



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

**Guiding Principles for Virtual Breakout Sessions to Discuss Hypothetical Scenario**

**October 22, 2020**

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1. Participation in the breakout session is completely voluntary.
2. Participants in the breakout session cannot ask questions of one another but can comment on the questions or prompts included in the scenario and on comments provided by other participants. FDA moderators and notetakers will interrupt you if you question one another. This restriction is a requirement of the Federal Advisory Committee Act.
3. FDA moderators will guide the discussion but will not be providing comments or feedback on the scenario. They will also not be acting in their role as FDA staff members but solely as moderators to ensure that your voice is captured.
4. Participants in the breakout session should mute their phone if they are not speaking.

## PEAC ARTIFICIAL INTELLIGENCE/MACHINE LEARNING SCENARIO

*Please note that this is a hypothetical scenario and is not describing a real device or patient situation. We ask that you imagine yourself in the scenario below as you answer the questions.*

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As a person of color with skin lesions and a family history of melanoma (a type of skin cancer), you are worried about your risk of developing skin cancer. You know that the risk of melanoma is low in people of color. You are proactive and want to undergo any testing that might detect it early. When you called to schedule an appointment with a dermatologist, you were informed that there would be a 12-month wait for the next available new patient visit. While sharing your concerns about waiting for the appointment, a friend recommends using Device B (an app) for skin cancer detection at home. You find some information online explaining that Device B is a mobile app that uses machine learning algorithms to classify skin lesions as high or low risk for cancer. To use Device B, you would upload videos and/or pictures of your skin lesions to the app. The app would provide you with a high cancer risk or low cancer risk determination for your skin lesion. You can store your skin lesion images and skin cancer risk determination in the app for review at a later time. Based on your internet research, you find that this app makes the decision of high vs. low risk by comparing images of your skin lesion to thousands of images from non-Hispanic White individuals with either a biopsy-confirmed cancer diagnosis or a confirmed non-cancer diagnosis.

**QUESTION 1: If you were to use Device B, what kind of information would you want to know about the app or the results it provides to have confidence and trust in its results concerning your skin lesions?**

You decide that you have enough information to try Device B. You load the app onto your mobile phone and take pictures of two skin lesions of concern on your feet. The first lesion near your ankle was read as low risk for cancer. This lesion has grown over the past year and was the one you were the most worried about. No additional information was provided by Device B. You just finished attending a meeting on artificial intelligence and machine learning in medical devices held at the FDA which makes you think about other questions about this app.

**QUESTION 2: How much trust do you have in the results provided by Device B?**

- a. **What additional information could help you make a decision about the need for urgent clinical follow up?**
- b. **What additional information would you want to know about the demographic and disease composition of the training and validation data used to develop Device B?**

Slightly reassured by the first result, you take a picture of the second lesion on the bottom of your foot. You receive a high cancer risk determination for this lesion. You are now panicking.

**QUESTION 3: What additional information would you want to know when receiving this test result?**

- a. **What additional features of Device B or information presented do you think would be helpful to assuage your concerns and direct you on the next steps to address the test result?**