FDA Questions to the Panel

Molecular and Clinical Genetics Panel
Shield
May 23, 2024

FDA seeks the Panel's input on whether the information submitted by Guardant is adequate to support the safety and effectiveness of the Shield for the proposed intended use. The key issues for this clinical study are listed below:

1. Shield is intended for colorectal cancer screening in individuals at average risk of the disease, age 45 years or older, as a primary screening option. The Guardant test demonstrated colorectal cancer (CRC) sensitivity of 83.1%, advanced adenoma (AA) sensitivity of 13.2%, and advanced neoplasia (AN) specificity of 89.6%. Please discuss:

    a. Based on the clinical performance of this device, the benefits and risks of the device for CRC screening, including considerations for the appropriate patient population and clinical scenario for this device.

    b. Does the clinical performance support use of the Shield test as a primary screening option (similarly to other non-invasive CRC screening options), or is it more appropriate for specific populations (e.g., patients who decline other CRC screening tests).

2. Patients with AA have a high risk of developing CRC cancer. The Guardant ECLIPSE study demonstrated 83.1% sensitivity for CRC, but only 13.2% sensitivity for the detection of AA. Please discuss:

    a. The benefits and risks of a CRC screening test with 13.2% sensitivity for AA.

    b. If risks are present, please discuss whether there are potential mitigations which might be deployed to ensure physicians and patients are able to make informed choices regarding screening test options to mitigate clinical risks of the Shield test's AA sensitivity.

3. If the device is determined to be safe and effective based on existing data, please discuss whether a post approval study (PAS) to gather additional information about benefits and risks of programmatic colorectal cancer screening (i.e., repeated testing over an established period of time) would be beneficial. Please discuss the types of information that would be important to collect during such a study.