24 Hour Summary
Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee Meeting
September 23, 2026

Introduction:

A hybrid, open session meeting of the Molecular and Clinical Genetics Panel of the Medical Device Advisory Committee was convened to discuss the premarket approval application (PMA) for Galleri sponsored by GRAIL, Inc. It is a first-of-a-kind device which is intended for screening for the early detection of multiple types of cancer, in adults aged 50 years or older. The panel was asked to provide input on the clinical data submitted in the PMA application and the implications of these data on the safety and effectiveness, benefit/risk profile, indications for use, labeling, and post approval study requirements.

FDA Questions/Panel Deliberations:

Question 1: The FDA Executive Summary and panel presentation described Galleri performance by overall 12-month episode sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), 12-month episode sensitivity per cancer type, and 12-month episode sensitivity by stage, as reported in the clinical studies (PATHFINDER 2 and NHS-Galleri).

a. *Please discuss the clinical significance of the results for patients and providers in the intended use setting, considering Galleri performance:*

    i. *Overall*
    ii. *Per cancer type*
    iii. *For cancer types with current guideline-recommended screening (i.e., breast, colorectal, lung, cervical, and prostate)*
    iv. *For cancer types without current guideline-recommended screening.*

In your discussion, please also discuss the clinical significance of any inter-study variability observed between PATHFINDER 2 and NHS-Galleri on the test's performance estimates.

b. *Please discuss whether Galleri performance by stage (overall and per cancer type) supports the proposed indications for use of "early" detection of multiple types of cancer.*

i. *If no, please discuss whether Galleri performance supports an alternate indication for the detection of multiple types of cancer, absent the "early" characterization.*
ii. *If yes, please identify the cancer types for which Galleri performance supports "early" detection, and discuss how "early" detection should be described in the test labeling (e.g., by cancer stage, intent for curative treatment available).*

c. *Please discuss whether there are any cancer types where Galleri's cancer type detection performance presents new risks (e.g., due to uncertainty in performance estimates) and for which risk mitigations may be needed. Where applicable, discuss what types of mitigations (e.g., labeling warnings or limitations) may be effective.*

Panel Deliberations:

The Panel agreed that the clinical significance of Galleri is greatest for cancers without guideline-recommended screening. The Panel believes that Galleri provides limited value in detecting cancer types that have established screening programs and Galleri should not replace established, guideline-recommended screening. The Panel discussed there is substantial variability in Galleri episode sensitivity across cancer types, with several panelists noting that for some cancer types very few cancers were observed in the clinical studies which makes it challenging to draw conclusions about Galleri performance for those cancers. The Panel believed transparency to the user through clear labeling of test performance was critical, and discussed the difficulty in interpreting cancer type and stage-specific episode sensitivity data. Some members noted that performance may be better expressed in terms of identifying overall cancer signal.

Some panelists noted there are differences in Galleri performance across PATHFINDER 2 and NHS-Galleri, while others believed Galleri performance was broadly consistent between the clinical studies. The Panel discussed there is some uncertainty in Galleri performance across certain demographic and clinical subgroups and agreed that further characterization would be helpful as data continue to be collected.

The Panel generally expressed doubt that the term "early" in the device's intended use related to claims of "early detection" was supported. Some panelists acknowledged that Galleri may detect cancer earlier than it would otherwise present clinically, particularly for cancer types without guideline-recommended screening. One panelist noted the term "early" has different meanings across cancer types, presenting a challenge for broad application of an "early" detection claim to Galleri, a test that detects a shared cancer signal across multiple cancer types. The Panel acknowledged there is some evidence that Galleri can detect some cancers in early stages while it generally did not detect stage I cancers as often as it detected cancers at stages II-IV.

The Panel recommended Galleri labeling should be as clear as possible about the performance and limitations of Galleri to inform shared decision making by healthcare providers and patients. This may include language such as clear descriptions of false negative Galleri results and the need for individuals to continue all guideline-recommended screening, and a discussion of the uncertainty in the ability of Galleri to detect certain cancer types found at low frequency in the clinical trial.

Question 2: Taking into consideration current guideline-recommended screening methods and the demonstrated performance of Galleri to detect multiple cancer types, including cancers with and without guideline-recommended screening, please discuss how test performance and use, including benefits, risks, and limitations, should be communicated to providers and patients to support shared decision-making in determining whether to use Galleri?

Panel Deliberations:

The Panel agreed that shared decision-making between providers and patients, clear labeling, and educational materials are needed for safe and effective use of Galleri. The Panel supported availability of clear and concise educational materials for both providers and patients. Some panelists recommended that providers be given resources to navigate diagnostic work-up following a positive Galleri result. The Panel recommended that several key elements be communicated to providers and patients, including that Galleri does not replace guideline-recommended screening, a positive test result does not confirm the presence of cancer, a negative result does not rule out cancer, and the long-term impact of Galleri on patient outcomes has not been established.

Question 3: If the device is approved based on existing data, please discuss whether one or multiple post-approval studies to gather additional information about benefits and risks of Galleri would be beneficial. Please discuss the types of information that would be important to collect during such studies.

Panel Deliberations:

The Panel was generally in favor of continued data collection to further refine performance estimates and collect data on patient benefit. Several panelists discussed the importance of collecting longitudinal follow-up data on the study participants enrolled in PATHFINDER 2 and NHS-Galleri.

The Panel recommended post-approval studies should collect information related to:

- Longer term follow-up data for ascertainment of outcomes and to gather information on an appropriate testing interval
- Additional data on test performance across demographic subgroups
- Galleri performance in the real-world setting, including the impact of false positive and false negative results
- Adherence to guideline-recommended screening after taking the Galleri test, including any impact of false reassurance on screening behavior
- Longer term follow-up data to better understand how Galleri testing impacts patient outcomes

Vote:

The panel voted on the safety, effectiveness, and risk benefit ratio of the

1. *Safety*- The panel voted 10 yes, 0 no, 0 abstain that the data shows that there is a reasonable assurance that *Galleri* is safe for patients who meet the criteria specified in the proposed indication.

   The Panel agreed there is reasonable assurance that Galleri is safe, provided there are adequate directions for use, labeling, and physician and patient education.

2. *Effectiveness*-_The panel voted 6 yes, 4 no, 0 abstain that the data shows that there is a reasonable assurance that *Galleri* is effective for use in patients who meet the criteria specified in the proposed indication.

   Panelists who voted "yes" believed Galleri to be effective in detecting cancers without guideline-recommended screening and as an adjunct to established screening programs. Some panelist conditioned their "yes" vote on removal of the "early" claim from the indication and additional post-approval studies. Some panelists who voted "no" expressed concern about uncertainties in Galleri effectiveness, particularly around potential bias in episode sensitivity and the absence of data on long-term patient outcomes. Some panelists who voted "no" indicated they could support a vote of "yes" if the indication were modified to remove the "early" claim.

3. *Benefit/Risk*-The panel voted 7 yes, 2 no, 1 abstain that the data shows that the benefits of *Galleri* outweigh the risks for use in patients who meet the criteria specified in the proposed indication

   Panelists who voted "yes" expressed support of a favorable benefit/risk balance, conditioned on additional post-approval studies, appropriate labeling, and provider and patient education. Panelists who voted "no" cited uncertainty in whether the cancers detected by Galleri would result in clinically meaningful improvements in patient outcomes. One panelist abstained and indicated uncertainty in the benefit/risk balance in the absence of long-term clinical outcomes data.

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Transcripts:

Transcripts may be downloaded from the link below when they become available:
September 23, 2026: Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee Meeting Announcement - 09/23/2026 | FDA

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