Center for Devices and Radiological Health (CDRH)
Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee

VOTING QUESTIONS

Galleri

The Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, as amended by the Safe Medical Devices Act of 1990, allow the Food and Drug Administration to obtain a recommendation from an expert advisory panel on designated medical device premarket applications (PMAs) that are filed with the Agency. The PMA must stand on its own merits, and your recommendation must be supported by safety and effectiveness data in the application or by applicable publicly available information.

Definitions of Safety and Effectiveness:

Safety as defined in (21 CFR § 860.7(d) (1)) - There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.

Effectiveness as defined in (21 CFR § 860.7(e)(1)) - There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

The applicant has proposed the following Indication for Use:

> *The Galleri® test is a qualitative, next-generation sequencing (NGS)-based in vitro diagnostic test intended to detect cancer-specific methylation patterns in cell-free DNA isolated from peripheral whole blood. Galleri is intended for screening for the early detection of multiple types of cancer, in adults aged 50 years or older. The test is also intended for the prediction of Cancer Signal Origin in individuals with a Cancer Signal Detected test result.*
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> *A test result of Cancer Signal Detected, including a predicted Cancer Signal Origin, may indicate the presence of an invasive solid tumor or hematologic malignancy and should be followed by a diagnostic workup recommended by qualified healthcare professionals. A test result of No Cancer Signal Detected does not rule out the presence of cancer, and individuals should continue with guideline-recommended single-cancer screening tests.*
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> *This test is performed at GRAIL, Inc. Prescription only.*

The following questions relate to the approvability of Galleri. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented today.

Voting Question 1:
Is there reasonable assurance that *Galleri* is safe for patients who meet the criteria specified in the proposed indication?

Voting Question 2:
Is there reasonable assurance that *Galleri* is effective for use in patients who meet the criteria specified in the proposed indication?

Voting Question 3:
Do the benefits of *Galleri* outweigh the risks for use in patients who meet the criteria specified in the proposed indication?

Panel members will be asked to state how they answered each question and to explain their answers.