BloodPAC
BLOOD PROFILING ATLAS IN CANCER

For Immediate Release
February 12, 2018

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Blood Profiling Atlas in Cancer Consortium (BloodPAC) Announces Milestone in Accelerating Development of Liquid Biopsy for Cancer: Initial Release of Open Data

On the One-Year Anniversary, Public Release of First Harmonized Datasets Will Open New Opportunities for Innovation and Collaboration

CHICAGO – Exactly one year after its establishment as an independent non-profit, The Blood Profiling Atlas in Cancer Consortium (BloodPAC) announced the public release and accessibility of an initial dataset. The dataset resides in the BloodPAC Data Commons and was developed to deepen the understanding of an individual patient's cancer and accelerate the development of liquid biopsy technology to improve the outcomes of patients with cancer. Prior to establishing itself as an independent entity, BloodPAC was a collaborative commitment to the Cancer Moonshot initiative spearheaded by former Vice President, Joseph R. Biden, Jr.

"Liquid biopsies hold great promise to improve the detection, diagnosis and management of cancer patients. However, like other areas of innovation in medicine, one of the biggest barriers we face in translating the science into clinical impact for patients is multi-stakeholder collaboration, data-sharing, and accepted best practices," said Phil Febbo, MD, chief medical officer of Genomic Health, Inc. "BloodPAC, in just one year, has delivered on the vision to build a shared data commons that will help the innovators across the research community work meaningfully towards that common goal of understanding how liquid biopsies can improve care for individuals with cancer."

The BloodPAC Consortium has developed a collaborative infrastructure that enables information sharing between stakeholders in industry, academia, and regulatory agencies. To date, the BloodPAC Consortium has gathered over five tera-bytes of raw data that now resides inside the BloodPAC Data Commons. The Data Commons aggregates, harmonizes, and will make freely available, key data elements including:

- Data from CTC, ctDNA, proteins including tumor associated autoantibodies, and exosome assays
- Associated clinical data, such as clinical diagnosis, treatment history and outcomes
- Data on sample collection, preparation and handling protocols

"To truly accelerate the development of liquid biopsy for patient benefit, we can't afford to duplicate efforts. Part of the power of the BloodPAC Data Commons is that it is based on the data sharing principles of the Open Commons Consortium (OCC) and shares the same APIs as the NCI Genomic Data Commons (GDC), so that applications and tools can easily analyze data

from both commons," said Robert Grossman, PhD, professor at the University of Chicago. "That allows the research community to build on and amplify the power of accumulated data."

The public pre-analytical minimal technical data elements (MTDEs) dataset can be found here. The dataset summarizes the initial submission of member projects and consists of:

- 16 projects, 29 studies;
- 1,147 cases, 3,599 aliquots;
- 3,290 samples, of which approximately 75 percent are clinical

BloodPAC is also publicly releasing select accompanying matrices for visualization of the summary counts. For more information on the MTDEs, please refer to the public BloodPAC Wiki and Data Dictionary.

To advance the regulatory standards for biomarker development and liquid biopsy, the BloodPAC Samples Working Group led a six-month project in early 2017 working with BloodPAC members and the FDA Center for Devices and Radiological Health (CDRH) to define an initial set of MTDEs needed to develop pre-analytical standard operating procedures (SOPs) for assay development. The group was led by Anne-Marie Martin, SVP, global head of precision medicine, Novartis Pharmaceuticals Corp., Howard Scher, head of the Biomarker Development Initiative, Memorial Sloan Kettering Cancer Center, and Phil Febbo of Genomic Health. "Any time scientific innovation outpaces the existing regulatory framework, it can slow progress in care for patients. To accelerate the translation of scientific innovation to the clinical setting, BloodPAC has actively engaged the FDA to catalyze rapid advances in this field," said Jim Godsey, vice president of Clinical Next Generation Sequencing and Oncology R&D at Thermo Fisher Scientific.

On November 3, 2017, the BloodPAC Consortium, with support from the FDA's CDRH, identified an initial set of 11 MTDEs for pre-analytical fields. These criteria are now established within the data commons to facilitate cross analysis and improve the usability and reliability of the data for liquid biopsy research.

The 11 data elements are metadata fields that must accompany the submission of all future blood profiling dataset contributions from consortium members to the BloodPAC Data Commons. "Our group has meticulously broken down the pre-analytic specimen and post-analytic patient factors that could affect assay results, independent of the assay itself. The knowledge we've gained will provide an invaluable resource to all stakeholders through the BloodPAC Data Commons, and will help avoid repetition of experiments by individual groups, which prolongs biomarker development timelines and increases costs," said Scher.

As part of its commitment to open data, the BloodPAC Consortium will also allow approved researchers to access raw, unprocessed datasets. The data storage and analytics team will work with BloodPAC members and the research community to develop standards for data use, user

authentication and authorization to ensure privacy and security, as well as data annotation and harmonization. Harmonization and data processing methods will be described using portable and reproducible methods to enable widespread adoption of standardized methods.

Having focused on defining pre-analytical standards in its first year, BloodPAC will focus its second year on establishing the next layer of MTDEs to define and support other steps in assay development.

“We’re extremely proud of the accomplishments in our first year. These achievements will serve as a critical foundation as we expand our work and collaborate with partners to expedite the development of safe and effective blood profiling diagnostic technologies that can accelerate drug development, streamline clinical research, and dramatically improve the lives of patients with cancer,” said Lauren Leiman, executive director of BloodPAC.

About the Blood Profiling Atlas in Cancer (BloodPAC)

The Blood Profiling Atlas in Cancer (BloodPAC) is focused on accelerating the development and validation of liquid biopsy assays to improve the outcomes of patients with cancer. BloodPAC is a nonprofit consortium managed by the Center for Computational Science Research, Inc. (CCSR), which is an Illinois-based not-for-profit corporation. Today, over thirty organizations have pledged support by contributing liquid biopsy data, protocols, and expertise into an open data commons.

BloodPAC participants include: Arkansas Bioinformatics Consortium (AR-BIC), AstraZeneca, Biodesix, Breast Cancer Research Foundation, Celgene, Center for Data-Driven Discovery in Biomedicine (D3b) on behalf of Children’s Hospital of Philadelphia (CHOP), College of American Pathologists (CAP), CytoLumina Technologies Corp., The Department of Defense (DoD), Eli Lilly and Company, Epic Sciences, The Food and Drug Administration (FDA), Foundation Medicine, Genomic Health, Guardant Health, Indivumed, Memorial Sloan Kettering Cancer Center, National Cancer Institute (NCI), Novartis, Open Commons Consortium(OCC), Personal Genome Diagnostics, Pfizer, Prostate Cancer Foundation (PCF), Provista Diagnostics, Seven Bridges, Streck, Inc., Sysmex Inostics, Thermo Fisher Scientific, University of Chicago, University of Michigan, University of Southern California, and Weill Cornell Medicine.

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