diagnosis to the patient.

The determination of what information should be submitted and when that information is submitted to FDA is based on risk. Risk is defined as a combination of the probability of harm occurring and the severity of that harm. As such, every medical device including AI/ML devices has some associated risks that are considered by the FDA.

a. What types of software modifications to AI/ML medical devices would be more concerning to you that warrant notifying FDA prior to implementation? Which types of modifications do you believe should trigger a communication update to the patients and the public?
b. Would your decision on communicating about modifications be different based on where the device is used (e.g., in the home, in the clinic) or by who is using it (e.g., doctor, patient)?
c. What approaches should FDA and industry use to share with the patients any added benefits (such as improvement in accuracy), changes in performance (such as decreased performance) or risks (such as limited applicability in certain populations) associated with using the AI/ML medical devices?
d. For some devices, at the time of the marketing authorization, there are periodic planned modifications (types of anticipated modifications

and method to implement the modifications) to the AI/ML device. What information including level of detail about the planned changes do you believe should be made available to patients to increase their trust in the device?

3) With all AI/ML including those that are continuously learning, there is the potential for the performance of the software algorithm to exceed the original reference gold standard (such as the current standard of care). This increased performance may raise the bar for other devices that may be seeking entry into the market. How do you weigh the benefits of infusing this improved performance standard (i.e., "better than standard of care" bar) for subsequent devices with the potential risk of inhibiting innovative technologies from having a chance to enter the marketplace?

4) Some AI/ML algorithms are shifting decision making from the current settings of a specialist to that of generalist or to the patient at their home. In addition, AI/ML devices are becoming capable of taking autonomous actions such as to call 911 or alerts their health care provider.
    a. What mitigations do you believe should be put in place to protect patients (e.g., informed consent, qualifying language in the diagnosis provided, warning/caution statements) if the decision-making setting is shifted as described above?
    b. What are some approaches you believe will help patients understand the probability of the harm and the severity of that harm (i.e., risk) associated with devices that take autonomous actions?

PATIENT-INTERFACE, TRANSPARENCY AND COMMUNICATING DEVICE INFORMATION

5) For AI/ML devices intended to be used by patients, the "information" that patients may see includes GUI (Graphical User Interface), menus, dialog boxes, and error and status messages. In addition, there may be information associated with the device placed directly on the device, on the company's website, and in tutorials informing how to use the device. These communication materials often include the software version number, the instructions for use, the user's guide, the "About" menu button and other information typically found in the software's splash-

screen. In contrast, other devices may be intuitive to use, where patients do not need an instruction manual or how-to guide to begin using them. Some devices may have functions that are locked to patients and only visible/available to their providers, while others may display readings to the patients to share with their healthcare provider.

a. As you think of devices that you intuitively use, what features do you consider to be intuitive? What do you believe manufacturers of AI/ML medical devices should consider to integrate intuitive features in their devices?
b. For understanding the effectiveness of mitigations such as warnings/caution statements and information for use, do you consider human factors/usability testing to be an important step? Please explain your response.
c. What information do you think should be included in the communication materials made available to patients using AI/ML medical devices?
d. Do you believe patients should have the ability to see functions or data that may only be visible to their healthcare provider? Please explain your response. If yes, what mitigations should be put in place to ensure patients understand and appropriately respond to the information presented?