2019 ANNUAL REPORT

Improving Patient Outcomes through Collaboration

BloodPAC

BLOOD PROFILING ATLAS IN CANCER

INTRODUCTION

Our Story

The Blood Profiling Atlas in Cancer (BloodPAC) Consortium was launched on October 17, 2016 to accelerate the development, validation and clinical use of liquid biopsy assays to better inform medical decisions and improve patient care and outcomes. With input from regulatory, industry and academic institution members, the BloodPAC Consortium established that many of the challenges in the broader field of liquid biopsy resulted from a lack of collaboration, not any limitations of technology platforms or stalled science.

To address this challenge, BloodPAC established a collaborative infrastructure to develop standards and best practices, organize and coordinate research studies through its members and operate the BloodPAC Data Commons (BPDC) to support the exchange of raw and processed data generated by the liquid biopsy research community. Data from retrospective basic, clinical and regulatory member studies, as well as projects BloodPAC has prospectively organized since its inception, is aggregated and contributed to the BPDC to establish an open, publicly accessible data commons for the global liquid biopsy community.

Today, the BloodPAC is entirely member funded and member driven. In addition to developing standards and aggregating data, BloodPAC works collaboratively with all stakeholders in the field to broaden awareness and implementation of the suggested guidelines and establish a wider chain of feedback and discussion in the community. BloodPAC's unique approach to collaboration in the field has led to the organization's success and helps to guide our work into the future.

"BloodPAC's work is fueled not just by member dues, but also by the investment of data, time and expertise from our members. This "all in" mindset creates a powerful multiplier effect for our work and has allowed us to create the data infrastructure needed to accelerate the development of liquid biopsy technologies today and ensure that it exists in perpetuity to support opportunities for future advances. The commitment & collaboration demonstrated by BloodPAC members serves as a model for all health sector stakeholders working to improve patient care through innovation."

— Lauren Leiman
Executive Director, BloodPAC

MISSION

Our mission is to accelerate the development, validation and accessibility of liquid biopsy assays to improve the outcomes of patients with cancer.

To do so, we lead a collaborative infrastructure that enables sharing of information between stakeholders in public, industry, academia and regulatory agencies.

"The formula behind BloodPAC's success is simple yet powerful. The organization convened stakeholders around a table while fostering an environment in which engaged experts across disciplines, aggregate and share data and transparently establish frameworks and standards. Taken together, these accomplishments have re-shaped the liquid biopsy landscape for development and increased the speed with which companies can bring innovation to patients."

– Phillip G. Febbo
Senior Vice President & Chief Medical Officer, Illumina

VISION

The BloodPAC consortium recognizes data sharing and evidence generation as two fundamental requirements for success and is pursuing them through dedicated workstreams:

EVIDENCE GENERATION
Align around a framework for evidence generation to bring liquid biopsy into routine clinical practice

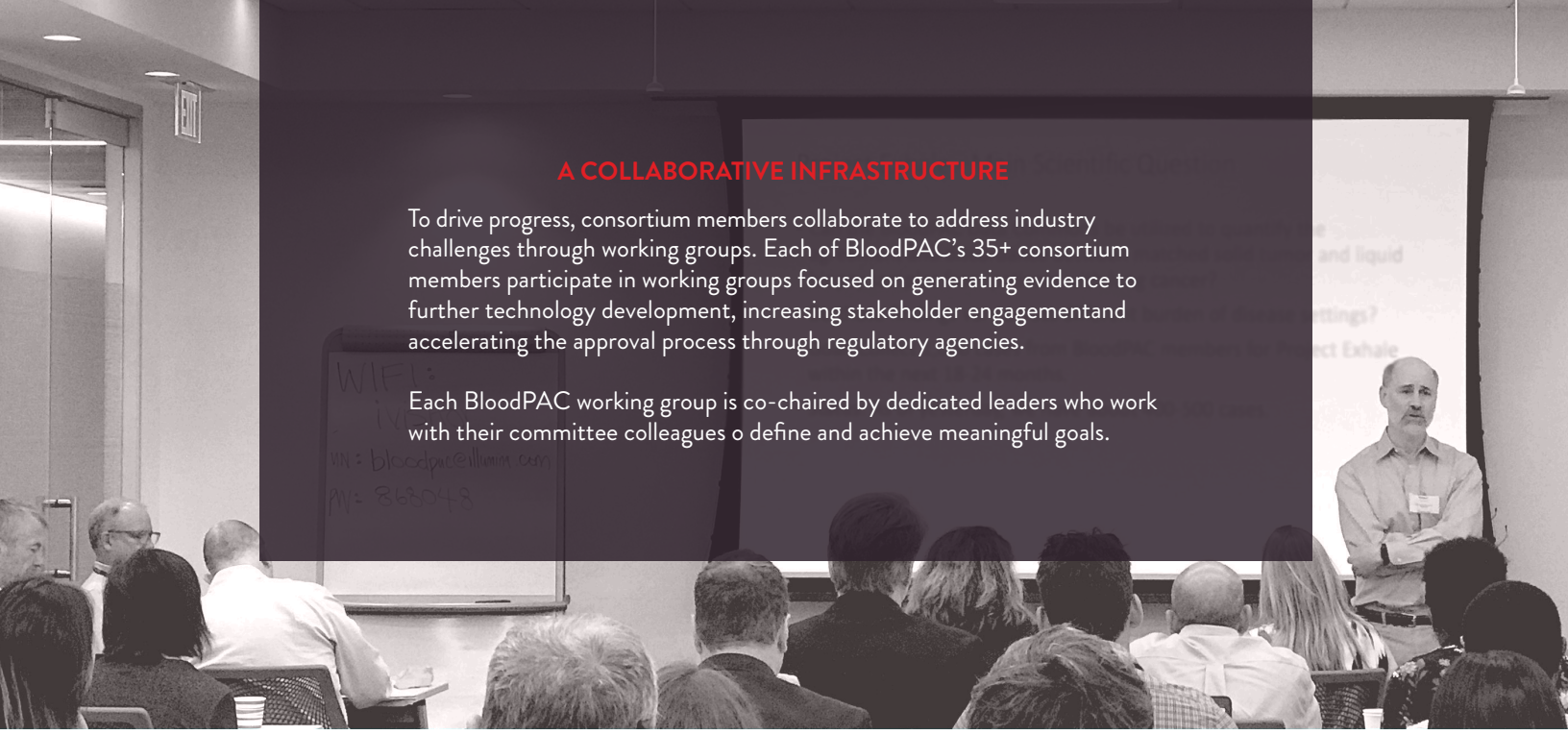
BLOODPAC DATA COMMONS
Create a BloodPAC Data Commons to serve all stakeholders within the liquid biopsy community.

STAKEHOLDER ENGAGEMENT
Accelerate approval through stakeholder engagement.

How We Work

"From the outset, our greatest risk was not achieving a deep level of collaboration within BloodPAC across competing organizations. However, we were able to attain this commitment to collaboration by building a transparent infrastructure, regular forums for dialogue and a culture of trust, all underpinned by a common desire for our industry to serve the needs of patients."

— Jake Vinson
Chief Executive Officer,
Prostate Cancer Clinical Trials Consortium



A COLLABORATIVE INFRASTRUCTURE

To drive progress, consortium members collaborate to address industry challenges through working groups. Each of BloodPAC's 35+ consortium members participate in working groups focused on generating evidence to further technology development, increasing stakeholder engagementand accelerating the approval process through regulatory agencies.

Each BloodPAC working group is co-chaired by dedicated leaders who work with their committee colleagues o define and achieve meaningful goals.

AN ITERATIVE APPROACH TO HELP SERVE THE LIQUID BIOPSY COMMMUNITY

COLLABORATION

Working Groups

BloodPAC working groups focus on projects related to specific areas of expertise to help accelerate progress.

"BloodPAC demonstrates the value of establishing open lines of collaboration among multiple stakeholders. This type of broad engagement allows for a better understanding of clinical, scientific and regulatory questions related to liquid biopsy that will ultimately drive the field forward and better serve the needs of patients."

— Julia Beaver
Director, Division of Oncology 1, FDA

EVIDENCE GENERATION

ANALYTICAL VALIDATION

Co-Charis: Jonathan Baden, BMS & Jim Godsey, Illumina

The Analytical Validation working group has collaborated to generate the Generic Analytical Validation Protocols for Cell-Free Assay Performance Verification, designed to provide test developers/manufacturers with a baseline of standardized protocols with which to document the analytical performance of a cell-free DNA assay. The generic protocols are intended for use by developers and manufacturers of NGS-based ctDNA in vitro diagnostic tests for oncology, regulatory bodies and clinical laboratories. The protocols were formally reviewed by the FDA via the agency's Pre-Submission process and published in the September 2020 issue of Clinical Chemistry. Establishing this vital industry standard will enable test developers to streamline their efforts to align with the FDA during their proposed product's Pre-Submission phase and in turn, help minimize the time spent by FDA reviewers on guiding test developers through the process.

CLINICAL & PATIENT CONTEXT VARIABLES

Co-chairs: Donald Johann, UAMS, Jean-Francois Martini, Pfizer & Howard Scher, MSKCC

The goal of the Clinical & Patient Context Variables working group is to identify, develop and build consensus around minimal and measurable Clinical Context and Patient Context Variable Data Elements recommended for collection and submission of data to the BPDC. The lists will focus on identifying patient and disease factors that may affect assay results at the time the biospecimen is acquired. These Minimal Technical Data Elements (MTDEs) ensure data submitted to the BPDC can be accurately evaluated and analyzed by BloodPAC participants and members of the broader liquid biopsy community.

JUST DO IT!

Co-chairs: Kelli Bramlett, Thermo Fisher Scientific & Matthew Ryder, Sysmex Inostics

The JUST DO IT! working group aims to increase quality and consistency of ctDNA analysis through inter-laboratory testing of well-recognized analytical tools and reference materials. JFDI testing will include measurements of accuracy and precision, as well as other metrics fundamental to ctDNA analysis. The JFDI team includes ten independent laboratories (all BloodPAC members) with interest in improving standardization and reliability of ctDNA testing, an essential step as an increasing number of clinical decisions have the potential to be based on liquid biopsy. The working group is currently developing a report to share results of this analytical study.

PRE-ANALYTICAL VARIABLE

Co-chairs: Philip Febbo, Illumina, Anne-Marie Martin, GSK & Howard Scher, MSKCC

The Pre-Analytical Variable working group has developed a list of 11 Pre-analytical Minimal Technical Data Elements (MTDEs), attributes recommended for collection and submission of data to the BPDC. These MTDEs ensure data submitted to the BPDC can be accurately evaluated and analyzed across BloodPAC participants and members of the broader liquid biopsy community.

RECOMMENDED DATA ELEMENT

Co-Chairs: Joel Lechner, Streck & Jake Vinson, PCCTC

The primary objective of the Recommended Data Element (RDE) working group is to provide and communicate clear justification and validation for the minimal technical data elements (MTDEs) that have been developed by the BloodPAC Consortium, including established pre-analytical, patient context and clinical variables. The team is working to accomplish this by first reviewing variables used by a variety of industry organizations to understand the landscape. The team will then analyze new and historical data based on the consensus MTDEs to recommend which MTDEs are deemed valid and necessary. Ultimately, the team will communicate and promote the validated data elements through various routes including, but not limited to, a joint publication.

BLOODPAC DATA COMMONS

DATA EXPERIENCE

Co-chairs: Anand Kolatkar, USC & Lea Salvatore, Open Commons Consortium

The Data Experience working group provides a secure and compliant data commons to store, harmonize and analyze liquid biopsy data submitted by member organizations with the goal of sharing this data with the larger liquid biopsy, translational and scientific communities. This working group maintains compliance with existing standards (FASTQ, BAM and VCF) and develops new standards and protocols for formatting and integrating data specific to liquid biopsy outputs.

DATA ROADMAP: PROJECT EXHALE

Co-chairs: Robert L. Grossman, UChicago CTDS & Open Commons Consortium, Donald Johann, UAMS, Jerry Lee, Chief Science & Innovation Officer, Laurence J. Ellison Institute for Transformative Medicine of USC

The Data Roadmap working group focuses on establishing the BPDC as a hub of curated information on liquid biopsy within the cancer data ecosystem. It will interoperate as part of a broader cancer data ecosystem supporting: i) research and discovery, ii) analytic validity, iii) clinical validity and iv) clinical utility. The group has initially established Project Exhale to establish BPDC as a source of rigorous scientific evidence, recognized by the FDA, to support regulatory submissions. This project initially builds upon lung cancer tissue and blood profiling work done by multiple BloodPAC members. The team collaborates with other BloodPAC working groups to define and address questions concerning: i) generic cancer, ii) organ specific cancer and iii) regulatory science. The working group's initial aim is to quantify the agreement and discordance between matched solid tumor and liquid biopsy samples from patients with malignancies. Importantly, the working group will assess whether these findings vary across different burdens of disease and organs of origin. All supporting data will be included within the BPDC, along with corresponding analyses.

STAKEHOLDER ENGAGEMENT

REIMBURSEMENT & POLICY

Co-chairs: Robert Dumanois, Thermo Fisher Scientific & Estevan Kiernan, Illumina

The Stakeholder Engagement working group is collaborating to acquire and socialize baseline understanding of payer perceptions of liquid biopsy's role in therapy selection and future monitoring applications. This baseline will be used to inform a roadmap which identifies coverage gaps for liquid biopsy, provides visibility on the health economic value; and affects change with one voice across all payer policymakers. Success will be measured by improvements in patient outcomes, made possible by accelerating and expanding payer coverage of tests that can provide actionable clinical insights.

SUSTAINABILITY

Co-chairs: Hakan Sakul, Pfizer & Jerry Lee, Chief Science and Innovation Officer, Ellison Institute

The focus of the Sustainability working group is on developing mid- and long-term strategies for the BloodPAC Consortium and BloodPAC Data Commons. Group members are working to better understand how to modify and evolve the organization's mission over time, create a nexus for liquid biopsy data, expand the organization's reach and relevance globally and clearly define the BloodPAC value proposition.

Impact

"When we set out, our goal was to make a decade of progress in five years. But in just three, we've translated that aspiration into tangible achievements, establishing an evidence-based, data science-driven environment for bringing new diagnostic technologies into clinical settings."

— Peter Kuhn,
Professor, University of Southern California

MILESTONES

Accelerating Progress

"Pathologists serve as a critical link to timely diagnosis and optimal treatment decisions for patients and their work depends on having a toolbox of reliable, validated diagnostic technologies. BloodPAC offers a critically important forum for identifying the best practices and guideposts that must be embedded into the framework for development, validation and regulatory review."

– Carolyn Compton
Professor Life Sciences, Arizona State University

SCIENTIFIC STUDIES

The BloodPAC Consortium has conceptualized and initiated two liquid biopsy clinical studies for cross-platform validation, multi-modal high-content and longitudinal monitoring. Complete datasets from both studies will be submitted to the BloodPAC Data Commons and analyzed. The studies have successfully incorporated the frameworks established by the BloodPAC Consortium around pre-analytical minimum technical data elements and patient context data elements.

BCRF BREAST CANCER RESEARCH FOUNDATION

Prostate Cancer Foundation
Curing Together.

POLICY & REIMBURSEMENT

The Policy and Reimbursement working group (RWG) was formed among a diverse group of market access, health economics and regulatory staff. In order to improve patient outcomes, the RWG has mobilized resources to support the growth of ctDNA testing in a public and immediate manner through positive changes to payer coverage policies.

Multiple advocacy letters were submitted to Medicare contractors in 2019 and our efforts were rewarded by amended language in Palmetto GBA's MolDX program Local Coverage Determination (L38043: Plasma-based Comprehensive Genomic Profiling in Solid Tumors).

PUBLICATIONS & FRAMEWORKS

Minimum Technical Data Elements for Liquid Biopsy Data Submitted to Public Databases

MTDEs defined as required for all projects submitted to the Data Commons.

Generic Protocols for the Analytical Validation of Next-Generation Sequencing-Based ctDNA Assays

A core set of generic protocols to serve as the starting point for analytical validation studies.

Collaborating to Compete

Pre-Analytic Minimal Technical Data Elements (MTDEs) was established & validated through a working group with FDA & CAP.

23 PAPERS CITE OUR WORK

2 FDA SUPPORTED FRAMEWORKS

GROUNDWORK

BloodPAC Data Commons

"Organizations involved in the development of diagnostic technologies must keep pace with breakthroughs in targeted cancer treatment being developed by the biopharmaceutical industry. The unique collaboration led by BloodPAC allows just that, enabling innovators of liquid biopsy assays to accelerate their work and develop tools needed to accurately profile cancers and inform treatment decisions."

– Anne-Marie Martin
Senior Vice President, *Global Head, Experimental Medicine Unit, GSK*

A data commons is a cloud-based software platform for managing, analyzing, harmonizing and sharing large datasets. Open Commons Consortium manages and operates the BloodPAC Data Commons using Gen3, an open source platform for developing data commons. Data commons accelerate and democratize the process of scientific discovery, especially over large or complex datasets.

BloodPAC is working to establish our data commons as a source of valid scientific evidence. We are defining several scientific questions and collecting enough data for each one to serve as a source of evidence to support submissions to regulatory agencies in premarket submissions and data for agencies and organizations making decisions about reimbursement.

Our next goal is to make BloodPAC Data Commons a hub for liquid biopsy data and to seamlessly support a broader cancer data ecosystem. Also, we are working to establish a formal standard operating procedure around data submission, curation and creation of data products.

5 TYPES OF ANALYTES

DNA
RNA
MORPHOLOGY
PROTEIN
CELL COUNT

BLOODPAC MEMBER SCIENTIFIC STUDY DATASETS **32**

THE DATA COMMONS IS INTEGRAL TO OUR MISSION

COLLABORATE & DEVELOP FRAMEWORKS

SUBMIT DATA TO THE BLOODPAC DATA COMMONS

ORGANIZE & ANALYZE DATA

14 TYPES OF CANCERS

PROSTATE
BREAST
BONE MARROW
STOMACH
PANCREAS
BRAIN
OVARY
SKIN
LIVER
LUNG
KIDNEY
UTERUS
SOFT TISSUE
COLORECTAL

PARTNERSHIP

Our Community

"Every time a patient is diagnosed with cancer, it elicits an array of questions that clinicians strive to answer to achieve the best outcome. These large, shared databases and protocols for validation are exactly the infrastructure needed to put answers within reach of clinicians – answers that ultimately improve patient care."

– Howard Scher
Physician and Head,
Biomarker Development Initiative
at Memorial Sloan Kettering Cancer Center

MEMBERS

American Cancer Society
Arkansas Bioinformatics Consortium
Association for Molecular Pathology
AstraZeneca
Bio-Rad Laboratories
Breast Cancer Research Foundation
Bristol Myers Squibb
Center for Translational Data Science at the University of Chicago
Center for Genetic Medicine Research at Children's National Medical Center
Ceres Nanosciences
Chan Soon-Shiong Institute of Molecular Medicine at Windber
Eli Lilly and Company
Epic Sciences
Fluxion Biosciences
Focused Ultrasound Foundation
Foundation Medicine, Inc.
Freenome
Friends of Cancer Research
GlaxoSmithKline
Guardant Health
Horizon Discovery Ltd.
Illumina, Inc.
Inivata
LGC/SeraCare
Memorial Sloan Kettering Cancer Center
Movember Foundation
National Cancer Institute at the National Institutes of Health
Novartis
Open Commons Consortium
Personal Genome Diagnostics
Pfizer, Inc.
The Prostate Cancer Clinical Trials Consortium
Prostate Cancer Foundation
SolveBio
Streck
Sysmex Corporation
Tempus Labs
Thermo Fisher Scientific
Thrive Earlier Detection
University of Southern California
Windber Research Institute

COLLABORATORS

AACR
Center for Medical Technology Policy
College of American Pathologist / Arizona State University
U.S. Department of Defense
U.S. Food & Drug Administration
FNIH

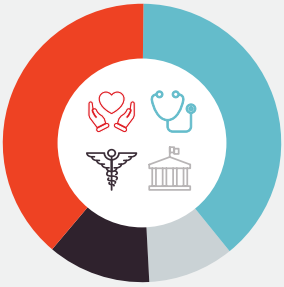
EXTERNAL DATA CONTRIBUTOR

University of California, Los Angeles

MEMBERSHIP BREAKDOWN

37%
Academic / Non Profit

12%
Pharmaceutical



41%
Diagnostic / Industry

10%
Government Agencies

Leadership & Financials

"Data opens countless doors to discovery. The vision we established for BloodPAC is to build and operate a data ecosystem so that liquid biopsy innovators and researchers can explore the most promising doorways to discovery that will lead to improved patient outcomes."

— Robert Grossman,
Professor, University of Chicago CTDS
& Founder/Director, Open Commons Consortium

OUR TEAM

Leadership & Executive Committee

LAUREN LEIMAN
Executive Director,
BloodPAC Consortium

PHILLIP G. FEBBO, MD
Senior Vice President &
Chief Medical Officer, Illumina

ROBERT L. GROSSMAN, PH.D.
Professor, University of Chicago CTDS
& Founder/Director, Open Commons
Consortium

PETER KUHN, PH.D.
Professor, University
of Southern California

ANNE-MARIE MARTIN, PH.D.
Senior Vice President, Global Head,
Experimental Medicine Unit, GSK

JAKE VINSON
Chief Executive Officer, Prostate
Cancer Clinical Trials Consortium

SCIENTIFIC CO-CHAIR COMMITTEE

KELLI BRAMLETT
Director of R&D, Thermo Fisher Scientific

DARYA CHUDOVA, PH.D.
Senior Vice President, Technology, Guardant Health

JIM GODSEY, PH.D.
Vice President, Assay Development, Illumina

JERRY LEE, PH.D.
Chief Science and Innovation Officer, Lawrence J Ellison Institute for Transformative Medicine of USC

HAKAN SAKUL, PH.D.
Vice President and Head of Diagnostics, Pfizer

HOWARD SCHER, M.D.
Physician and Head, Biomarker Development Initiative at Memorial Sloan Kettering Cancer Center

JENNIFER DICKEY, PH.D.
Vice President, Regulatory and Quality, Personal Genome Diagnostics

BLOODPAC DATA COMMONS TEAM

ROBERT L. GROSSMAN, PH.D.
Professor, University of Chicago CTDS & Founder/Director, Open Commons Consortium

PLAMEN MARTINOV
Chief Information Security Officer, Open Commons Consortium

LEA SALVATORE
Director of Operations, Open Commons Consortium and Project Manager, BloodPAC

Financials

"BloodPAC has demonstrated great leadership by bringing together multiple stakeholders around a common cause and delivering many achievements in such a short time. Our success has also become our motivation to expand our collaboration model to more organizations around the world for sustainable global impact in clinical diagnosis and care."

— Hakan Sakul,
Vice President and Head of Diagnostics, Pfizer

STATEMENT OF FINANCIAL POSITION
Year ended December 31, 2019

ASSETS	
Cash & cash equivalents	$694,464
Membership fees receivable	$75,000
Due from program	$38,735
TOTAL ASSETS	**$808,199**
LIABILITIES	
Deferred membership fees	$150,000
TOTAL LIABILITIES	**$150,000**
NET ASSETS	
Without donor restrictions	$658,199
TOTAL NET ASSETS	**$658,199**
TOTAL LIABILITIES & NET ASSETS	**$808,199**

STATEMENT OF ACTIVITIES
Year ended December 31, 2019

REVENUE	
Membership dues	$707,000
TOTAL REVENUES	**$707,000**
EXPENSES	
Program Services	$318,610
Management & General	$91,755
TOTAL EXPENSES	**$410,365**
CHANGE IN NET ASSETS	**$296,635**
NET ASSETS	
Begining of year	$361,564
END OF YEAR	**$658,199**

Supplemental information from the 2019 Center for Computational Science Research, Inc. audited financial statements.

BloodPAC

BLOOD PROFILING ATLAS IN CANCER