BLOODPAC

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Re: Docket No. FDA–2023–N–4720
Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.

Dear Sir or Madam:

This letter is in response to the November 29, 2023 meeting of the Molecular Genetics Advisory Committee, [Docket No. FDA-2023-N-4720] Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments - - Multi-cancer Detection Devices.

The Blood Profiling Atlas in Cancer (BLOODPAC) Consortium appreciates the opportunity to comment on study design and outcome recommendations related to multi-cancer detection (MCD) in vitro diagnostic devices (tests). BLOODPAC was launched on October 17, 2016 as a commitment to the White House Cancer Moonshot and is now an independent collaborative not-for-profit with over 65 member organizations spanning key stakeholders in the liquid biopsy community. Our mission is **to accelerate the development**, **validation and accessibility of liquid biopsy assays to improve the outcomes of patients with cancer**. To achieve this, BLOODPAC leads a collaborative infrastructure that enables sharing of information between stakeholders in public, industry, academia, patient advocacy, payers, and regulatory agencies.

The Early Detection and Screening (ED&S) Working Group is one of several working groups within BLOODPAC and is specifically tasked with driving progress in blood-based assays for early cancer detection with efforts focused on generating and publishing frameworks to further evidence generation and assessment, increasing stakeholder engagement, and accelerating the approval process through regulatory agencies.

The near-term goals of the ED&S Working Group include 2 main topics as outlined below:

1) <u>Developing and building consensus for a common lexicon</u>

With the rapid advancement of technological innovation in the development and validation of blood-based assays for early cancer detection, it is critical that the field establish a standardized lexicon of frequently used terms. A standardized lexicon will not only drive consensus in the field, but also provide an opportunity for increased understanding for those who will eventually utilize these assays. To this end, BLOODPAC has engaged with the FDA through the Q-Submission Program (Q-sub program) regarding lexicon development, incorporated their feedback, and plans to submit a manuscript for publication in early 2024.

In addition, during the creation of the lexicon and conversations with the agency and other groups, the topic of risk and how it is defined for different populations emerged as an important

area of interest requiring further discussion. As a result, BLOODPAC will host a virtual seminar in early 2024 for BLOODPAC members, including the FDA, to discuss this topic in more detail.

2) Standardizing frameworks for evidence generation during clinical validation

As blood-based assays for early cancer detection advance into clinical validation, it is essential that assay developers ensure the incorporation of appropriate study design elements, establish approaches to determine clinical truth, and develop strategies to evaluate benefits and risks. The current goal of the ED&S working group is to recommend best practices for demonstrating the clinical validity of blood-based early cancer detection tests. We will focus on key areas such as assay performance, length of follow-up, and intended use populations. To address each of these areas, the working group will gain consensus internally and solicit feedback from the FDA (utilizing the Q-sub program) and other organizations. Following feedback and additional alignment, the information will be disseminated via publication.

Delineating best practices for demonstrating the clinical validity of blood-based early cancer detection tests will ensure transparent and consistent reporting of the safety and effectiveness of blood-based assays for early cancer detection as they move into broader adoption.

The efforts of the BLOODPAC ED&S working group align well with the interest and efforts of the FDA to understand and define the blood-based early cancer detection test space. As a consortium encompassing a broad spectrum of stakeholders, BLOODPAC offers to serve as a resource to the FDA and others in the community.

BLOODPAC believes that the FDA, as the regulatory agency tasked with evaluating the safety and effectiveness of *in vitro* diagnostics, can play a unique role in accelerating the evaluation of blood-based assays for early cancer detection, by facilitating the alignment and distribution of information critical to companies pursuing early detection and screening technology. As part of its unique role, the FDA has an opportunity to work with stakeholders on a short- and long-term communication strategy that encompasses both content to device developers and the broader public about blood-based assays for early cancer detection. This will assist developers in providing information aligned to Agency expectations and communicate the safety and effectiveness of these assays to healthcare providers and patients. The BLOODPAC ED&S working group would be happy to participate in such an effort.

Thank you for your attention to this important topic. BLOODPAC is committed to continuing to partner with the FDA to serve as a voice of liquid biopsy stakeholders and to enable efficient alignment and dissemination of information. Specifically, the ED&S working group looks forward to working with you as we move forward in this exciting area.

Thank you for considering our views.

Respectfully,

Lauren Leiman
Executive Director
BLOODPAC