



FDA CDRH
Molecular and Clinical Genetics Panel of the
Medical Devices Advisory Committee

November 29, 2023
*****Virtual*****

For the benefit of US public health, this general advisory panel meeting will explore and obtain expert scientific and clinical input regarding the design of multi-cancer detection (MCD) in vitro diagnostic tests as well as study design and approaches to assess probable benefits and risks of MCD screening tests. The information gained from this meeting will help inform future Agency regulatory efforts for these novel tests.

9:00 a.m.	Call to Order	Colleen M. Gallagher, Ph.D. Panel Chair
	Conflict of Interest Statement Panel Introductions	Candace Nalls Designated Federal Officer
9:15 a.m.	Welcome, Introduction, Background	Timothy Stenzel, M.D., Ph.D. Director, OHT7: Office of In Vitro Diagnostics, CDRH, FDA <i>and</i> Donna Roscoe, Ph.D. Acting Director, Division of Molecular Genetics and Pathology, OHT7: Office of In Vitro Diagnostics, CDRH, FDA
9:45 a.m.	*Open Public Hearing	
10:45 a.m.	Break	
10:55 a.m.	Topic 1: Clinical study design considerations for FDA submissions, including evaluation of cancer specific performance – <i>Questions for the Panel</i>	Colleen M. Gallagher, Ph.D. Panel Chair

12:15 p.m.	Lunch	
1:15 p.m.	Topic 2: Use of Tissue of Origin (TOO) assays to help identify tumor location versus other methods, patient work up considerations following positive results, and follow-up for patients with negative results – <i>Questions for the Panel</i>	Colleen M. Gallagher, Ph.D. Panel Chair
2:05 p.m.	Break	
2:20 p.m.	Topic 3: Benefit/risk considerations, including postmarket study considerations – <i>Questions for the Panel</i>	Colleen M. Gallagher, Ph.D. Panel Chair
3:30 p.m.	Break	
3:45 p.m.	Panel Deliberations	Colleen M. Gallagher, Ph.D. Panel Chair
4:45 p.m.	Panel Summation	Colleen M. Gallagher, Ph.D. Panel Chair
5:00 p.m.	Adjourn	Colleen M. Gallagher, Ph.D. Panel Chair

*** 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.