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

AGENDA

September 23, 2026

9:00 a.m.	**Call to Order** **Opening Remarks** **Introductions (5 mins)**	**Deborah K. Armstrong, MD, FASCO** Chair
9:05 a.m.	**Administrative Announcements** **Conflict of Interest Statement (10 mins)**	**Evella Washington** Designated Federal Officer
9:15 a.m.	**FDA Welcome (5 min)**	**Michelle Tarver, MD, PhD** Director, Center for Devices and Radiological Health
9:20 a.m.	**GRAIL Presentation (65 min)**	
10:25 a.m.	**Clarifying Questions from the Panel (15 min)**	
10:40 a.m.	**Break (15 min)**	
10:55 a.m.	**FDA Presentation (60 min)**	**Catherine Fischer, PhD, MPH** Team Lead CDRH/OPEQ/OHT7/DMGP **Anand Pathak, MD, PhD, MPH** Medical Officer CDRH/OPEQ/OHT7/DMGP
11:55 a.m.	**Clarifying Questions from the Panel (15 min)**	
12:10 p.m.	***Lunch (50 min)***	

1:00 p.m.	**Open Public Hearing* (75 min)**	
2:15 p.m.	**Panel Deliberations (60 min)**	
3:15 p.m.	**Break (10 min)**	
3:25 p.m.	**Questions for the Panel (120 min)**	**Catherine Fischer, PhD, MPH** Team Lead CDRH/OPEQ/OHT7/DMGP
5:25 p.m.	**Vote (15 min)**	**Evella Washington** **Designated Federal Officer**
5:40 p.m.	**Summary of Panel Recommendations (15 min)**	**Deborah K. Armstrong, M.D. FASCO** Chair
5:55 p.m.	**Adjourn**	

*** Open Public Hearing –** Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.