Questions for CAC on the use of biomarkers to identify patients at increased risk for progression to Barrett's Esophagus (BE)

Is there sufficient data to use molecular testing to identify and risk-stratify patients with BE with low or high-grade dysplasia?

Does the existing evidence define a patient population that would most benefit from the testing? Have any of the studies included patients >65 years of age?

Is there evidence available to indicate that there are minimally invasive biomarkers tests that would preclude the need for invasive procedures such as endoscopy/biopsy by themselves? If so, how confident are you in your decision to use or not use such currently available testing.

What evidence is there to indicate that there could be differences between performing molecular biomarker testing on biopsy samples obtained through endoscopy versus samples obtained through less invasive procedures such as a swallowable balloon, sponge, or other cell collection device?

What evidence has been published to indicate a reasonable success rate of swallowing for a non-endoscopic device used for molecular biomarker testing?

What outcomes are there in the literature indicating how to follow a patient with BE with molecular testing instead of endoscopy?

> For the outcomes above, how frequently would this test need to be repeated to ensure continued confidence that the patient has not developed disease needing further investigation?

Have studies determined the percentage of patients with BE, dysplasia (low or high grade), or esophageal adenocarcinoma that may be missed by molecular testing and if so, how long is the delay in diagnosis and are there any associated adverse outcomes?

If a clinically validated biomarker test was available, what are additional barriers to its use?

Is there evidence defining the clinical setting in which a non-invasive biomarker assay could be performed?