Improving Patient Outcomes through Collaboration
"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 infrastructure needed to accelerate the development of liquid biopsy technologies.

The commitment and collaboration demonstrated by BLOODPAC members serves as a model for all health sector stakeholders working to improve patient care through innovation."

—Lauren C. Leimen, Executive Director, BLOODPAC
BLOODPAC’s work is sustained by a deep commitment to collaboration among our members. This year, we had the opportunity to reflect on the accomplishments we achieved over our first few years and chart a course for the future.

BLOODPAC’s work since 2016 has been guided by the ambitious goals set by our founding group of stakeholders: to accelerate the development, validation and clinical use of liquid biopsy assays to equip clinicians and patients with the information they need to improve decision-making and outcomes. It was with this aim that the Blood Profiling Atlas in Cancer (BLOODPAC) Consortium was launched, fostering a unique effort among regulatory, industry and academic experts committed to realizing the full clinical potential of liquid biopsy.

Efforts driven by BLOODPAC have yielded critical strides in developing standards and best practices, supporting research studies, and operating one of the largest repositories of raw and processed data from liquid biopsy research community, the BLOODPAC Data Commons (BPDC). Each accomplishment is proof of the core concept underpinning our work. Collaboration isn’t at odds with competition in the marketplace — it’s an essential to healthy competition in the marketplace.

While we’re deeply proud of our work to date, we know that there is much more to be done to realize the vision of BLOODPAC. It’s essential that not only clinicians and patients understand the potential benefits of this technology, but also the payer community. In addition, bringing standardized frameworks to support regulatory decision-makers around the globe will serve to bring technologies to patients everywhere.

I’m so grateful to each of BLOODPAC’s members and supporters. Their time, expertise and shared passion has borne much fruit in a short time, and we’re equipped and ready to chart continued progress in service to patients.
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.

"Since its inception, BLOODPAC has always been a safe space for collaboration, where stakeholders representing commercial entities, academics, patient advocates, and government agencies — each representing different interests and missions — can come together and say, ‘What can we do together that we can’t do separately?’ That’s the underpinning of every accomplishment BLOODPAC has achieved.”

—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.
“By focusing on the big challenges – challenges that impact the entire industry – BLOODPAC members have been able to deliver on critical milestones. Our working groups represent ‘neutral ground’ where members can come together and solve a problem. It’s hard to overstate how much we’ve all grown in our own knowledge simply by listening to each other and hearing the other team’s perspective about a problem. The result is that each of us is more effective in our roles, because we’re able to come together, solve a common problem, and do it faster than we would have done sitting in our own shops and working on it alone.”

—Jim Godsey, Vice President, Molecular Genomics & Oncology R&D, Quest Diagnostics
To drive progress, consortium members collaborate to address industry challenges through working groups. Each of BLOODPAC’s 60+ consortium members participate in working groups focused on generating evidence to further technology development, increase stakeholder engagement, and accelerate the approval process through regulatory agencies.

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

**OUR ITERATIVE PROCESS**

BLOODPAC takes an iterative & integrated approach to develop standards & guidance to help serve all stakeholders in the liquid biopsy community.

- **Framework & Protocol Development**: Utilize industry experience and expertise to develop mutually agreed upon standards to benefit broader liquid biopsy community.
- **Supporting Data Aggregation**: Create a BLOODPAC Data Commons to serve all stakeholders in the liquid biopsy community.
- **Distribution & Community Engagement**: Evolve to meet emerging technology through ongoing engagement and refinement.

Deliverables
COLLABORATION

Working Groups

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

“Liquid biopsy technology is innovative and complex, making collaboration essential in establishing standards for validation and demonstrating accuracy and precision. The end result of innovation isn’t an idea—it’s bringing that idea into reality, ensuring it works as intended, and putting it into the hands of patients and clinicians. That is the long last mile that the BLOODPAC is helping to cross very actively.”

—Darya Chudova, Senior Vice President of Technology, Guardant Health

EVIDENCE GENERATION

ANALYTICAL VALIDATION

Co-Chairs: Jonathan Baden (BMS), Kevin D’Auria, (Guardant), & Jimmy Lin (Freenome)

The Analytical Validation working group has collaborated to generate the Generic Analytical Validation Protocols for Cell-Free Assay Performance Verification v1.0, 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 blood-based liquid biopsy 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. As follow up deliverables, the working group is focusing on two additional protocol documents, including:

MRD PROTOCOL

Jon Baden (BMS) and Jimmy Lin (Freenome)

BLOODPAC formed the MRD Analytical Validation Working Group (BLOODPAC MRD AV WG) to develop a set of generic analytical validation protocols for blood-based Molecular Residual Disease (MRD) testing of solid tumors. The BLOODPAC MRD AV WG recognizes that the end goal of MRD testing for oncology is to provide diagnostic information for the presence of disease following a clinical intervention as well as recurrence, and for this information to help inform specific decisions as evidence supports over the course of the patient journey for improved outcomes and to reduce costs associated with treatment of disease recurrence.
**bTMB PROTOCOL**

*Jon Baden (BMS) and Kevin D’Auria (Guardant)*

BLOODPAC formed the bTMB Analytical Validation Working Group (BLOODPAC bTMB AV WG), at the request of Friends of Cancer Research, and was charged with drafting a supplement to the original v1.0 document such that the v1.1 document also contained the information and protocols required to perform analytical validation of bTMB tests, in addition to the original AV protocols. BLOODPAC bTMB AV WG recognizes that there are numerous approaches for design of a Comprehensive Genomic Panel (CGP) to assess bTMB for solid tumors currently under development, and attention is focused on increasing standardization and advancing best practices. As every test is unique, it is suggested that the guidance developed by BLOODPAC should serve as a generic foundation from which test-specific validation strategies can evolve.

**EARLY DETECTION & SCREENING**

*Co-Chairs: Christina Clarke Dur (GRAIL), Kathryn Lang (Guardant) & Girish Putcha (Freenome)*

The goals of the Early Cancer Detection and Screening Working Group are to develop and build consensus around common definitions and standardized frameworks for evidence development relevant to novel blood-based technologies for early cancer detection. The field of early cancer detection lacks a common lexicon, and standards for evidence generation in areas such as clinical validation and clinical utility. By creating a forum for industry, academic, non-profit, policy, regulatory, and reimbursement leaders in this area, the Working Group will articulate and align upon these key issues for blood-based early detection tests targeting single or multiple cancers. The Working Group will disseminate their work as peer-reviewed publications further supporting the advancement of this space.

**JUST FREAKING DO IT!**

*Co-chairs: Kelli Bramlett (Thermo Fisher Scientific), Adam Corner (Bio-Rad) & Kyle Hernandez, (University of Chicago)*

The JUST FREAKING 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.

**MOLECULAR RESIDUAL DISEASE (MRD) STRATEGIC STEERING**

*Co-Chairs: Andy Hadd (Natera) & Angela Silvestro (GSK)*

The goal of the Molecular Residual Disease (MRD) Strategic Steering group is to identify and address barriers to the implementation of MRD in solid tumors in non-metastatic disease, and to develop projects and resources to address these challenges. The working group’s long-term aim is to validate MRD as an early endpoint in solid tumors. The Strategic group organizes and advises the efforts of two subgroups — MRD Analytical Validation and MRD RDE— with the overall goal of addressing specific barriers to MRD adoption and utilization in clinical trials and medical practice. The Strategic Steering group is currently developing a lexicon to standardize terms related to MRD testing and create a controlled vocabulary. The lexicon is intended to assist manufacturers, clinicians and pharmaceutical companies in the field build upon work to date and form a common framework for the different applications and uses of MRD.
RECOMMENDED DATA ELEMENTS  
**Chair: Jake Vinson (Prostate Cancer Clinical Trials Consortium)**  
The primary objective of the Recommended Data Element (RDE) working groups are to provide and communicate clear justification and validation for the minimal technical data elements (MTDEs) that have been developed by the BLOODPAC Consortium, recommended for collection and submission of data to the BLOODPAC Data Commons (BPDC).

CLINICAL & PATIENT CONTEXT VARIABLES  
**Christina Lockwood (Association for Molecular Pathology) & Jason Merker (American Society of Clinical Oncology)**  
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.

PRE-ANALYTICAL VARIABLE  
**Philip Febbo (Illumina), Anne-Marie Martin (GSK), & Howard Scher (Memorial Sloan Kettering Cancer Center)**  
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.

LANDSCAPE ANALYSIS  
**Christina Lockwood (Association for Molecular Pathology) & Jason Merker (American Society of Clinical Oncology)**  
The Pre-Analytical Variable Landscape Analysis working group is authoring a review of the pre-analytical variables recommended for data collection. The goal of this Landscape Analysis is to better understand and promote harmonization of minimal standards for data collection in the liquid biopsy field. The working group includes representation from a variety of organizations, including CAP, ASCO, NCI, ISBER, ESMO, ISO, CLSI, and AMP.
BLOODPAC DATA COMMONS

DATA EXPERIENCE

Co-chairs: Jeff Jensen (Fluxion Biosciences) & Plamen Martinov (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 and Open Commons Consortium), Donald Johann (University of Arkansas for Medical Sciences), Jerry Lee (USC)

The Data Roadmap working group focuses on establishing the BLOODPAC Data Commons (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: Suzanne Belinson (Tempus), Maude Champagne (Illumina), Robert Dumanois (Thermo Fisher Scientific)

In 2020, the working group acquired a baseline understanding of payer perceptions of liquid biopsy’s role in therapy selection and monitoring applications. This baseline informs a roadmap to address coverage gaps for liquid biopsy through “above brand” evidence-based payer education. The working group speaks with one voice across all payer policymakers, and develops a new framework for them to assess quality of liquid biopsy assays and health economic value. Success is measured by improvements in patient access and outcome, made possible by accelerating and expanding payer coverage, coding, and payment for these medically necessary tests.
“Developing standards for new technologies might not be seen as exciting work. But it’s critically important because progress depends on having confidence in the data. Having a common set of standards doesn’t just give us assurance that our data is high quality, but it also allows us to integrate it into the data commons, where it’s available to everybody. Bringing those standards to countries outside the U.S. will make a tremendous difference in accelerating global access to these technologies.”

—Anne-Marie Martin, Senior Vice President, Global Head of Experimental Medicine, GSK
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 of liquid biopsy assays.”

—Carolyn Compton, Professor of 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.
(2017) COLLABORATING TO COMPETE: BLOOD PROFILING ATLAS IN CANCER (BLOODPAC) CONSORTIUM
Clinical Pharmacology and Therapeutics
This initial publication describes BLOODPAC’s mission, structure, and goals.

(2020) MINIMUM TECHNICAL DATA ELEMENTS FOR LIQUID BIOPSY DATA SUBMITTED TO PUBLIC DATABASES
Clinical Pharmacology and Therapeutics
This publication captures a list of 11 Pre-analytical Minimal Technical Data Elements (MTDEs) suggested for liquid biopsy data collection and submission to the BloodPAC Data Commons (BPDC). These MTDEs ensure that data can be accurately evaluated and analyzed across BLOODPAC participants and members of the broader liquid biopsy community.

(2020) GENERIC PROTOCOLS FOR THE ANALYTICAL VALIDATION OF NEXT-GENERATION SEQUENCING-BASED CTDNA ASSAYS
Clinical Chemistry
A core set of protocols intended to serve as the starting point for liquid biopsy test developers and define industry standards in assay validation.

(2021) BLOODPAC DATA COMMONS FOR LIQUID BIOPSY DATA
JCO Clinical Cancer Informatics
A description of the data model, objectives, and uses of the BLOODPAC Data Commons, the platform used to manage the data for the consortium.
ENGAGEMENT

Reimbursement & Policy

The Reimbursement & Policy 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. We are working collectively, above brand, to demonstrate the value of liquid biopsy-based applications.

To achieve the group’s goals, the team focuses on three different areas:

**MEMBER EDUCATION**
*Maude Champagne (Illumina)*

There is significant diversity in the work being done by BLOODPAC members. This subgroup ensures that coverage and policy changes are shared with the broader reimbursement and policy team. It creates a space for sharing best practices and mobilizing across industries to increase liquid biopsy access.

**ADVOCACY**
*Robert Dumanois (Thermo Fisher Scientific)*

The Advocacy sub-committee highlights payer and reimbursement regulatory issues and educates the BLOODPAC membership on diagnostic reimbursement. Each quarter, the team facilitates a presentation from a payer to provide BLOODPAC with this unique perspective, providing opportunities to innovate and align.

**RISK HOLDER ENGAGEMENT**
*Suzanne Belinson (Tempus)*

This subgroup aims to educate payers, laboratory benefit managers and other risk holders on the evidence-based clinical utility, economic value and patient benefit of liquid biopsy. Working collaboratively with risk holders to align incentives and develop evidence frameworks is also primary to the mission of this group.
The BLOODPAC Data Commons (BPDC) is the leading repository for liquid biopsy data. Scientific and clinical data is contributed by members and non-members. This provides the scientific evidence to support the frameworks and standard protocols being developed by the BLOODPAC Consortium. Our overarching theme is to establish a standardized and secure repository that will speed scientific and clinical advances leading to improved patient outcomes involving liquid biopsies and their clinical applications.

The BLOODPAC Data Commons utilizes a cloud-based software platform for managing, analyzing, harmonizing and sharing large liquid biopsy datasets allowing users to:

- Accelerate the process of scientific discovery, especially over large or complex datasets
- Standardize data submission to develop common approaches for data harmonization
- Provide the infrastructure and necessary frameworks to do analysis securely in place

Today, the BLOODPAC Data Commons serves as a source of valid scientific evidence to support submissions to regulatory agencies, supply data for agencies and organizations making decisions about reimbursement and provide a rich data source for researchers.


"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, SVP, Global Head of Experimental Medicine, GSK
“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, Oncologist and Head of the Biomarker Development Initiative at Memorial Sloan Kettering Cancer Center
MEMBERS
Adela
American Cancer Society
Arkansas Bioinformatics Consortium
Association for Molecular Pathology
AstraZeneca
Bio-Rad Laboratories
Breast Cancer Research Foundation
Bristol Myers Squibb
C2i Genomics
Center for Translational Data Science
at UChicago
Center for Genetic Medicine Research
at Children’s National Medical Center
Ceres Nanosciences
Epic Sciences
Delfi Diagnostics
Eli Lilly and Company
Exact Sciences
Focused Ultrasound Foundation
Foundation Medicine, Inc.
Fluxion Biosciences
Freenome
Friends of Cancer Research
GlaxoSmithKline
Guardant Health
GRAIL
Horizon Discovery
Illumina, Inc.
Invitae
Inivata
LGC/SeraCare
Lungevity Foundation
OncoRNA Lab Ghent University
Memorial Sloan Kettering Cancer Center
Merck
Movember Foundation
Natera
National Cancer Institute at the NIH
Novartis
Open Commons Consortium
Personal Genome Diagnostics
Personalis
Pfizer, Inc.
The Prevent Cancer Foundation
The Prostate Cancer Clinical Trials Consortium
Prostate Cancer Foundation
Quest Diagnostics
Seven Bridges
SiO2 Materials Science
Streck
Sysmex Corporation
Tempus Labs
Thermo Fisher Scientific
University of Southern California
U.S. Department of Veterans Affairs
Windber Research Institute

COLLABORATORS
AACR
Center for Medical Technology Policy
College of American Pathologists
/ Arizona State University
Foundation of the National Institute of Health
U.S. Department of Defense
U.S. Food & Drug Administration

EXTERNAL DATA CONTRIBUTORS
University of California, Los Angeles
Henry Ford Health System
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 Center for Translational Data Science & Founder/Director, Open Commons Consortium
OUR TEAM

Leadership & Executive Committee

LAUREN C. LEIMAN
Executive Director, BLOODPAC

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

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

PETER KUHN, PhD
Professor, University of Southern California

ANNE-MARIE MARTIN, PhD
Senior Vice President, Global Head of Experimental Medicine, GSK

JAKE VINSON
Chief Executive Officer, Prostate Cancer Clinical Trials Consortium

SCIENTIFIC COCHAIR COMMITTEE

KELLI BRAMLETT
Director of R&D, Thermo Fisher Scientific

DARYA CHUDOVA, PhD
Senior Vice President of Technology, Guardant Health

JENNIFER DICKEY, PhD
Vice President, Regulatory and Quality, Personal Genome Diagnostics

JIM GODSEY, PhD
Vice President, Molecular Genomics & Oncology R&D, Quest Diagnostics

JERRY LEE, PhD
Associate Professor, USC

HAKAN SAKUL, PhD
Director of R&D, Thermo Fisher Scientific

HOWARD SCHER, MD
Oncologist and Head of the Biomarker Development Initiative at Memorial Sloan Kettering Cancer Center

BLOODPAC DATA COMMONS TEAM

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

PLAMEN MARTINOV
Chief Information Security Officer, Open Commons Consortium

GINGER RIESEN, CPA
Accountant, BLOODPAC

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

LAURA TRAMONTOZZI
Brand & Design, 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

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|               |         |         |         |
| **LIABILITIES** |         |         |         |
| Deferred membership fees | $485,000   | $586,000 | $150,000 |
| Accrued payroll     | $10,450  | -       | -       |
| Due to Programs     | $25,454  | $9,393  | -       |
| **TOTAL LIABILITIES** | $520,904 | $645,393 | $150,000 |

|               |         |         |         |
| **NET ASSETS**  |         |         |         |
| Without donor restrictions | $1,467,309 | $951,570 | $658,199 |
| **TOTAL NET ASSETS** | $1,467,309 | $951,570 | $658,199 |

| **TOTAL LIABILITIES & NET ASSETS** | $1,988,213 | $1,596,963 | $808,199 |

### STATEMENT OF ACTIVITIES

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