# Ten Years of Progress in Five

Fulfilling BLOODPAC's Commitment to the Cancer Moonshot

 BLOODPAC

"BLOODPAC plays a critical role in helping educate the liquid biopsy community on what a good test looks like. Our goal is to enhance credibility and confidence in existing and future assays, and it's towards this end that we are creating standards, collecting data, and developing protocols. As we achieve key milestones and deliver much needed tools for progress, we're bringing the potential of widespread access to liquid biopsy closer to being a reality for all cancer patients."

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**LAUREN C. LEIMEN**
Executive Director,
BLOODPAC

# BLOODPAC Turns Five

There is a lengthy distance to cover between an initial scientific discovery and the improvement of care for patients. These gaps between innovation and application are most often measured in years and decades. When BLOODPAC came together as an organization in 2016, our founding members were galvanized by a shared commitment to closing that gap in liquid biopsy for cancer care. The science supporting the development of liquid biopsy assays was clear and rapidly growing, but the path for bringing these scientific advances to patients was not.

In order to accelerate the process of bringing technologies into clinical settings for patient benefit, we worked to create a roadmap through collaboration. Over the course of five years we've engaged a range of stakeholders to create this roadmap, including regulatory, industry, academic, nonprofit, patient advocacy and payer entities. Together, we've yielded results that condensed the timeline for bringing technologies to patients and fulfilled our original commitment to the Cancer Moonshot — to drive 10 years of progress in half the time.

We were deeply proud to recognize these accomplishments at our 5-year summit and to see just how far we've come. For a half-decade, BLOODPAC has served as a collaborative ecosystem where members can openly share data and craft common standards that establish essential guideposts for assay development.

None of our achievements would be possible without the vision, talent and time contributed by BLOODPAC's members.

They've leaned in, invested deeply, checked organization-specific interests at the door and created the vital infrastructure needed to develop community-wide standards and frameworks. By creating this strong collaborative foundation, BLOODPAC enables the development, approval and access to novel liquid biopsy technologies to better inform medical decisions and improve patient care.

Our work is far from done, and with key infrastructure elements in place we're positioned to tackle the next set of challenges. BLOODPAC's robust collaboration with the FDA in the U.S. can serve as a model to ensure global regulators are equipped to navigate review of new technologies. Validating the use of liquid biopsy to monitor for disease recurrence is a clear scientific opportunity and a pressing need for patients. And ensuring that technologies are accessible for all communities by maximizing coverage and education is critical to expanding appropriate clinical use of liquid biopsy.

The strength and diversity of BLOODPAC's members means that there are few limits on what we can accomplish. I'm excited about the opportunities for progress that the next 5 years will bring and the big challenges we'll tackle together.

**LAUREN C. LEIMAN**
*Executive Director,*
*BLOODPAC*

## KEY SUCCESSES

Hosted a fifth anniversary Liquid Biopsy Summit in March 2022 with over 500 virtual attendees.

Pubished "Creating Standards for Liquid Biopsies: the BLOODPAC Experience" in Expert Review of Molecular Diagnostics focusing on the importance of BLOODPAC's standards work to date as well as looking ahead to creating frameworks for MRD and bTMB

Published "BLOODPAC: Collaborating to chart a path towards blood-based screening for early cancer detection" in Clinical and Translational Science".

Concluded analysis and findings of Phase II of the JFDI working group project, and received manuscript approval for publication in The Journal of Molecular Diagnostics

Established two new working groups focused on achieving a 5-year long-term goal of validating MRD as an early endpoint in solid tumors

Established BLOODPAC's first disease-specific working group focused on addressing an underserved need in the liquid biopsy field, the CSF for Primary Brain Tumors Working Group

## BLOODPAC BY THE NUMBERS

**60+**

*global collaborators are part of BLOODPAC*

**2**
*FDA Supported Frameworks*

**6**
*peer-reviewed BLOODPAC publications*

**106**
*papers cite BLOODPAC work*

*The BLOODPAC Data Commons contains*

**70+**
*studies & projects*

*spanning nearly*
**4,500 cases**

*leveraging almost*
**33,000 files**

*and a total of*
**33 TB data**

**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 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.

*01*  |  *How We Work*

"As they say, standards are like toothbrushes. Everybody has one, and nobody wants to use anyone else's. This is one of the big barriers to data reuse that BLOODPAC has worked to break down in the past few years. It's thankless work, but we believe that introducing and maintaining high data standards will make a world of difference in accelerating liquid biopsy assay development."

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**JERRY LEE**
Associate Professor, University of Southern California
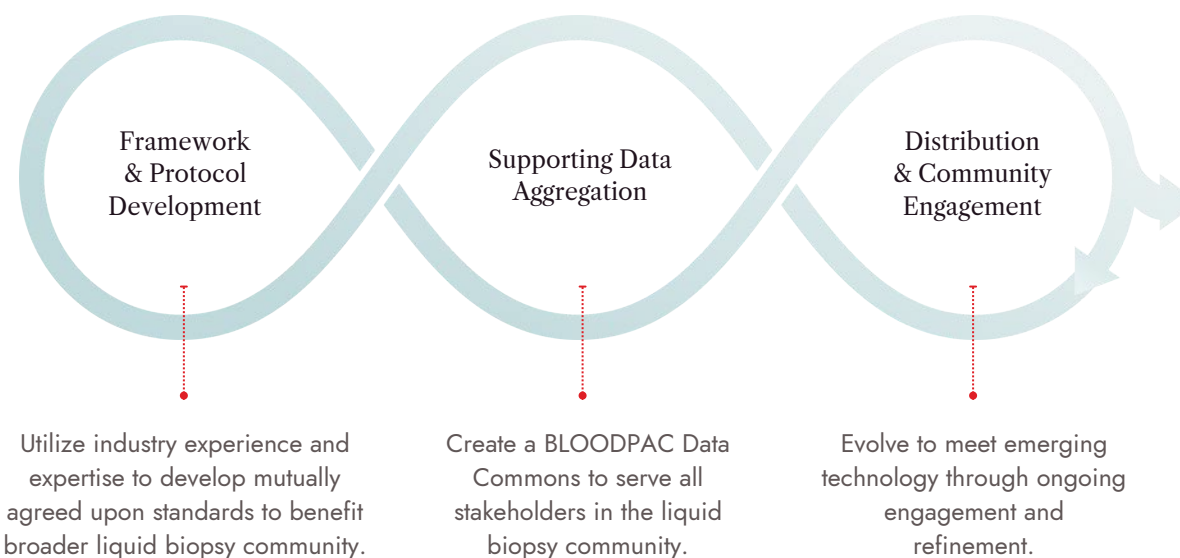and Chief Science and Innovation Officer, Ellison Institute

## A COLLABORATIVE INFRASTRUCTURE

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

# Reflecting on Five Years of Accomplishments & Mapping the Path Forward

CELEBRATING 10 YEARS
OF PROGRESS IN

2017     **5**     2022

BLOODPAC

In May 2022, BLOODPAC hosted its first-ever summit to provide stakeholders with an update on the state of the science in liquid biopsy and outline strategic objectives for the next five years.

BLOODPAC's executive director, Lauren C. Leiman, opened the conversation by discussing BLOODPAC's key accomplishments over the past five years that have helped move the industry forward, including establishing an open data commons, evaluating reference materials, and publishing consensus-driven standards for analytical validation and preanalytical minimum technical data elements.

Throughout the day, these accomplishments aided us in establishing the most pressing areas of interest and critical need for the liquid biopsy community.

"We're here to solve a problem that is not any one company's goal, but rather something that's necessary for society as a whole. All our members have made a commitment that we're in it together, because we believe in the need to advance the clinical utility of liquid biopsies for patients."

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

## *Molecular Residual Disease (MRD)*

Anne-Marie Martin, PhD, of GSK presented on the state of the science for using liquid biopsy to monitor for disease recurrence and treatment response, including standards development and the design of clinical trials. Anne also discussed a roadmap for BLOODPAC's 5-year goal of validating MRD as an early endpoint in solid tumors. The session featured guest speaker Erica Carpenter, MBA, PhD of the University of Pennsylvania who discussed the emerging data on liquid biopsy for MRD and the importance of validating approaches in interventional trials.

▶ **WATCH THE SESSION**

## Global Regulatory Landscape

Hakan Sakul, MD, of Pfizer, led a discussion highlighting the barriers to developing and harmonizing regulatory standards to accelerate global adoption of liquid biopsy. The discussion included a "fireside chat" with experts from the FDA, including Reena Philip, PhD, Director of the Division of Molecular Genetics and Pathology, OIR/CDRH and Julia Beaver, MD, Chief of Medical Oncology at the FDA's Oncology Center of Excellence, and moderated by Elaine Katrivanos of Tempus Labs, Inc. The panel discussed approaches for validating the role of liquid biopsy across the cancer care continuum, including MRD, cancer early detection, and treatment selection, as well as the opportunities to leverage the accessibility of liquid biopsy to support decentralized clinical trials.

▶ **WATCH THE SESSION**

"BLOODPAC has created a unique collaborative platform across liquid biopsy stakeholders, allowing BLOODPAC to create high-quality guidance on factors that influence performance of the technology. These documents provide valuable educational resources for all liquid biopsy developers, and help create efficiencies for the FDA by raising the quality and consistency of regulatory submissions."

**JULIE SCHNEIDER**
Associate Director for Research Strategy and Partnerships, Oncology Center of Excellence, FDA

> "The single biggest advantage of a liquid biopsy with respect to patient access is that it's so much easier to administer than traditional procedures. The integration of blood-based biopsies into cancer early detection will have a major impact on the adoption of such preventative measures."

**PHIL FEBBO, MD**
Senior Vice President & Chief Medical Officer, Illumina

## *Accessibility*

Phil Febbo, MD, of Illumina facilitated the discussion of challenges and opportunities in bringing liquid biopsy technologies into greater clinical use, especially as the COVID-19 pandemic delayed routine screening and highlighted pervasive health disparities. Although there is great potential for liquid biopsy to improve cancer care, addressing accessibility is key to ensuring liquid biopsy can reduce — not exacerbate — health disparities.

To re-focus on the big picture, Robert Dumanois from Thermo Fisher Scientific facilitated a discussion with cancer survivor AJ Patel and patient advocate Sandra M. Brown, MS, LCGC, of Providence St. Joseph Health. Together, they discussed the complexities that patients face in obtaining a diagnosis and treatment, including the accessibility of the information shared with patients.

**▶ WATCH THE SESSION**

# BLOODPAC Working Groups

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

## 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. The working group just published a report sharing the results of this analytical study—the full publication can be found here.

## MOLECULAR RESIDUAL DISEASE (MRD) STRATEGIC STEERING
*Co-Chairs: Andy Hadd (Natera) & Angela Silvestro (GSK)*

TThe 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 three subgroups — MRD Clinical Validation, 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.

### MRD CLINICAL VALIDATION
*Carol Pena (Merck) & Asaf Zviran (C2i Genomics)*

This newly created group is working on mapping the path forward for clinical validation and utility of ctDNA-based molecular residual disease (MRD). The group has begun by defining the specific clinical applications of MRD testing across the patient journey, with a focus on clinical study design elements needed to validate these use cases. Following a comprehensive review of the state of the field the group will initially choose one application on which to focus, with others to follow in future steps. This process will yield a comprehensive overview of the MRD landscape, potential applications, and guidelines to achieve clinical validation. Following FDA feedback, these insights will be captured in a white paper publication with the aim of accelerating adoption of MRD testing as a key element for optimizing patient management.

## 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.

### MOLECULAR RESIDUAL DISEASE/EARLY DETECTION AND SCREENING RDE
*Duane Hassane (Tempus) & Greg Jones (Inivata)*
The molecular residual disease and early detection & screening (MDS/EDS) RDE working group is applying the lens of MRD and EDS testing to BLOODPAC's existing work on minimal technical data elements (MTDEs) for liquid biopsy data reporting. This team is first developing a list of MRD- and EDS-specific pre-analytical MTDEs, and will next work on assembling analytical, patient and clinical variables. The MRD/EDS RDE working group is closely aligned with the umbrella MRD and EDS working groups and their lexicon projects, to ensure that a controlled vocabulary is used throughout the publications that result from these efforts.

### PRE-ANALYTICAL VARIABLE
*Philip Febbo (Illumina), Anne-Marie Martin (GSK), & Howard Scher (Memorial Sloan Kettering Cancer Center)*
The initial completed project for the Pre-Analytical Variable working group was the development of 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. The publication can be found here.

### 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

*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

### ACCESSIBILITY
*Chair: Phil Febbo (Illumina)*
The focus of the Accessibility working group is to identify key barriers to clinical use and equitable access to liquid biopsy tests, address disparities, and democratize the use of this technology. The working group is currently finishing a report on accessibility challenges and proposed solutions, and will next work on developing educational content for providers and patients on liquid biopsy technology and clinical applications, for dissemination by member organizations. Ultimately, the aim of this group is to ensure that the next decade will bring utilization of this novel precision medicine technology to improve outcomes in all communities.

### GLOBAL REGULATORY
*Co-Chairs: Jennifer Dickey (PGDx), Elaine Katrivanos (Tempus) & Hakan Sakul (Pfizer)*
The Global Regulatory working group was founded to address the opportunity for international regulatory standards for diagnostic testing with liquid biopsy. The goal of the group is to facilitate the harmonization of guidelines and expectations for review of liquid biopsy technologies to enable rapid regulatory approval for patient benefit. In the short term, members are working to establish a global regulatory partnership and obtain input on current BLOODPAC deliverables. In the long term, the working group will facilitate the development of additional deliverables with input from global regulatory agencies.

### 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.

*02* | *Impact*

"The end result of innovation isn't an idea, but rather bringing that idea into reality, ensuring it works as intended and putting it into the hands of patients and clinicians. Liquid biopsy technology is innovative and complex, making collaboration essential in establishing acceptable standards for validation and demonstrating accuracy and precision. The journey from a test that works in the laboratory to a test that is validated and accessible to patients in clinical settings is the long last mile that BLOODPAC is helping to cross."

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

# Accelerating Progress

## 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.

Prostate Cancer Foundation
Curing Together.

BCRF
BREAST CANCER RESEARCH FOUNDATION

## PUBLICATIONS & FRAMEWORKS

*2022* ● **BLOODPAC: COLLABORATING TO CHART A PATH TOWARDS BLOOD-BASED SCREENING FOR EARLY CANCER DETECTION**

*Clinical and Translational Science*

In this publication, BLOODPAC members chart both the opportunities and challenges ahead for the clinical use of blood-based tests for screening and early detection in cancer.

● **CREATING STANDARDS FOR LIQUID BIOPSIES: THE BLOODPAC EXPERIENCE**

*Expert Review of Molecular Diagnostics*

A summary of BLOODPAC's work creating MTDEs and analytical validation protocols to date, and a look to next steps in these efforts.

*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.

*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.

● **MINIMUM TECHNICAL DATA ELEMENTS FOR LIQUID BIOPSY DATA SUBMITTED TO PUBLIC DATABASES**

*Clinical Pharmacology and Therapeutics*

This publication captures a list of pre-analytical Minimal Technical Data Elements (MTDEs) suggested for liquid biopsy data collection to ensure that data can be accurately evaluated and analyzed.

*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.

# 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 focus of the subgroup is to generate comment letters on topics related to the use of liquid biopsy in the clinical setting. This includes public comments on CMS topics, including NCDs and LCDs, commercial payer medical policy issues, professional guidelines, and other ad hoc topics identified by the reimbursement working group. Examples of recent correspondence may be seen here.
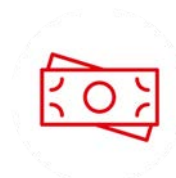
### RISK HOLDER ENGAGEMENT
*Suzanne Belinson (Tempus)*
This subgroup aims to educate payers, laboratory benefit managers and other risk holders on the evidence-based clinical utility, economic value and patient benefit of liquid biopsy. Working collaboratively with risk holders to align incentives and develop evidence frameworks is also primary to the mission of this group.
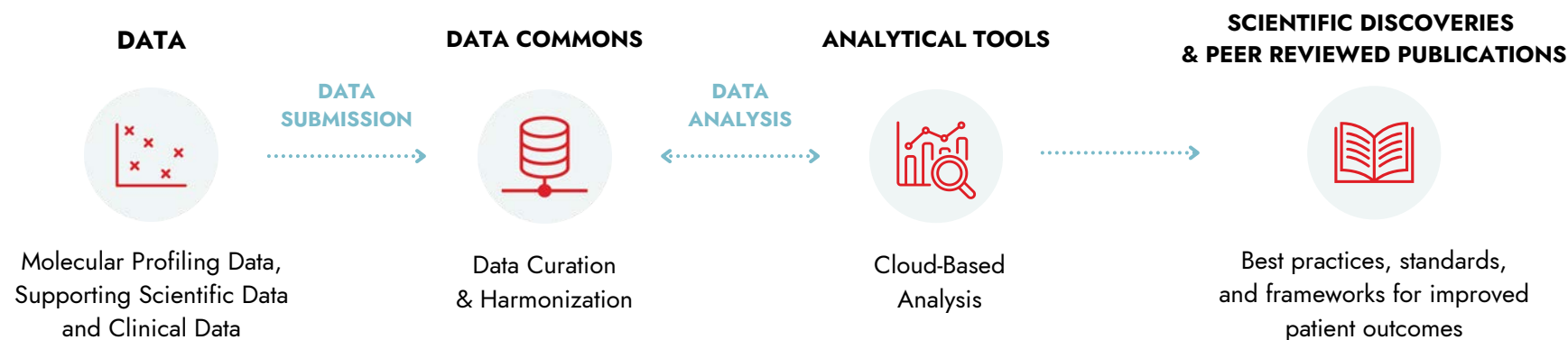
# BLOODPAC Data Commons

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.

| DATA | | DATA COMMONS | | ANALYTICAL TOOLS | | SCIENTIFIC DISCOVERIES & PEER REVIEWED PUBLICATIONS |
|---|---|---|---|---|---|---|
| | DATA SUBMISSION | | DATA ANALYSIS | | | |

Molecular Profiling Data, Supporting Scientific Data and Clinical Data

Data Curation & Harmonization

Cloud-Based Analysis

Best practices, standards, and frameworks for improved patient outcomes
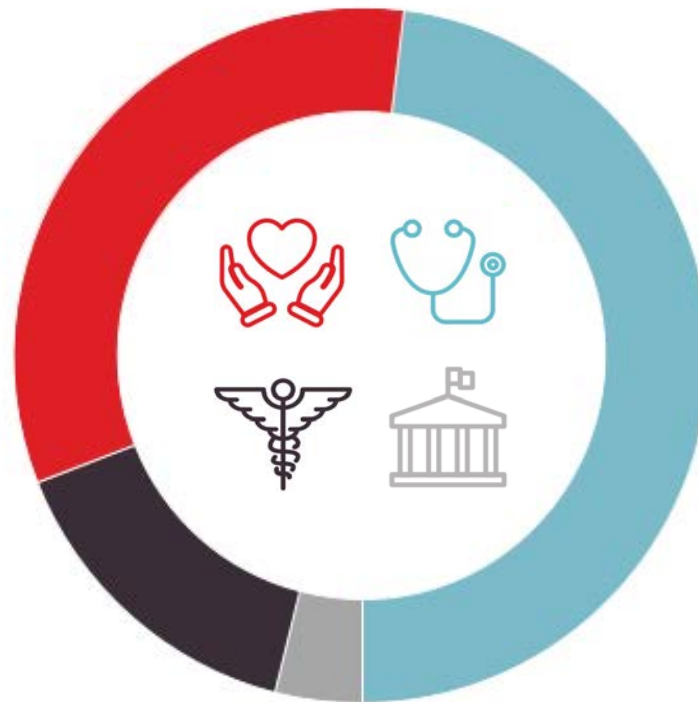
## MEMBERS

Adela, Inc.
American Cancer Society (ACS)
Arkansas Bioinformation Consortium
   (AR-BIC)
Association for Molecular Pathology (AMP)
AstraZeneca
Bio-Rad
Breast Cancer Research Foundation (BCRF)
Bristol Myers Squibb
C2i Genomics
Center for Genetic Medicine Research at
   Children's National Medical Center
   (CNMC)
Center for Translational Data Science
   at the University of Chicago
Ceres Nanosciences
CVS/Aetna
Daiichi Sankyo
Delfi Diagnostics
Eli Lilly and Company
Exact Sciences
Focused Ultrasound Foundation
Foundation Medicine, Inc.
Freenome
Friends of Cancer Research (FOCR)
GRAIL
Guardant Health
GSK
Horizon Discovery Ltd.
Illumina, Inc.
Inivata
LGC / SeraCare
LUNGevity Foundation

Memorial Sloan Kettering Cancer Center
   (MSKCC)
Merck
Movember Foundation
Natera
National Cancer Institute at the National
Institutes of Health (NCI/NIH)
National Cancer Institute / Cancer
Biomarkers Research Group
Novartis
OncoRNALab Ghent University
Open Commons Consortium (OCC)
PreAnalytiX
Personal Genome Diagnostics (PGDx)
Personalis
Pfizer, Inc.
Prevent Cancer Foundation
Prostate Cancer Foundation
Quest Diagnostics
SiO2 Materials Science
Streck
Sysmex Inostics
Tempus
The Prostate Cancer Clinical Trials
Consortium (PCCTC)
Thermo Fisher Scientific
U.S. Department of Veterans Affairs
University of Southern California
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

03

Leadership &
Financials

"They say the whole is greater than the sum of its parts, and that is absolutely true of the BLOODPAC consortium. When all the key stakeholders come together, the speed, efficiency, consistency, and quality that comes out of what we do will speak for itself. And who benefits? The patient, and that's all that matters."

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**STELLA SOMIARI**
Senior Director,
Windber Research Institute

# 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*

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*Oncologist and Head of the Biomarker Development Initiative
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## BLOODPAC DATA COMMONS TEAM

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*Professor, University of Chicago CTDS & Founder/Director, Open
Commons Consortium*

**PLAMEN MARTINOV**
*Chief Information Security Officer, Open Commons Consortium*

**GINGER RIESSEN, CPA**
*Accountant, BLOODPAC*

**DENISE PRIOR**
*Head of Communiations, BLOODPAC*

**LAURA TRAMONTOZZI**
*Brand & Design, BLOODPAC*

# FINANCIALS

## STATEMENT OF FINANCIAL POSITION

| ASSETS | 2022 | 2021 | 2020 |
|---|---|---|---|
| Cash & cash equivalents | 2,592,677 | $1,826,213 | $1,584,963 |
| Membership fees recievable | 12,000 | $162,000 | $12,000 |
| Due from program | 74,926 | - | - |
| **TOTAL ASSETS** | **2,679,603** | **$1,988,213** | **$1,596,963** |

| LIABILITIES | | | |
|---|---|---|---|
| Deferred membership fees | 418,000 | $485,000 | $586,000 |
| Accrued payroll | 22,205 | $10,450 | - |
| Due to Programs | - | $25,454 | $59,393 |
| **TOTAL LIABILITIES** | **440,205** | **$520,904** | **$645,393** |

| NET ASSETS | | | |
|---|---|---|---|
| Without donor restrictions | 2,239,398 | $1,467,309 | $951,570 |
| **TOTAL NET ASSETS** | **2,239,398** | **$1,467,309** | **$951,570** |

| TOTAL LIABILITIES & NET ASSETS | 2,679,603 | $1,988,213 | $1,596,963 |
|---|---|---|---|

## STATEMENT OF ACTIVITIES

| REVENUE | 2022 | 2021 | 2020 |
|---|---|---|---|
| Membership dues | 1,526,000 | $1,142,250 | $811,250 |
| **TOTAL REVENUES** | **1,526,000** | **$1,142,250** | **$811,250** |

| EXPENSES | | | |
|---|---|---|---|
| Program Services | 632,027 | $545,586 | $413,163 |
| Management & General | 121,884 | $80,925 | $104,716 |
| **TOTAL EXPENSES** | **753,911** | **$626,511** | **$517,879** |
| **CHANGE IN NET ASSETS** | **772,089** | **$515,739** | **$293,371** |

| NET ASSETS | | | |
|---|---|---|---|
| Beginning of year | 1,467,309 | $951,570 | $658,199 |
| **END OF YEAR** | **2,239,398** | **$1,467,309** | **$951,570** |

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