NBDA CONVERGENCE CONFERENCE I

"Converging on Biospecimen Standards For Genomics"

DECEMBER 8TH & 9TH 2014

THE OMNI SCOTTSDALE RESORT & SPA AT MONTELUCIA

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NBDA
National Biomarker Development Alliance

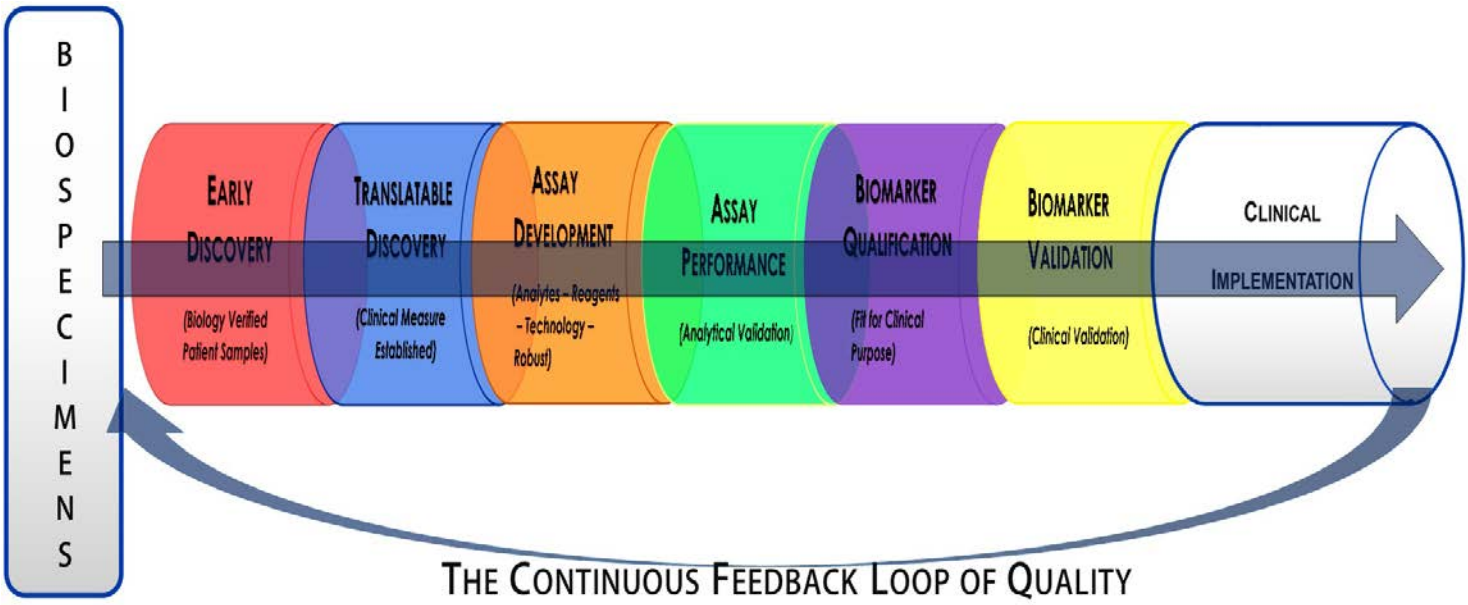
NBDA Convergence Conference I

December 8-9, 2014

"Converging on Biospecimen Standards for Genomics"

BIOSPECIMEN QUALITY CHALLENGES IN GENOMICS

WELCOME



Welcome to National Biomarker Development Alliance's Consensus Conference on Genomics!

The National Biomarker Development Alliance (NBDA) exists to define, deconstruct and actively address the issues that contribute to the widespread failure of biomarker development that plagues biomedical research, medical product development, and the practice of precision medicine. To that end, the NBDA has been conducting a series of multidisciplinary, multi-stakeholder workshops ("think tanks") including thought leaders from across the country and around the world that have set the stage for strategic action grounded in a deep understanding of the issues.

This unique event represents the first of NBDA's "do tanks". It is a bold step forward to directly address the quality requirements for human biospecimens that are destined for genomic analysis by next generation sequencing (NGS) technologies and define a plan to assure that those requirements are met for all relevant patient samples.

Next generation sequencing technologies and the data generated from them are now widely used in discovery and translational biomedical science and are moving rapidly to clinical application. The power of sequencing technology to analyze DNA and RNA species is proving transformative, but challenges remain in defining the technical and medical standards that are needed to produce accurate, consistent, and clinically meaningful results for both research and patient care.

We are here today to focus on the essential quality standards for the starting materials for these analyses: human biospecimens. Our goal is to define the essential performance standards for the assurance of requisite biospecimen quality and move toward implementation of those performance standards across the biomedical community. The ultimate aim is to eliminate, to the greatest degree possible, the "garbage in" paradigm from NGS analysis of patient biospecimens.

We expect the results of this conference to be nothing short of historic in proportion. We propose to come to consensus on the most significant quality-compromising procedures ("pre-analytical variables") related to biospecimen acquisition, handling and stabilization. We propose to identify performance metrics that would have the greatest positive impact on biospecimen quality for the least expense and effort (the "biggest bang for the buck"). Lastly, we further propose to define and carry out an implementation strategy, supported by all stakeholders, to assure that those metrics are widely met. If successful, we will move from the current reality of uncontrolled, undefined levels of molecular quality for tissue or blood samples destined for NGS analysis to a new reality in which all patient samples are of known quality and "fit" for that purpose.

The NBDA team thanks you for being part of this disruptive transformation.

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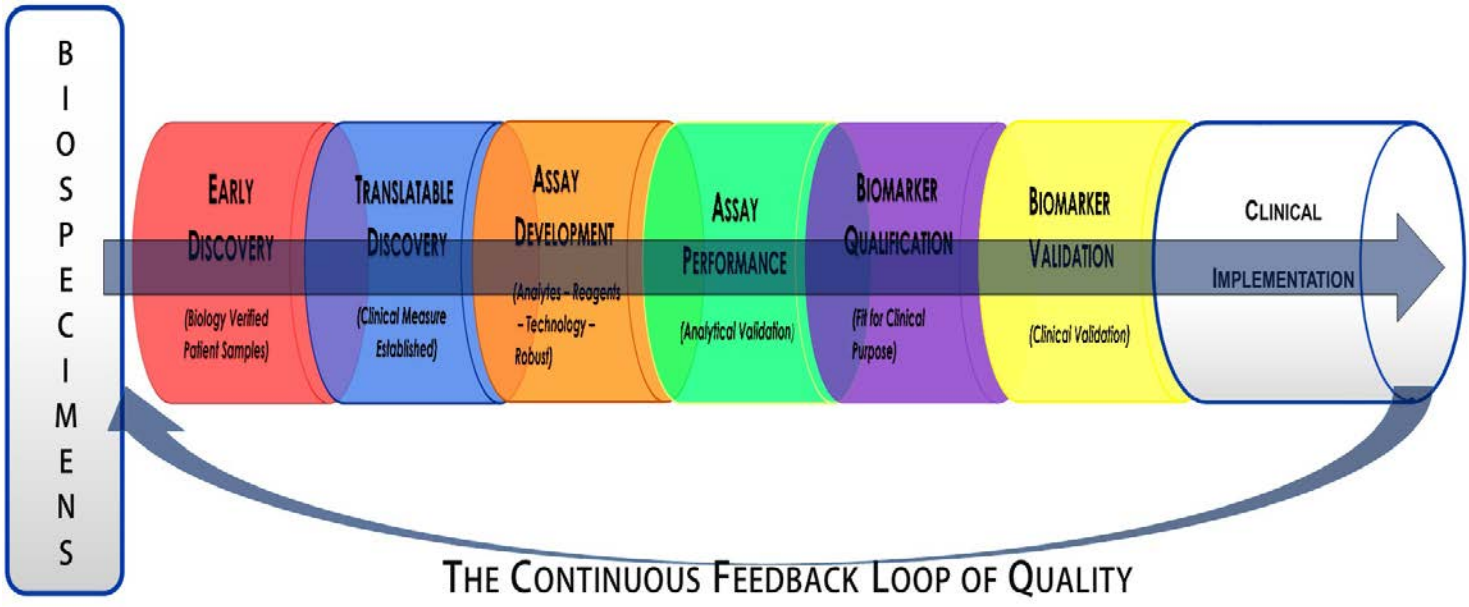
AGENDA



NBDA
National Biomarker Development Alliance

Converging on Biospecimen Standards for Genomics

Convergence Conference I Convened by the National Biomarker Development Alliance

Montelucia Resort, Scottsdale, AZ
Meeting Room: Alhambra

December 8-9, 2014

Agenda

Meeting Co-Chairs: **Carolyn Compton, MD, PhD**
NBDA, Arizona State University and Mayo Clinic
Anna D. Barker, PhD, NBDA and Arizona State University

Ken Bloom, MD, GE Healthcare, Clarient Laboratories

Facilitation: **Robert Mittman, MS, MPP,** Director, Biomedical Strategy and Knowledge Development, Complex Adaptive Systems; Professor of Practice, Ira A. Fulton Schools of Engineering, Arizona State University

Conference Objective

To develop a strategy and action plan to mitigate and, if possible, eliminate major causes of quality compromise in tissue and blood biospecimens for genomic analysis

Outcomes

- Identify and reach agreement on a small but meaningful set of *quality-compromising pre-analytic variables* in the collection and processing of tissue and blood biospecimens for analysis using next-generation sequencing technology platforms.
- Identify and reach agreement on *target performance measures* of those quality-compromising pre-analytic variables and *documentation standards of actual performance* in biospecimen collection and processing.
- Identify and reach agreement on individual and collective strategies for implementing those target performance measures and standards for documenting performance as widely as possible.

Agenda

Monday, December 8, 2014

7:30 – 8:20 AM	**Breakfast – Alhambra Foyer**
8:30 – 9:30 AM	**Welcome and Introductions** **Carolyn Compton, MD, PhD,** **Ken Bloom, MD,** **Robert Mittman, MS, MPP** • Introduction to the NBDA and rationale for meeting • Meeting description • Participant introductions
9:30 – 9:50 AM	**Biospecimens, Biomarkers and Genomics—What's the Issue and Why Does it Matter?** **Carolyn Compton, MD, PhD**
9:50 – 10:00 AM	**The Importance of the Issue to ASCO** **Richard Schilsky, MD** CMO, ASCO Via Skype **The Importance of the Issue to the FDA** **Janet Woodcock, MD** Director, Center for Drug Evaluation and Research Via Mendelspod Podcast
10:00 – 10:20 AM	**Break**
10:20 - 10:50 AM	**Genomic Analysis Technologies—Requirements and Limitations** **Ken Bloom, MD, FCAP**
10:50 AM 12:00 PM	**Specimen Acquisition and Handling - The Practical Reality of the Biospecimen Lifecycle in Clinical Medicine** **Roundtable Discussion:** • **Ed Staren, MD – surgical procedures and operating room logistics** • **James Robb, MD – acquisition, handling and stabilization** • **Scott Jewell, PhD – acquisition, handling and stabilization** • **Jan Nowak, MD – blood acquisition and processing** • **Richard Friedberg, MD, PhD – intra- and inter-institutional procedural and logistical variation**

A roundtable and large group discussion on the personnel, clinical practices and logistics that contribute to the life cycle of the biospecimen during the pre-analytical phase (preceding specimen analysis) –focus on the perspective of potential variation introduced by each and potential impact on the molecular quality and/or composition of the biospecimen. What happens in the biospecimen lifecycle? What range of variation occurs? What standards are in place to control, monitor or record variation? Who is responsible for specimen custodianship? What are the gaps? How do the logistics, work flows, and systems in patient care institutions contribute to the variation? What variables contribute most to compromising quality?

12:00 – 1:00 PM **Lunch – Alhambra Patio**

1:00 – 2:00 PM **The Impact of Collection Variation on Analytic Results**
Roundtable Discussion:

- **Peter Kuhn, PhD**
- **Andrew Brooks, PhD**
- **Fraser Symmans, MD**
- **Katherine Call, PhD**
- **Joe Vockley, PhD**

A roundtable and large group discussion on how pre-analytical variation in general and specific pre-analytical steps in particular, affect the "fitness" of the specimen for the purpose of NGS sequencing. Both DNA and RNA will be considered. Both tissue and blood specimens will be considered. What analytes are most affected by pre-analytical variation? How? What variables are "deal breakers" (preclude analysis altogether) for analysis on NGS platforms? What variables compromise the quality and validity of the sequencing data? What is being done right now about these issues? Can pre-analytical quality compromise be compensated for by technical or bioinformatics means? What are the limitations to this? What variables contribute most to compromising quality?

2:00 – 2:50 PM **Brainstorm: Quality-Compromising Pre-Analytic Variables**

2:50 PM **Break**

3:10- 4:10 PM **Lessons Learned—Experience from the Field**
Roundtable Discussion:

- **Carrie Browning, MS – NGS platform manufacturer/developer**
- **Bob Penny, MD, PhD – academic team science/TCGA**
- **Diane Fahri, MD – CROs and industry clinical trials**
- **Andreas Jeromin, PhD – diagnostics industry**
- **Yun-Fu Hu, PhD – FDA**

	Roundtable and large group discussion representing a range of stakeholders with a dependency on biospecimen quality, will discuss how pre-analytical variation and consequent specimen quality variation affects their data, products and goals. What are the issues and challenges? What lessons have you learned in addressing them? What were the wins and losses? What were the costs, financial and otherwise? Argue for the importance of the quality-compromising variables.
4:10 – 4:40 PM	**Prioritization of Quality-Compromising Pre-Analytic Variables** Facilitated group discussion and voting: most important and most fixable quality-compromising variables
4:40 – 5:20 PM	**Implementation On the Ground** Facilitated group discussion: performance metrics needed to address variables above and challenges to implementation
5:20 PM	**Preview of Day Two**
5:30 PM	**Adjourn for the Day**
6:00 PM	**Reception – Cortijo Plaza**
6:30 PM	**Dinner - Castillo Lucena**

AGENDA

Tuesday, December 9

7:30 AM **Breakfast – Alhambra Foyer**

8:00 – 8:30 AM **Recap and Recalibrate**

8:30 – 8:45 AM **Framing the Working Sessions**

- Tissue performance metrics
- Tissue implementation issues
- Blood performance metrics
- Blood implementation issues

8:45 – 10:15 AM **Working Sessions Convene**

- **Performance issues groups**

For each high-priority pre-analytic variable, what is the recommended performance measure? Why? What is the recommended approach to documenting performance? What other annotation is required? Recommended? What information is available to help guide NGS analysis as a function of variation in performance (nomograms)? If that information is not available, what research is needed to develop it? Where should that research take place?

- **Implementation issues group**

What will it take to achieve compliance and reimbursement? Who's involved and what are their roles in the solution? What are their priorities? What are the side benefits (or damages) for the stakeholders? Consider government researchers, regulators, industry, medicine/surgery, pathology, payers, research funders, journal editors, patients, others.

10:15 – 11:45 AM **Convergence Session Convenes**

Each group has 10 minutes to deliver its convergent pitch on what they recommend and why and what we can do. Group discussion follows.

11:45 – 12:20 AM **Closing Session—Next Steps**

12:20 PM **Wrap-Up**

12:30 PM **Lunch – Alhambra Patio**

1:00 PM **Adjourn**

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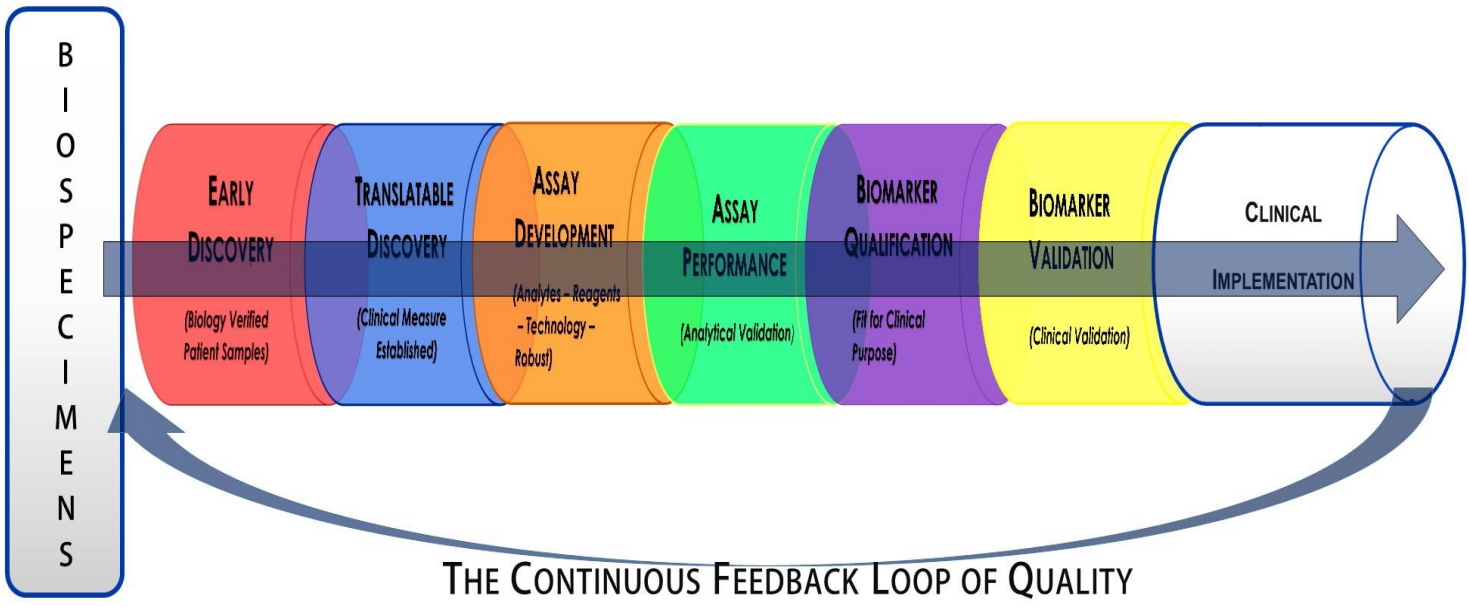
ABOUT THE NBDA



Fact Sheet

NBDA National Biomarker Development Alliance

Collaboratively creating standards for end-to-end evidence-based biomarker development—to advance precision medicine

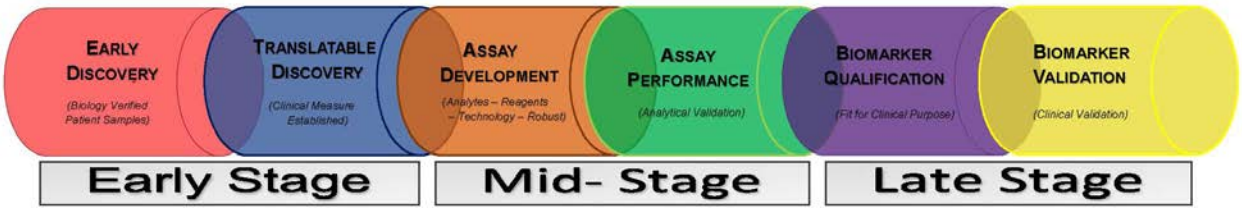
THE PROBLEM: We are living in a remarkable time. U.S. health care costs are projected to increase to an unsustainable $4.4 trillion (19.8% of the U.S. gross GDP) by 2020 (Centers for Medicare & Medicaid Services), yet much heralded molecularly based medicine, also known as precision or personalized medicine, represents a potentially transformative approach to disease diagnosis, treatment, and prevention that promises to significantly reduce these costs. So, what's the problem? Biomarkers, measurable and reproducible specific indicators (signals) of normal or disease-related processes (or pharmacological responses to therapy), are critical to enable this transformation. There is no shortage of biomarkers today—more than 150,000 reported as "discovered" by 2012 alone—yet the FDA has approved less than 1.5 per protein biomarkers per year since the early 1990s and less than 100 biomarkers are routinely used in the clinic. Currently biomarker development is expensive, unpredictable, and fraught with failure. There is currently no predictable, reliable, evidence-based system for end-to-end biomarker development. This is a daunting challenge, but one that must be met. Otherwise, biomarkers will continue to fail, targeted therapeutics development will continue to be high risk and uncertain, the molecular diagnostics industry will remain an unattractive target for investors, and, most importantly, patients will fail to benefit from the promise of precision medicine.

THE NBDA: The NBDA is an independent nonprofit (within the new Research Collaboratory at ASU) that is dedicated to meeting this challenge. Through trans-sector networks, the NBDA will create "standards" (inclusive of best practices, guidelines, standard operating procedures, etc.) to support new models of end-to-end biomarker development. The Alliance will integrate existing knowledge, and/or create new knowledge where needed, and make its data, processes, and standards publicly available. The NBDA was founded on the principle that de-convoluting the complexity of transitioning biomarkers from discovery through development and delivery to patients is ultimately achievable. Moreover, this collaborative knowledge network model must become a "movement" engaging the entire health care ecosystem if the vision for precision medicine is to become reality for all patients.

STATUS OF THE NBDA: The NBDA began as a question! "Could networks of organizations and individuals who will benefit from the successful development of biomarkers unite through a unique management construct to solve what has heretofore been an "unsolvable" problem?" Over the last 18 months the initial question has catalyzed the emergence of the NBDA; an organization committed to answering this question in the affirmative. Funded by ASU, the ASU Foundation, and Virginia G. Piper Charitable Trust and others that have provided planning and/or financial support, the NBDA has matured from concept to reality. Subsequently informed by several workshops involving large numbers of trans-sector groups of experts from across the biomarker discovery, development, and delivery continuum, inclusive of the FDA and the affected industries, the NBDA has achieved significant progress. Moreover, *the NBDA was developed not just to relegate the current biomarker development processes to history, but also to serve as a working example of what convergence of purpose, scientific knowledge, and collaboration can accomplish.*

THE NBDA FOCUS AND FUTURE PLANS: Over the past two years, the NBDA leadership and management team has undertaken an unprecedented in-depth analysis of the barriers that exist in advancing biomarkers from initial discovery to successful delivery. Through this analysis, it has become clear that biomarker development occurs in overlapping but discrete "modules" – all of

which, represent decisions and investment points. These "modules" are captured in the figure below. Biomarker failure begins in discovery, where the field suffers from a lack of reproducibility due to factors ranging from poor and/or insufficient numbers of samples to a lack of technology standards to flawed design and inadequate analytics. In reality, only a small number of biomarkers are sufficiently robust and effective that they should ever advance beyond the discovery stage. Unfortunately, today there are thousands of putative protein biomarkers that move well beyond discovery - at great cost - and fail late in the development process. Given the investment needed to advance biomarkers beyond discovery, each phase is similarly limited by barriers that can only be solved by acceptance and use of standards in end-to-end models.



The NBDA's Biomarker Research and Development (R&D) Modules

Working with trans-sector teams, the NBDA has already undertaken the design of demonstration projects for major classes of biomarkers including genomic, proteomic, imaging, and complex biomarkers. Led and managed by the NBDA, collaborating partners, such as the ISPY-2 team, M.D. Anderson, ASU's Biodesign Institute, and others will work through virtual teams to reach consensus on existing standards, create new ones, and/or develop "ideal" development pathways for emerging biomarkers such as next-gen sequencing profiles. The NBDA will also undertake efforts to create and/or assemble unique resources to serve the biomarker communities including a national biomarker-focused biorepository; a network to reproduce selected biomarker results; and a common biomarker database. As part of its mission, the NBDA will provide education initiatives for the research, provider, and advocacy communities. As part of its mission, the NBDA will provide education initiatives for the research, provider and advocacy communities. These latter activities will be performed in partnership with Arizona State University and other organizations that are dedicated to educating the industry and the public on the use of patient's molecular profiles in precision medicine - and on the value of diagnostics. We are well underway, and will begin publishing our findings, standards, and recommendations as soon as they are finalized.

BECOME PART OF THE SOLUTION: ALIGN WITH THE NBDA: Join us to move beyond silos - to shift from a culture of acceptance of biomarker failure to one of transparent, predictable end-to-end processes based on scientifically robust processes that the FDA will welcome and patients will embrace. Become a partner or collaborator in one of NBDA's networks. The NBDA needs financial resources, and we welcome investment from membership, philanthropy and support for national resources and/or special projects. Since NBDA will achieve solutions to shared problems through networks of stakeholders, we also need expertise and experienced collaborators to join our teams; participate in consensus conferences; and engage in NBDA's educational initiatives. To request more information about the NBDA, email or call us as detailed in the box below. We look forward to working with you and to a future where biomarker-based precision medicine is available to all those in need.

MANAGEMENT TEAM:
Anna D. Barker, Ph.D., President and Director
George Poste, D.V.M., Ph.D., Interim Chief Science Officer
Carolyn Compton, M.D., Ph.D., Chief Medical Officer
Kenneth Buetow, Ph.D., Director, Bioinformatics & Data Management
Anne Marie Geary, Director, Events and Administration

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National Biomarker Development Alliance (NBDA)

Collaboratively creating the standards for end-to-end, evidence-based biomarker development processes

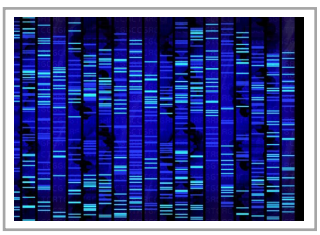
... to advance personalized medicine

NBDA National Biomarker Development Alliance

The National Biomarker Development Alliance

Current State of U.S. Health Care

U.S. health care costs are projected to increase from $2.7 trillion (2011) to $4.4 trillion (nearly 20 percent of the U.S. GDP) by 2020 (Centers for Medicare & Medicaid Services). The current "illness-focused" model of treating what is often late-stage disease is not sustainable. Due primarily to an aging population, the estimated economic burden of major diseases such as cancer ($280 billion in 2012[1]), Alzheimer's disease ($230 billion in 2013[2]), diabetes ($245 billion in 2012[3]), and cardiovascular disease ($312 billion in 2012[4]) are projected to increase significantly in the coming decade and beyond. This emerging reality could prove catastrophic to the U.S. economy. Biomarkers represent a real and achievable strategy to address this looming crisis by improving the accuracy of diagnosis, disease staging, and rationalization of treatment selection.



Biomarkers

Biomarkers are essentially biological signals. They are specific reproducible and measurable changes in disease-related (or normal) processes, or responses to therapy. Biomarkers take many forms, from physical representations (e.g., imaging) to biochemical measurements of changes in genes or proteins, or more complex changes in molecular pathways, referred to as "biosignatures."

Precision Medicine

The completion of the human genome project established the basis for sequencing an individual's genome. Today, 21st century genome sequencing is advancing rapidly to define genomic changes in most diseases. It is estimated that more than 1 million human genomes will be sequenced globally by the end of 2014,[5] with exponential future growth projected. The "biological signals" or biomarkers that represent these changes in genes, RNA, proteins, etc. are the foundation for molecularly based, precision medicine. These molecular alterations drive complex functional changes, and what were historically treated as single diseases are increasingly recognized as a number of different molecular subtypes. Precision medicine describes a new generation of biomarker-driven interventions—diagnostics, therapeutics, and preventives—specifically targeted to these molecular subtypes in a patient.

Biomarkers and Precision Medicine

The successful development of biomarkers is a prerequisite for, and the key to achieving, the promise of precision medicine for most diseases. Beyond disease diagnosis, treatment, and prevention, certain types of biomarkers can support disease prognosis, assignment to clinical trials, monitoring therapeutic response, disease risk prediction, and drug development.

The Biomarker Problem(s)

Although biomarker-driven precision medicine is a potentially transformative strategy, the development of validated biomarkers is unpredictable and currently fraught with failure. Despite advances in genomics, proteomics, and the molecular sciences, FDA approval of new protein biomarkers has been essentially the same since the early 1990s: less than 1.5 per year despite more than 1,500 submissions. Today, fewer than 100 biomarkers are routinely used in clinical practice. Moreover, the development of a new drug can take up to two decades and cost a billion dollars or more. While biomarkers are a key strategy for addressing many of these problems and advancing precision medicine, the field is plagued with a lack of rigor, problems of data reproducibility, and myriad other issues. Add to these obstacles the recent entry of advanced technologies such as whole-genome sequencing and a flood of non-FDA regulated laboratory developed tests, plus consumer genomes, and the problem seems almost irreducibly complex. However, one fact is clear: The most critical barrier, and ultimately the reason for failure of most biomarkers, is the lack of broadly accepted and applied standards-based, predictable, end-to-end systems for biomarker development. Solving this problem is the core of the NBDA mission.

> The NBDA was developed not just to relegate the current biomarker development processes to history, but also to serve as a working example of what convergence of purpose, scientific knowledge, and collaboration can accomplish.

The NBDA Is a "Big Idea"

The NBDA is a new nonprofit dedicated to assembling and/or creating the best practices, guidelines, standard operating procedures, etc. (NBDA standards) needed to advance biomarkers through each stage of biomarker development and make the information and knowledge publicly available.

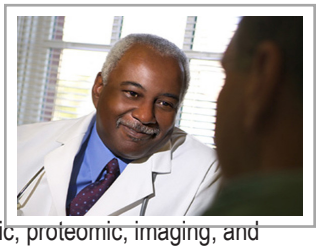
The NBDA Model

Led by an experienced management team, the NBDA will work through networks of stakeholders from all sectors to integrate expertise and knowledge to address and remove barriers identified as critical for each module of biomarker development. Solutions will be in the form of evidence-based standards assembled and/or created through workshops, consensus conferences and transparent collaborative demonstration projects, and/or new research. The results will be available through the NBDA website, publications, tutorials, whitepapers, and public meetings. All of the NBDA's findings and recommended standards will be made available to the FDA and international regulators to inform current policy as appropriate. NBDA's goal is ultimately the implementation of predictable, transparent regulatory biomarker pathways.

Status of the NBDA

The NBDA concept has been nearly two years in development. To identify and understand specific barriers in biomarker development from discovery through translation into clinical trials and ultimately clinical practice, the NBDA sought expert planning input and analysis from local organizations including Arizona State University and others, as well as groups of experts working across all relevant sectors nationwide.

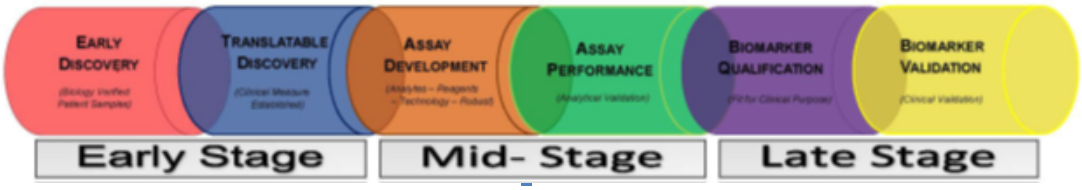
Specifically, during the past year the NBDA brought together experts in think tanks and workshops to define a rational NBDA biomarker development concept(see below) and identify major barriers that negatively impact progress in each of the individual phases, or modules. In collaboration with these experts, the NBDA has analyzed each of the biomarker development modules and organized its initial work around four classes of biomarkers: genomic, proteomic, imaging, and complex or multicomponent biosignatures. Going forward, the NBDA will assemble and/or collaboratively create standards for biomarker discovery and development based on the clinical question, sample size and quality, technology platform standards, experimental/clinical trials design, data quality, and analysis. Four demonstration projects, representing the targeted biomarker classes, are in late-stage planning and will be launched in 2014.



> The audacious goal of the NBDA in the future is to grant a "seal of excellence" for compliant biomarkers and biomarker developers.

Become an NBDA Partner/Collaborator

The NBDA faces a daunting challenge, but one that can and must be met. Failure will mean the fate of biomarker development and late-stage clinical trials will continue to be uncertain, the molecular diagnostics industry will remain an unattractive target for investors, and precision medicine will remain a theoretical ideal, but a largely unattainable vision for most patients. The NBDA illustrates the power of assembling and building knowledge through collaborative networks. Addressing this problem is not the FDA's responsibility. It falls to all of the stakeholders to solve. Contact us to become an NBDA Partner, Collaborator, and/or Supporter. Invest in the NBDA. Share knowledge, sponsor meetings—contribute as appropriate to your interests.



The NBDA's Biomarker Research and Development (R&D) Modules

[1]National Cancer Institute; [2]Alzheimer's Association; [3]American Diabetes Association; [4]American Heart Association; [5]National Human Genome Research Institute

The NBDA Leadership/Management Team

The NBDA team brings unprecedented experience and expertise in all aspects of biomarker discovery, development, regulatory science, and commercialization to achieve its mission. The team has deep experience in major large-scale scientific initiatives, biospecimen and biorepository research and development, bioinformatics and computational modeling, drug and diagnostics development, advanced technologies, and executive leadership. The management construct will operate at scale by building knowledge networks of experts from the full spectrum of biomarker communities. NBDA governance includes steering and scientific advisory committees and a local advisory council.

Contact the NBDA:

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Anna D. Barker, Ph.D., director and president, works with the NBDA leadership team, external experts, and stakeholders to define the scope of targeted projects and programs for the alliance. She was formerly deputy director of the National Cancer Institute and served as founding co-chair of the NCI-FDA Interagency Task Force and founding co-chair of the Cancer Steering Committee of the FNIH Biomarkers Consortium. Prior to the NCI she served as a senior scientist and executive at Battelle Memorial Institute and subsequently co-founded a public biotechnology company engaged in biomarker development. She is co-director of Complex Adaptive Systems and professor in the School of Life Sciences at Arizona State University (ASU). She completed her M.A. and Ph.D. degrees at The Ohio State University.

Carolyn Compton, M.D., Ph.D., chief medical officer, collaborates with external biomarker experts to plan and execute specific programs and demonstration projects across the complex biomarker development continuum. She formerly served as CEO of Critical Path Institute, director of Biorepositories and Biospecimen Research for the NCI, and chair of the Department of Pathology at McGill University. She is a member of the Complex Adaptive Systems and professor in the School of Life Sciences at ASU. Dr. Compton received her M.D. and Ph.D. degrees from Harvard University.

George Poste, D.V.M., Ph.D., interim chief science officer, identifies key biomarker scientific and development problems and builds networks among relevant biomarker stakeholders to plan and implement solution strategies. He founded and developed the ASU Biodesign Institute and serves as co-director of Complex Adaptive Systems and Regents Professor at ASU. He was formerly chief science and technology officer and president, research and development, of SmithKline Beecham. Dr. Poste received his D.V.M., Ph.D., and D.Sc. degrees from the University of Bristol, U.K. He is a fellow of the Royal College of Pathologists and the U.K. Royal Society.

Kenneth Buetow, Ph.D., director of bioinformatics and data management, oversees development of the NBDA's foundational infrastructure and programs in bioinformatics, data management, and computational programs. He previously served as director of the Center for Biomedical Informatics and Information Technology for the NCI. He is director of the computational sciences and informatics program for Complex Adaptive Systems and professor in the School of Life Sciences at ASU. He received his Ph.D. degree in human genetics from the University of Pittsburgh.

Anne Marie Geary, director of events and administration, heads planning and implementation of workshops, think tanks, seminars, and all NBDA events. She also oversees the NBDA's administrative, financial programs and website. She previously served in senior administrative roles at Columbia University including, Administrative Director for the National Center for Disaster Preparedness; Director of Operations and Administration for the Office of the Provost; Director of Recruitment for Executive Education at The School of International and Public Affairs (SIPA); Program/Event Manager for the FDNY Officer's Management Institute (FOMI) through SIPA's Institute for Not-for-Profit Management and the New York City Fire Department and Assistant Dean for Curriculum and Faculty Affairs. Ms. Geary currently serves as a director on the Jackson Family Foundation board and Chair of the Events Task Force for Lost Our Home Pet Foundation as well as a volunteer animal technician.

Startup funding for the NBDA provided by Arizona State University, Office of the President and workshop support from the Virginia G. Piper Charitable Trust.

NBDA
National Biomarker Development Alliance

Editorial

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Biomarkers in Medicine

The National Biomarker Development Alliance accelerating the translation of biomarkers to the clinic

"The end-to-end systems approach proposed by the National Biomarker Development Alliance, underpinned by broadly accepted standards, can dramatically reduce the number of candidate biomarkers eligible to move forward to development..."

Keywords: biomarker discovery • biomarker standards • biomarkers • biospecimens • National Biomarker Development Alliance • precision medicine • translational research

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Biomarker development is rarely successful

Realizing the much vaunted promise of precision (personalized) medicine is linked inextricably to the availability of robust and clinically relevant biomarkers. Given their importance in supporting more informed treatment decisions, enabling earlier diagnosis and driving the development of molecular based therapies, biomarkers arguably represent the greatest potential value in biomedicine today. In short, biomarkers are the 'holy grail' of precision medicine.

The BCR–ABL and HER-2 proteins are prototypic examples of the clinical utility of biomarkers in cancer that have transformed the classification of lymphocytic leukemia and HER-2 positive breast cancer, respectively, and driven more rational treatment decisions. Unfortunately, these remain rare examples. The potential of biomarkers to revolutionize the detection, diagnosis and clinical management of cancer remains largely unrealized, with fewer than 100 biomarkers approved by regulatory agencies as companion diagnostics for molecular profiling to guide treatment selection [1]. There is a staggering asymmetry between the several 100,000 publications describing candidate biomarkers and the mere fraction of 1% of these that ever progress to clinical practice [2]. The systematic failure in biomarker R&D is further illustrated by the fact that the US FDA has approved less than one protein biomarker per year since the mid 1990s [3]. The burden of these failures, which come at incalculable cost in wasted investment, intellectual resources and patient samples, are incompatible with charting a reliable intellectual foundation for molecular medicine and improved patient care.

Understanding why biomarkers fail

Many of the root causes of failure in biomarker R&D have been reviewed at length [3–8]. The most publicized biomarker failures, and certainly the most costly, are those that occur in advanced phase clinical trials. Regretfully, these failures are rarely investigated to identify why errors occurred and at what stage in the multiple steps involved in moving from discovery to clinical validation and regulatory approval. Far too often, these interdependent steps are disconnected and lack standardization. Errors that occur early in the R&D cycle are often propagated undetected across these inadequately connected processes and undermine downstream validation making resulting failure inevitable.

Most biomarker discovery still takes place in government-funded university laboratories that are ill equipped to undertake the myriad procedures required for stringent biomarker profiling on the scale required to achieve the evidence needed to attract larger investment in clinical trials. Too often these discovery studies use biospecimens of dubious, unknown or unreported provenance, are statistically underpowered with insufficient sample numbers, and lack access to

Future Medicine part of fsg

clinical data to demonstrate an unequivocal relationship between the biomarker(s) and clinical outcomes thereby limiting their perceived clinical utility and adoption.

Failure begins in discovery

While acknowledging that most flawed biomarker studies may involve multiple, cascading errors [9,10], the penalty for mistakes in early discovery, especially bias in sample collection or lack of standards for collection and storage is manifest in late stage failure. The unacceptable consequences of not considering 'samples, standards and scale' when embarking on biomarker discovery has provoked calls for improved reproducibility in biomedical research, particularly in settings in which biomarker profiling has direct implications for treatment decisions. Sample selection, sources and quality must be relevant to the claimed clinical utility. Investigators ignore this key issue at their peril [11,12].

Consequences of biomarker failure

Collectively, the problems that plague biomarker R&D often render the studies unable to answer the clinical question they set out to address [4]. In turn, this has created growing concern about the lack of reproducibility of many reported biomarker findings [9]. Most biomarkers fail when independent laboratories are unable to reproduce the original claims. In several very conspicuous cases, this has not occurred until very late in the development process despite earlier peer-reviewed publications in authoritative scientific journals, formation of companies, hyped promotion in the lay press, and elevated patient expectations.

> "...biomarker R&D is a modular, highly interdependent process that requires a systems-based, end-to-end approach to ensure seamless transfer of candidate markers across a series of modules from early discovery to clinical validation and their final regulatory approval."

The lack of data sharing and forums for publication of negative results contributes significantly to this problem. Failed approaches may be repeated or compounded indefinitely, due to the near total lack of disclosure of raw data and failed efforts. Amgen recently reported that only six (11%) of 53 seminal peer-reviewed published studies in drug discovery (a field completely dependent on robust biomarkers to identify therapeutic targets or toxicity) could be reproduced [10]. Sadly, little of practical value to the scientific community was derived from this effort because nondisclosure agreements blocked making the study details public. Similar studies by Bayer Healthcare reported higher, but still dismal reproducibility rates of 25% [13]. Reproducibility is a fundamental tenet of sound science. It is alarming that this problem exists at all, let alone so pervasively. Without robust reproducibility, biomarker development and clinical utility are all but impossible.

Even biomarkers that achieve clinical validation and FDA approval are endorsed as a practice standard and enjoy widespread clinical use and payer reimbursement may still suffer from undetected errors made earlier in the R&D process. For example, following approval of the companion diagnostic HercepTest® by the FDA in 1998, widespread testing of breast cancer patients for HER2 overexpression revealed false-positive and false-negative rates of approximately 20% [14] Since this test is the key decision gateway to use of the life-saving but expensive targeted therapeutic Herceptin®, the clinical and economic consequences of poor predictive test values are substantial. To correct the problem, the American Society of Clinical Oncology and the College of American Pathologists jointly developed and enforced standards in an approach that included test execution, operator proficiency and biospecimen handling [15]. This example illustrates an urgent need to identify where standards, applied throughout biomarker R&D could improve the translation of biomarkers into clinical application.

Standards are the foundation of biomarker R&D

The newly launched National Biomarker Development Alliance (NBDA), represents a unique trans-sector alliance dedicated to solving this complex problem. The NBDA has spent nearly 2 years analyzing the biomarker discovery and development process using consultative think tanks involving all stakeholders (academics, clinicians, pharmaceutical and diagnostic companies, regulators, payers and patient advocacy groups). The consensus from this analysis was that biomarker R&D is a modular, highly interdependent process that requires a systems-based, end-to-end approach to ensure seamless transfer of candidate markers across a series of modules from early discovery to clinical validation and their final regulatory approval [16]. The NBDA analysis further determined that decision-making to successfully migrate a biomarker across the interdependent modules of early discovery, translational discovery, assay development and analytical validation, regulatory qualification and clinical validation requires definitive standards for each module and transition point.

It is not that standards do not exist. The literature is replete with claimed standards that are untested, ignored or applied sporadically in ways that fail to

consider the multidimensional nature of the entire biomarker R&D process. As a result, there are no robust templates and protocols for predictable, standards-based, end-to-end approaches for biomarker R&D, no consistent guidelines, no best practices and inadequate decision criteria about whether to advance a biomarker to the next module in the overall process. This is a formula for disaster. Although the FDA has sought to raise the bar for biomarker regulatory submissions, they have been appropriately emphatic in indicating that the standards problem that plagues the biomarker 'ecosystem' must be addressed by its affected communities.

The NBDA has identified six strategic elements in biomarker R&D that must be supported by appropriate standards, best practices and/or guidelines:

- The clinical question (correctly defined at the outset);
- Specimen provenance, quality and numbers;
- Experimental design and statistical robustness;
- Technology platform standards;
- Data and metadata quality;
- Analysis and analytics.

Failure of most biomarkers can be mapped back to these elements: small sample sizes; variable biospecimen quality and associated clinical data; inconsistent performance of measurement technologies and resulting test accuracy; flawed experimental design; poor data quality; faulty data analysis methods; and the omnipresent risk of bias associated with many of these parameters. Any of these issues, alone or in combination, or occurring at any phase in the biomarker R&D cycle can derail the entire process. Most important, a biomarker developed for clinical use must successfully inform a clinical decision that influences patient care. The prudent and logical planning process for biomarker R&D would therefore be to work backwards from the end points of clinical need and regulatory requirements to define the best methods and standards needed to validate biomarkers to meet these performance specifications.

Flawed planning and implementation mistakes in any one of these strategic elements in the interconnected continuum from discovery to clinical validation will lead to failure. Integration of these strategic elements into a cogent end-to-end systems approach is obligate to guide biomarker development and as a vehicle to better learn from published biomarker failures and limit future repetition.

A possible future

A comprehensive systematic approach to biomarkers has not been undertaken or even seriously proposed perhaps due to the daunting multidisciplinary scope, scale and logistics. However, it can and must be confronted as an urgent imperative. There is a high level of frustration with the current level of poor productivity. Addressing this problem will require that the "silos" which charcterize the field give way to new collaborative, integrative approaches. The stakeholder communities (and funding agencies) must embrace a greater willingness to seek solutions via new collaborative trans-sector networks to mobilize the diverse expertise and substantial resources demanded by biomarker R&D.

> "Biomarkers are key to achieving precision (personalized medicine) medicine."

The NBDA was founded on the premise that the current dysfunctional and disjointed status of biomarker R&D can be re-engineered for success. It is a bold step towards the goal of advancement and coordination of standards and practices to achieve a seamless flow of meritorious biomarkers within and across the modules of the discovery and development pipeline. Only by adoption of a standards-based, end-to-end systems approach can we hope to redress the current situation which in any other field of research would be considered a catastrophic failure. Accomplishment of these audacious goals requires that the diverse stakeholders in the biomarker R&D effort (academia, pharmaceutical and diagnostics companies, regulators, payers and patient advocates) work collaboratively to define and implement solutions

Biomarkers are key to achieving precision (personalized medicine) medicine. Although thousands of biomarkers are reported as 'discovered' each year, in areas such as oncology, less than one protein biomarkers per year have been approved by the US FDA since the early 1990s and fewer than 100 are routinely used in clinical practice. The root cause of most of these failures (and indeed the current national conversation on the lack of reproducibility in biomarker R&D) is a glaring lack of accepted and broadly standards to inform every module and decision point of biomarker discovery and development. This problem is further compounded by the failure to view the biomarker R&D process as a highly interdependent end-to-end system. The newly launched National Biomarker Development Alliance represents a unique trans-sector approach to understand and solve these very complex problems.

The end-to-end systems approach proposed by the NBDA, underpinned by broadly accepted standards, can dramatically reduce the number of candidate bio-

markers eligible to move forward to development; while simultaneously increasing the number of biomarkers with the credentials to pass scrutiny and survive the long and tortuous journey to the clinic.

Financial & competing interests disclosure

G Poste wishes to disclose assistance from the Board of Directors, Caris Life Sciences and Scientific Advisory Board, Synthetic Genomics. AD Barker wishes to disclose assistance from the Scientific Advisory Board, Caris Life Sciences. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

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www.NBDAbiomarkers.org

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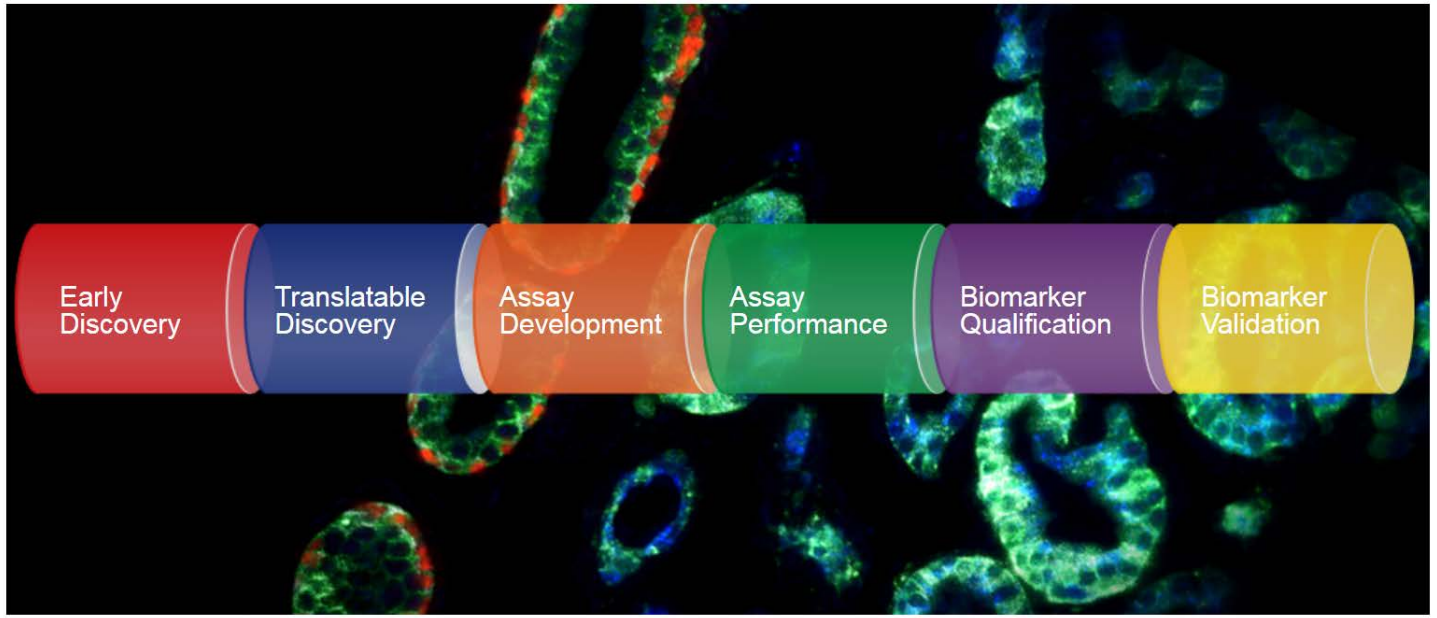
NBDA
National Biomarker Development Alliance

"collaboratively creating the NBDA Standards required for end-to-end, evidence - based biomarker development to advance precision (personalized) medicine"*

ABOUT | WORKSHOPS | STANDARDS/PROJECTS/RESOURCES | EDUCATION | NEWS & COMMUNICATIONS | NBDA MEMBERSHIP



NBDA's Biomarker R&D Modules Overview

Successful biomarkers should move systematically and seamlessly through specific R&D "modules" - from early discovery to clinical validation. NBDA's end-to-end systems approach is based on working with experts from all affected multi-sector stakeholder communities to build an in-depth understanding of the existing barriers in each of these "modules" to support decision making at each juncture. Following extensive "due diligence" the NBDA works with all stakeholders to assemble and/or create the enabling standards (guidelines, best practices, SOPs) needed to support clinically relevant and robust biomarker development.

About NBDA

More >>

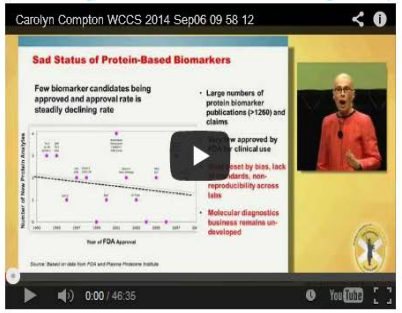
Mission: Collaboratively creating the NBDA Standards* required for end-to-end, evidence - based biomarker development to advance precision (personalized) medicine.
NBDA Standards include but are not limited to: "official existing standards", guidelines, principles, standard operating procedures (SOP), and best practices.

NBDA News

- The Impact of Biobanks and Fit-for-Purpose Biospecimens on Precision Medicine Podcast
- The Daunting Task of Managing Biospecimens at the World's Largest CRO: Diane Farhi, Quintiles
- Janet Woodcock, FDA, on Biomarker Development and the Future of Clinical Trials

- Biosampling Basics with Scott Jewell, Van Andel Institute

- World Congress on Skin Cancer in Edinburgh in September 2014



- The National Biomarker Develoment Alliance Accelerating the Translation of Biomarkers to the Clinic
- Paperwork, Not Algorithms the Biggest Challenge for Large Bioinformatics Projects, Says David Haussler, U
- The Impact of Biobanks and Fit-for-Purpose Biospecimens on Precision Medicine
- Why Internet Traffic Directors Should Sit Down with Biologists: George Poste Talks Complex Systems
- F.D.A. Acts on Lab Tests Developed In-House

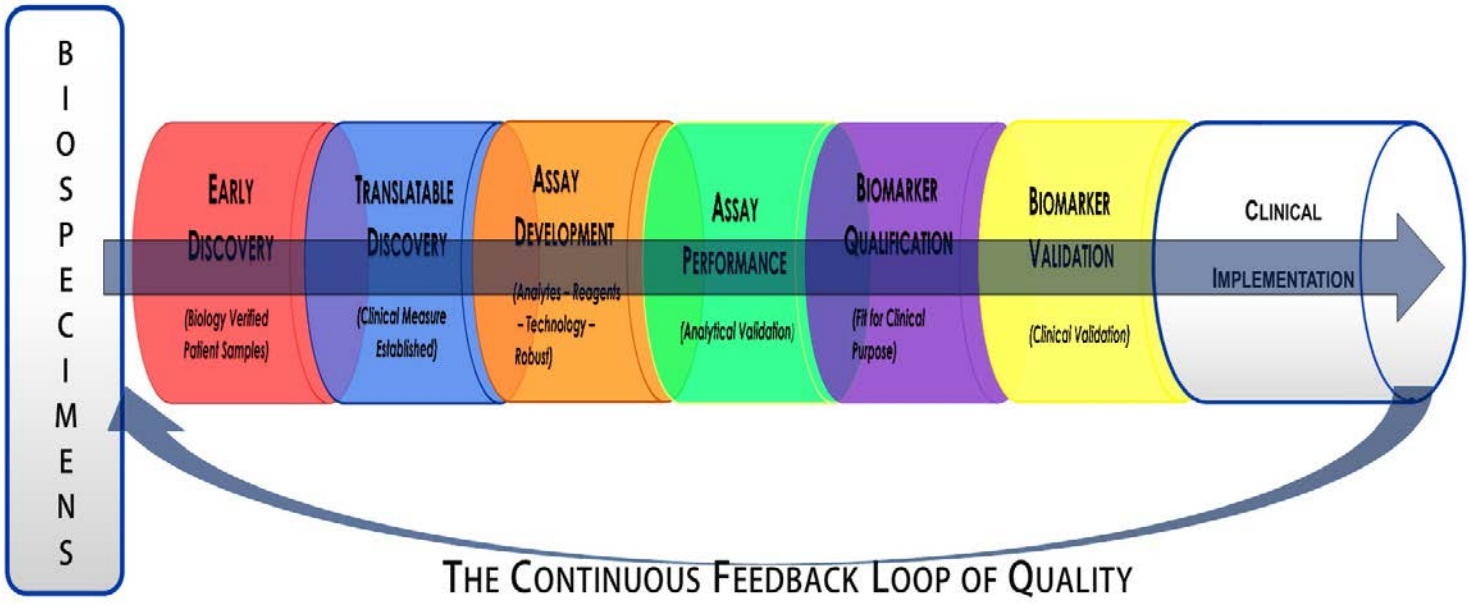
NBDA Convergence Conference I

December 8-9, 2014

"*Converging on Biospecimen Standards for Genomics*"

BIOSPECIMEN QUALITY CHALLENGES IN GENOMICS

KEY CONCEPTS



Disappearing Line of Demarcation between Biomarker Discovery, Development and Clinical Use

Molecular Data

Diagnosis / Therapy

Translational Research

PERSONALIZED CANCER CARE

Biospecimen Analysis

Biospecimen Collection

Biospecimen Processing and Banking

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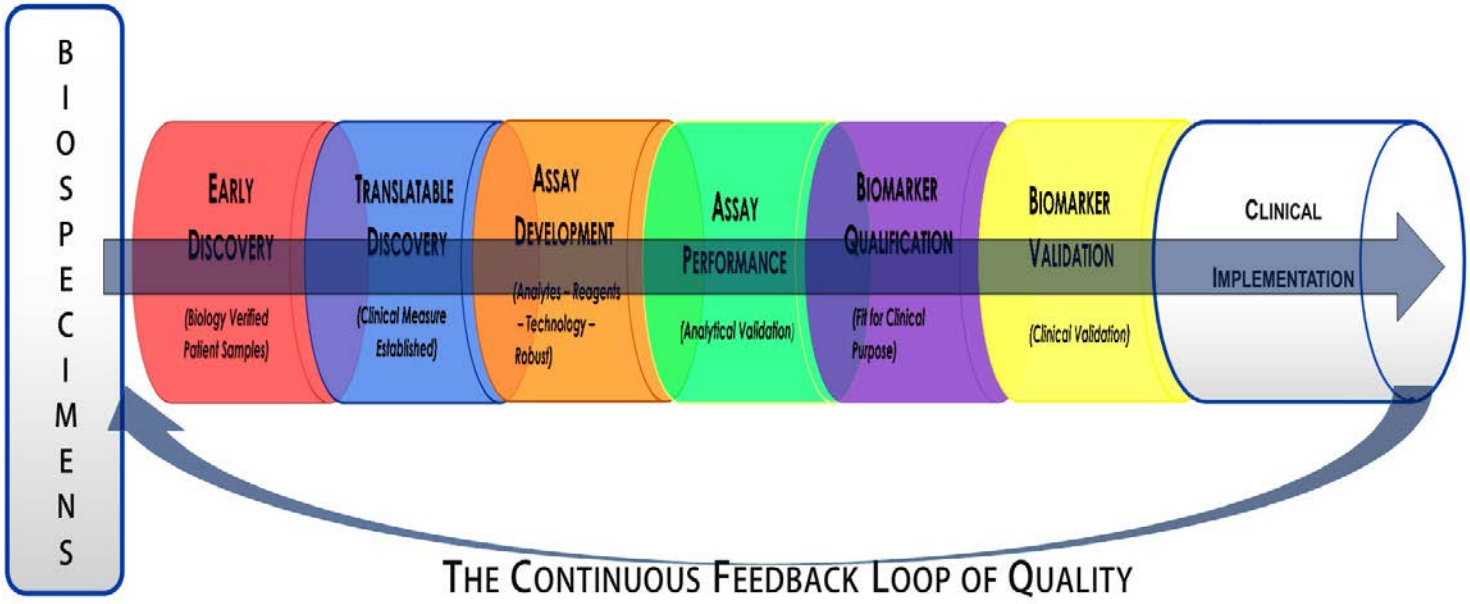
BIOMARKER RECOMMENDATIONS FROM NBDA WORKSHOPS



NBDA Workshop V
Breakout Group 3:
Biospecimens Working Group

What do we need to do to fix the problem of limited availability of high-quality human biospecimens for biomarker development??

Key concepts put forth from the breakout group:

- Develop standardized modular consents for the use of diagnostic patient samples for unspecified research purposes.
- Standardize the key pre-analytical variables that compromise the molecular quality and/or alter the molecular make-up of samples. (Most biospecimens are of unknown quality; molecular quality is highly variable.)
- Activate the regulatory agencies to implement the compliance of universal standards for certification and reimbursement of clinical medicine.
- Standardize patient consent to use samples for unspecified future research and to link them to clinical data.
- Develop universal standardized modular, universal, consents for broad the use of patient samples for unspecified future research purposes.
- Standardize best practices for the collection, processing, handling, tracking, storage of biospecimens.
- Assure implementation of and compliance with quality practices and standards through regulatory and funding agencies (e.g., the NIH, FDA, hospital and/or laboratory accreditation organizations).

The samples group summarized their deliberations with a single declarative statement: in order to fix the problems related to biospecimens in biomarker development, we need to fix the underlying system of biospecimen acquisition, handling and stabilization at the clinical level. Clinical specimens are the most common source of samples for translational research and clinical trials-related correlative science. Improving the quality of those samples would require improving the quality of all samples from all patients through the clinical system.

There are many applications for clinical biospecimens: convenience samples for discovery research; clinical trial samples for correlative science and product development; post-market samples for assessing product efficacy and safety; comparative effectiveness research samples; reference samples for assay development, calibration, and performance assessment; etc. Such samples are all derived primarily from the same flawed source: the highly variable and uncontrolled systems of biospecimen acquisition, handling and stabilization existing within the greater clinical enterprise. Best practices and standards exist for collection and handling of biospecimens prospectively collected for research, but these vary type and degree of technical detail and are not universally enforced.

Additionally, education, training and communication about biospecimen standards are poor, and operators at any level within the system may adversely affect specimen quality. Existing SOPs are often ignored because they are neither monitored nor enforced.

The group's first recommendation to the NBDA was to generate a set of scientifically-based principles for SOP development that would address the quality requirements for biospecimens across the whole spectrum of end-to-end specimen workflow in clinical medicine. Specimen collection, handling, stabilization, and storage are key area recognized for needing standardized SOPs at the clinical level. Controlling and monitoring the way specimens are collected and handled in clinical practice would represent a fundamental change that would positively impact biomarker science by making every "convenience sample" a sample of known, consistent quality. This would also increase the number of usable samples that are available for all biospecimen applications.

Changing the method of collection alone will not be sufficient for the needs of biomedical science. Another recognized problematic issue is the method of consenting patients who are donating samples for research use. There is no universal consent in clinical medicine. Individual IRBs often require institution-specific elements. Many consents do not allow researchers to link a sample to the patient's clinical data, limiting its usefulness for research. Significantly, consents may lack language that allows samples to be utilized for unspecified future research. Standardizing consents will greatly increase the number of samples available for research that requires specimen acquisition from different institutions in order to achieve adequately powered study results. Thus, the second recommendation to the NBDA is the development of a multi-tiered, multi-level, standardized and universal consent. This consent would require a modular language that could be applied to any patient sample weather it is destined for use in clinical medicine, research, clinical trial, etc. To ensure that a standard is maintained for all samples, the NBDA is also encouraged to endorse the following approach: an IRB may opt in or opt out of the modular consent, or it individual components, but may not customize or modify the consent. The development of the consent language could be achieved if the NBDA leveraged existing fora, such as the Global Health Alliance, so that any patient can be part of research and the development of personalized medicine.

In order to achieve practical change within the clinical medicine system the group made its final recommendation that the NBDA take part in the development of incentives that will drive change. It has been noted that there is a universal lack of incentive to do anything to change the current system. There are no consequences for continuing to practice at the current standard. The group recommended creating a carrot and stick model to incentivize the change that would be needed to standardize specimen collection and handling. A carrot would be a value proposition that would drive change through funding and reimbursement and a stick could be realized through regulatory bodies that could mandate the change through accreditation. The development of the carrot and stick model

requires inclusion of perspectives of patients, clinicians, investigators and institutions.

The biospecimen industry is on the brink of a global crisis. While there are currently many potential available sources of specimens, many large medical research institutions are closing their doors and reserving samples exclusively for their own research use. In addition, samples acquired for clinical use are being minimized in quantity, making excess sample available for research extremely limited or nonexistent. It is suggested that NBDA addresses the above issues related to human biospecimens before the impending crisis becomes a true emergency. Quality biospecimens are the cornerstone to biomarker discovery and development, as well as the implementation of personalized medicine.

BIOSPECIMENS BREAKOUT GROUP

NBDA WORKSHOP V

JULY 15, 2014

Sample Quality

Associated Consent

Incentives to Change

PROBLEM 1: QUALITY OF THE SAMPLES

The quality of biospecimens is highly variable.

- Convenience Samples
- Clinical trials samples
- Post-market samples
- Comparative effectiveness research samples

They all originate from the same flawed system…which is the medical standard of care.

RECOMENDATION 1

Standardize best practices for the collection, processing, handling, tracking, and storage of biospecimens in clinical medicine.

Generate SOP's that cover the whole spectrum of end to end specimen workflow.

- Low hanging fruit, standardization of what pathologists are already doing.
- Compliance with existing best practices

PROBLEM 2: THE PROBLEM OF CONSENT

The is no universal consent in clinical medicine

- To link to clinical data.
- For unspecified future research purposes.

Individual IRBs require institution specific elements.

RECOMMENDATION 2

Develop universal modular consent language that can be applied to any patient sample, clinical medicine, or clinical trial.

Endorse the option of the IRB to opt in or opt out but not to customize or modify the consent.

Leverage existing forums so any patient can be part of research

- IOM
- Global Health Alliance
- And others

PROBLEM 3: THE RESISTANCE TO CHANGE

There is a universal lack of incentive, without consequences, to change the current system.

RECOMMENDATION 3

Develop carrots and sticks to drive change

- Carrot: value proposition that will provide the incentive and the infrastructure to implement change.

- Stick: CAP, FDA, CLIA, CMS

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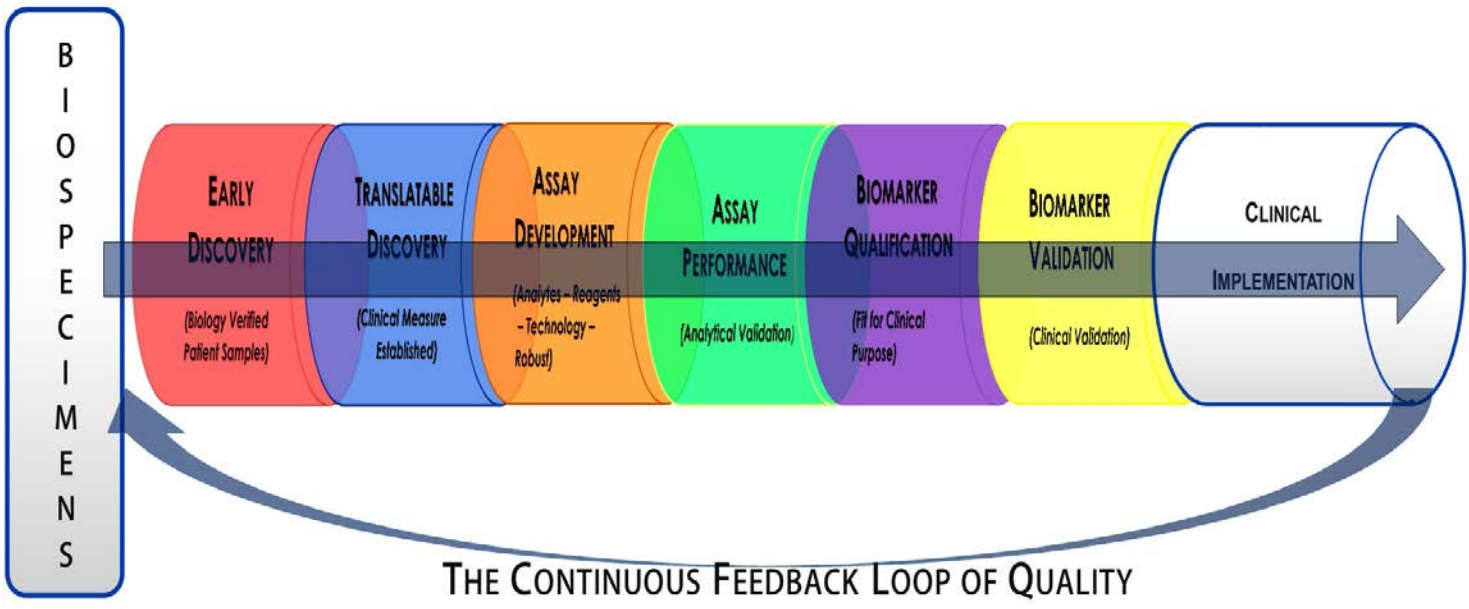

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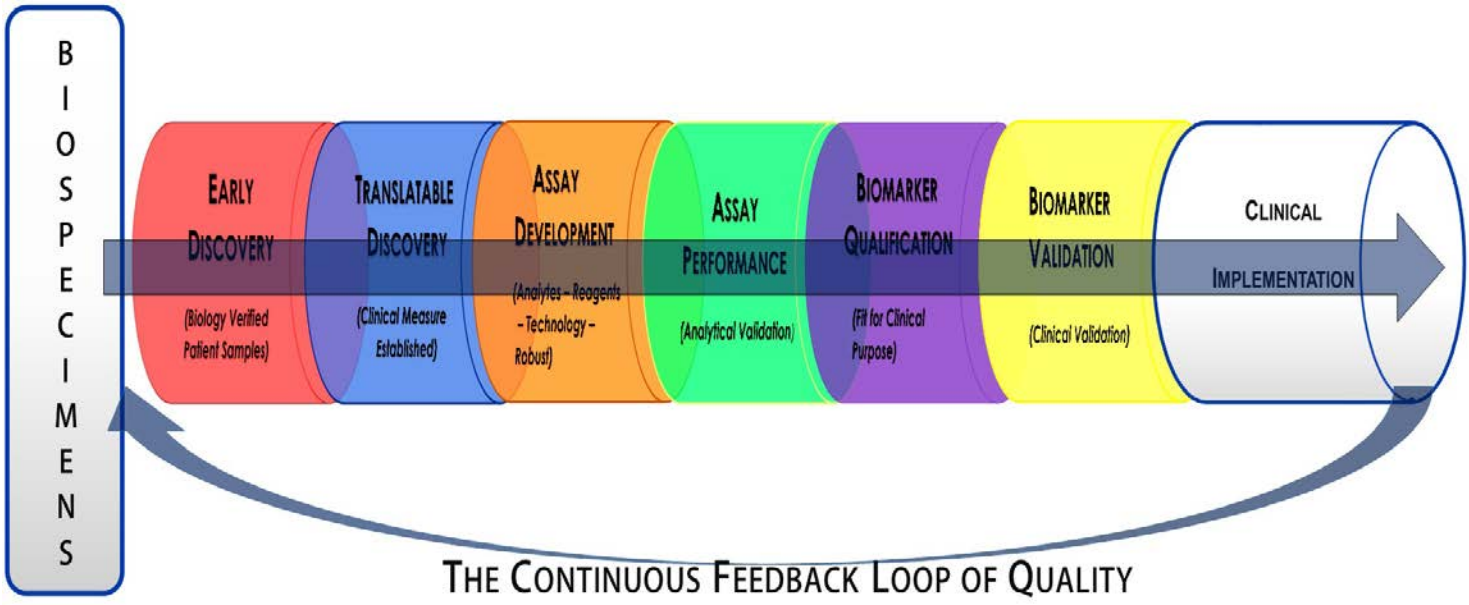
BIOGRAPHICAL SKETCHES



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Vice President, Translational Research

Dr. Daniel Auclair, who managed the MMRF Multiple Myeloma Genomics Initiative from 2007-2010, has rejoined the company after three years at the Broad Institute of MIT and Harvard. As senior leader in the Cancer Program at the Broad Institute, Dr. Auclair was involved with a wide range of academic and industry collaborations centered around cancer genomics and personalized medicine. Prior to this, he spent a decade in the pharmaceutical industry, most notably at Bayer Healthcare where he led a number of cancer drug discovery efforts. Dr. Auclair holds graduate and post-graduate degrees in Biochemistry and Nutrition from the University of Montreal and conducted postdoctoral studies at the Dana-Farber Cancer Institute/Harvard Cancer Center.

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Senior Vice President of Research and Chief Research Officer
Phoenix Children's Hospital

Dr. Aziz is responsible for the strategic direction and growth of research at Phoenix Children's Hospital. Dr. Aziz has overall executive management responsibilities for developing, coordinating, and stimulating research and the operational management of research at the Phoenix Children's Research Institute.

In her most recent position, Dr. Aziz was the Director of Molecular Medicine at the College of American Pathologists (CAP). In this role, she was responsible for initiating and guiding genomic strategies and projects at CAP, along with developing relations with key partners. During her tenure at CAP, she directed the development of the first set of laboratory accreditation standards for clinical tests using next generation sequencing and non-invasive prenatal screening. Dr. Aziz is a member of workgroups at the CDC, NIST, AMP and ACMG involved in developing best practice guidelines and standards for genomic analysis using NGS testing. Dr. Aziz is also a member of the board of overseers of Marine Biological Laboratories/University of Chicago.

In her prior positions, Dr. Aziz served as Vice President of Research and Development at Interleukin Genetics; Vice President of External Research at Point Therapeutics; and Director of Translational Research at Novartis Institute of Biomedical Research. In her industry career, she focused on personalized medicine, biomarkers, genetic tests, and development of drugs in cancer and diabetes. Prior to joining the biotechnology industry, Dr. Aziz was an assistant professor at Harvard Medical School and Children's Hospital in Boston where she discovered and characterized the function of a new gene involved in recessive polycystic kidney disease.

Dr. Aziz received her Ph.D. in molecular genetics at Massachusetts Institute of Technology, where her doctoral research resulted in the discovery of a novel mechanism of regulation of translation of mRNAs. She received her MS in biochemistry at the Massachusetts Institute of Technology and her BA from Wellesley College in Massachusetts. She has published extensively in the medical and scientific literature and has been invited to speak at numerous national and international conferences.

ANNA D. BARKER, PH.D.

President and Director, National Biomarker Development Alliance; Director, Transformative Healthcare Knowledge Networks; Co-Director, Complex Adaptive Systems; Professor, School of Life Sciences, Arizona State University

As director and president of the NBDA, Dr. Barker leads the areas of strategic planning, staffing, program development, and implementation. She works closely with the management team, advisors, external experts, and other stakeholders to define the scope of targeted scientific and education projects and to achieve the mission of the NBDA.

Dr. Barker is co-director of Complex Adaptive Systems at Arizona State University (ASU), which serves as an organizing construct to understand and solve multidimensional problems in the biological and social and sciences, such as those represented by the NBDA. In this role, she has directed efforts to develop transformative knowledge networks that leverage convergent knowledge, innovative teams, and novel funding approaches to better prevent and treat acute and chronic diseases. The NBDA will employ this model.

Prior to joining ASU, Dr. Barker served as deputy director of the NCI and as deputy director of the NCI's Strategic Scientific Initiatives for several years, where she developed and implemented multidisciplinary and transdisciplinary programs, including the Nanotechnology Alliance for Cancer, The Cancer Genome Atlas (TCGA) (in collaboration with the National Human Genome Research Institute), the Clinical Proteomics Technologies Initiative for Cancer, the Physical Sciences-Oncology Centers, and major national efforts in biospecimen best practices (caHUB) and bioinformatics (caBIG). All of these programs emphasize the synergy of large-scale and individual-initiated research, precompetitive research, public databases and clinical to more effectively detect prevent and treat cancer. She also oversaw the NCI's international cancer research programs, including pilot programs in Latin America and China.

In the biomarker area, Dr. Barker was the founding co-chair of the NCI-FDA Interagency Task Force, founding co-chair of the Cancer Steering Committee of the Foundation for the National Institutes of Health (FNIH) Biomarker Consortium, and founding director of the NBDA. She has a long history in research and in the leadership and management of research and development in the academic, nonprofit, and private sectors. She served as a senior scientist and subsequently as a senior executive at Battelle Memorial Institute for 18 years and cofounded and served as the CEO of a public biotechnology drug development company. She has received a number of awards for her work in support of cancer research, cancer patients, professional and advocacy organizations, and the ongoing national effort to prevent and cure cancer. Dr. Barker's research interests include biomarker discovery and development, complex adaptive systems science, and free-radical biochemistry in cancer etiology and treatment. She completed her MA and Ph.D. degrees at The Ohio State University, where she trained in immunology and microbiology.

MICHAEL E. BERENS, PH.D.

Deputy Director, T-Gen Research Resources; Director, Cancer and Cell Biology Division; Professor, Brain Tumor Unit, Translational Genomics Research Institute

In additional roles at the Translational Genomics Research Institute (TGen), Dr. Berens serves as director of the Cancer and Cell Biology Division and professor and head of the Brain Tumor Laboratory Unit. He was a member of Governor Jane Dee Hull's 2002 Taskforce on Genomics, which developed strategies for the funding, partnerships, and recruitment that launched TGen. Dr. Berens' academic career has included appointments at the University of Zurich, the Bowman Gray School of Medicine of Wake Forest University, the University of California, San Francisco, and the Barrow Neurological Institute. At the Barrow Institute, he served for 12 years as senior investigator and director of neurology research. Dr. Berens is pursuing a translational research program in brain tumor research that includes preclinical therapy development, novel treatment target discovery, and the study of malignant cell motility. His research program includes collaborations with Barrow Neurological Institute, Mayo Clinic, multi-institutional consortia, and international laboratories in Seoul, Tokyo, Sydney, and Bergen (Norway). Dr. Berens' current research is funded by the NIH and private medical foundations. He holds four patents and is the founder of two for-profit ventures: Creative Scientific Methods Inc., and Avolix Pharmaceuticals, Inc. Dr. Berens serves on the editorial boards of several scientific journals and on committees that support governmental agencies, professional societies, and nonprofit organizations. He is also active in the technology and public policy sectors and is past chairman of the Arizona Technology Council. Dr. Berens received his Ph.D. degree from the University of Arizona.

KENNETH J. BLOOM, M.D., F.C.A.P.

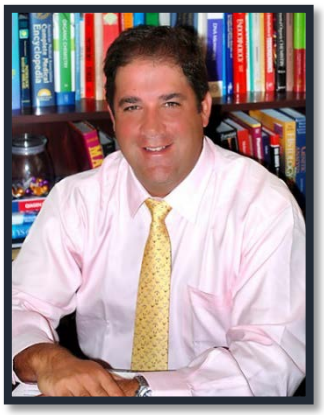
Chief Medical Officer, Clarient

Kenneth J. Bloom, M.D. has been the Chief Medical Officer since 2005 and was the original Medical Director of Clarient Diagnostic Services. Dr. Bloom's career spans more than 30 years including key positions in start-up companies, University-based Medical Centers and commercial laboratories. As an early adopter of information technology, Dr. Bloom developed the Pathology Information System at Rush Medical Center and helped design the hospital's Tumor Registry and Surgical Information System. Using this technology, Dr. Bloom co-founded Initiate Systems, which just prior to its sale to IBM, was estimated to hold an 80% share of the software market that linked individual patient records across various healthcare databases. During his residency, Dr. Bloom developed the first commercial Telepathology system and co-authored the key technical papers. He was an invited speaker at the First International Conference on Clinical Application of Telemedicine in Tromso, Norway in 1993.

Dr. Bloom came to Clarient from Irvine, CA-based US Labs, where he served as Senior Medical Director since 2002. Dr. Bloom's academic posts have included Clinical Professor of Pathology at USC, Keck School of Medicine, Associate Professor of Pathology at Rush Medical College and one year as a visiting Professor in the Department of Computer Science at DePaul University. Over the past 15 years, Dr. Bloom has held more than 10 appointed positions at Chicago-based Rush Presbyterian-St. Luke's Medical Center, one of the leading cancer research hospitals in the US. Those positions included Director of Laboratory Operations, Director of Immunohistochemistry, Consultant to the Rush Breast Cancer Center, and Director of Information Services for the Rush Cancer Institute.

Dr. Bloom has, for more than three decades, been a prolific researcher and lecturer in the fields of pathology, cancer, telemedicine and informatics. He is a sought after speaker both nationally and internationally and has presented for the College of American Pathologists, International Academy of Pathology, Royal College of Pathologists of Australasia, American Society of Oncology, American College of Surgeons, American Society of Breast Surgeons and numerous state and local pathology societies. He has published over 50 peer-reviewed articles, more than 100 abstracts and several book chapters. He has been a member of the College of American Pathologists since 1987 and has served on several committees including the Diagnostic Immunology Resource Committee, the Immunohistochemistry Committee, the Technology Assessment Committee, the Personalized Healthcare committee and as a member of the initial CAP/ASCO guideline committee for HER2 assessment. Dr. Bloom is a member of the House of Delegates for the College of American Pathologists and is a Foundation Board Member of the US and Canadian Association of Pathology.

Dr. Bloom has served as principle investigator of more than a dozen clinical trials and has served as an advisor to numerous Pharmaceutical and Bio-Technology Companies. He is President and CEO of Clarient Pathology Services.



ANDREW BROOKS, PH.D.

Chief Operating Officer, RUCDR Infinite Biologics; Rutgers University

Dr. Brooks is the Chief Operating Officer of RUCDR Infinite Biologics and Director of the Bionomics Research and Technology Center at Rutgers University. He is also one of the founding members of the Bioprocessing Solutions Alliance. Dr. Brooks is a molecular neuroscientist whose research focuses on deciphering the molecular mechanisms that underlie memory and learning. Dr. Brooks is a well-recognized genomicist and has been involved in the development and implementation of cutting edge molecular based technologies for nucleic acid and protein analyses.

CARRIE BROWNING, MS

Senior Pharma Business Specialist, Illumina, Inc.

Carrie Browning, Senior Pharma Business Manager with Illumina residing in Raleigh, North Carolina works with Pharmaceutical and CRO clients to assist with development of genomic biomarker applications. Carrie was most recently at BioStorage Technologies, where she was the Program Director for the Targeted Medicine program integrating specimen management and biorepository services with genomic biomarker analysis for drug development. During her time at BST she led efforts to develop specimen best practices for sample collection for immediate testing and long term stored samples to allow for testing at a future time. Prior to that she was at Gentris, where she led the commercial sales and marketing organization as the VP of Business Development. In total, she has over 8 years of commercial experience in genomic biomarker services and technology within the biotech and pharmaceutical market. She spent several years at Duke as a Laboratory Research Analyst working on population and disease trait mapping in CNS applications after receiving both her BS degree in Animal Science/Biology and Masters in Reproductive Physiology from The Ohio State University. In her spare time, Carrie spends time with her son, Andrew, who will be entering Middle School in the fall. She also rides and competes with her horse in dressage.

KENNETH BUETOW, PH.D.

Director of Bioinformatics and Data Management, NBDA; Director, Computation and Informatics Core Program, Complex Adaptive Systems, Arizona State University

Dr. Buetow is a human genetics and genomics researcher who leverages computational tools to understand complex traits such as cancer, liver disease, and obesity. He also is a professor in the School of Life Sciences in ASU's College of Liberal Arts and Sciences.

CAS@ASU applies systems approaches that leverage ASU's interdisciplinary research strengths to address complex global challenges. The Computational Sciences and Informatics program is developing and applying information technology to collect, connect, and enhance transdisciplinary knowledge both within ASU and across the broader knowledge-generating ecosystems. CAS@ASU is creating a Next Generation Cyber Capability to address the challenges and opportunities afforded by "Big Data" and the emergence of 4th Paradigm Data Science. This capability brings state-of-the-art computational approaches to CAS@ASU's transdisciplinary, use-inspired research efforts.

Dr. Buetow previously served as director of the Center for Biomedical Informatics and Information Technology within the NCI. In that capacity he initiated and oversaw the NCI's efforts to connect the global cancer community through community-developed, standards-based, interoperable informatics capabilities that enable secure exchange and use of biomedical data. Dr. Buetow designed and built one of the largest biomedical computing efforts in the world. He was responsible for coordinating biomedical informatics and information technology at the NCI. The NCI center he led focused on speeding scientific discovery and facilitated translational research by coordinating, developing, and deploying biomedical informatics systems, infrastructure, tools, and data in support of NCI research initiatives.

KATHERINE CALL, PH.D.

Senior Director and Head, Proteogenomics, Genzyme R&D Center, Sanofi US

Katherine M. Call has extensive experience in the fields of biologics and genomics, having identified and validated disease genes and drug targets and advanced molecules into development in several therapeutic areas. She is currently Senior Director and Head, Proteogenomics, a newly established group with a strong translational science component in the Sanofi-Genzyme R&D Center. Dr. Call was Head of US Biologics Research from 2010 - mid 2012 and led the establishment of Sanofi Discovery Biotherapeutics globally from 2005 - 2007. She joined Sanofi as Head of Molecular Genomics at the Cambridge Research Center in 2000 and was subsequently appointed Global Head, Genomics Technology Transfer/ Management. As a co-founder of the Cambridge Genomics Research Center in 1997, Dr. Call's team established molecular genomic platforms and applied these to bone and cancer projects to identify and validate therapeutic targets. This joint venture demonstrated strong value in a short period and was acquired by Sanofi in 2000. She also has experience with external partners, having initiated External Research Strategy and Innovation in the greater Boston area, identified external biologics opportunities and been involved in strategic alliances.

Dr. Call holds a Bachelor degree in Biology, awarded with highest honors, from the University of California at Santa Cruz. At MIT, she earned a Ph.D. in Applied Biology / Genetic Toxicology and did post-doctoral training in human genetics and genomics at the Koch Center for Cancer Research. She was awarded a NIH postdoctoral fellowship in which she successfully cloned a Wilms' tumor gene. A landmark accomplishment - the second tumor suppressor gene and one of the first disease genes isolated based on genetic map information and genomics approaches.

She was a faculty at Harvard School of Public Health and Harvard Medical School, a key investigator on large NIH Human Genome Center grants for mapping and sequencing of chromosomes 10 and 11, has published 35 scientific papers and holds issued patents on a Wilms' tumor gene, bone disease genes and genomics technology methods. Dr. Call has served extensively in external scientific communities - on grant review panels, as a committee member and Deputy Editor for human chromosome 10 and in a consultant and advisory board capacity to life sciences companies & organizations.

CAROLYN COMPTON, M.D., PH.D.

Chief Medical Officer, National Biomarker Development Alliance,
Professor, School of Life Sciences, Arizona State University
Professor Laboratory Medicine and Pathology, Mayo Clinic

As chief medical officer of the NBDA, Dr. Compton works closely with transsector external experts on all phases of specific network-enabled projects to address major barriers in the biomarker development process. In this role she plans and implements consensus conferences and prioritizes and integrates existing guidelines, best practices, and other standards to identify targeted needs for demonstration projects and new research. Dr. Compton also leads the NBDA's programs in biospecimens and biorepositories and implements specific programs that include clinical trials.

She is a nationally prominent academic pathologist specializing in gastrointestinal disease and is board certified in both anatomic and clinical pathology. Dr. Compton is a professor at ASU and an adjunct professor of pathology at both the University of Arizona and Johns Hopkins. At ASU she is on the faculty of the School of Life Sciences, and at Mayo Clinic she is a research affiliate in the Department of Pathology and Laboratory Medicine.

Dr. Compton is a member of The Biodesign Institute and the Complex Adaptive Systems Initiative. She is a former professor of pathology at Harvard Medical School, chief of Gastrointestinal Pathology at Massachusetts General Hospital, and pathologist-in-chief at Boston Shriners Children's Hospital. More recently she has served as the CEO and President of the Critical Path Institute (2012), director of Biorespositories and Biospecimen Research and the Innovative Molecular Analysis Technologies program at the NCI (2005-2011), and the Strathcona Professor and Chair of the Department of Pathology at McGill University and pathologist-in-chief of the McGill University Health Center (2000-2005). Dr. Compton is immediate past chair of the American Joint Committee on Cancer (AJCC) and chair of the AJCC's Precision Medicine Core. She has authored more than 500 scientific manuscripts, review articles, books, and chapters. Dr. Compton received her M.D. and Ph.D. degrees from Harvard University.

MICHAEL J. DEMUERE, M.D.

Director & Clinical Professor, Rare Cancer Unit, Rare Cancer Program
Translational Genomics Research Institute (TGen)

Dr. Demeure is a fellowship-trained endocrine surgeon who has been in academic surgical practice since 1991. He had maintained an active clinical and basic research program during this time focusing on the mechanisms of tumor metastases. Dr. Demeure went to medical school at Hahnemann University, and completed his surgical residency at the University of Arizona. His fellowship in endocrine surgery was in Perth, Australia and then at the University of California, San Francisco. Subsequently, Dr. Demeure took an academic appointment at the Medical College of Wisconsin where he practiced surgical oncology for 11 years before moving to the University of Arizona where he was a tenured professor of surgery and chief of general surgery. He then moved to the Phoenix area full time in 2008 in order to further the translational therapeutics program in ACC. He has published over 80 manuscripts and book chapters. Dr. Demeure served as the president of the American Association of Endocrine Surgeons from 2008 to 2009. He is also a member of many surgical societies including the American College of Surgeons and the Society of Surgical Oncology. Dr. Demeure is the Director of the Pancreatic Cancer Biospecimens Repository for a recently awarded pancreatic cancer program project grant from the NIH. His role in this project is to enroll and manage multiple institutions whose investigators submit cancer and blood specimens for researches involved in the study of the molecular genetics of pancreatic cancer. This role is similar to a key function of this adrenocortical cancer project. Dr. Demeure started the ACC project at TGen which, along with Dr. Kim Bussey, he now directs. Dr. Demeure has been a Clinical Professor with TGen since 2005.

DIANE C. FARHI, M.D.

Senior Medical Director, Quintiles Transnational Corporation
Former Professor of Pathology and Laboratory Medicine, Emory University

As Senior Medical Director of Quintiles' North American laboratories, Dr. Farhi is responsible for the management of clinical trials samples, from protocol design through pre-analytical and analytical testing. This role includes considerable cross-functional teamwork with Logistics, Kit-Building, Assay Development Laboratories, Project Services, and Data Management, as well as the directorship of the Expression Analysis, Quintiles' next-generation sequencing laboratory.

Quintiles is the world's leading contract research organization (CRO), developing 100% of the top 100 best-selling drugs of 2013. Clients include all major and mid-sized pharmaceutical companies and many biotech companies, as well as providers and developers of special technical services. Dr. Farhi's laboratory in Atlanta helped design the College of American Pathologists' biorepository accreditation standards, and was the first central laboratory to be accredited.

Past roles include professorships at several academic institutions, most recently Emory University, and leadership roles with Quest Diagnostics. Dr. Farhi is the author of over 150 peer-reviewed articles, book chapters, and reviews, and the author of a widely-used textbook of hematopathology, Pathology of Bone Marrow and Blood Cells.

RICHARD C. FRIEDBERG, M.D., PH.D., FCAP

President-Elect, College of American Pathologists (CAP)
Chair, Department of Pathology, Baystate Health
Medical Director, Baystate Reference Laboratories
Professor and Deputy Chairman, Department of Anatomic & Clinical Pathology, Tufts University School of Medicine

At Baystate Health, Dr. Friedberg leads a hybrid academic/private practice group of 21 pathologists and a regional reference laboratory with more than 500 FTEs, providing exclusive diagnostic services to 5 hospitals, 3300 providers, and numerous nursing homes, which generate over 50,000 surgical specimens, 60,000 cytology specimens, and 6 million laboratory tests. He is also Professor and Deputy Chairman of the Department of Pathology, Tufts University School of Medicine.

Dr. Friedberg holds a Bachelor Science (BS) with Honors from Stanford University, an M.D. from Duke University, a Ph.D. in coagulation biochemistry from Duke University, and a Master's (SM) in Health Care Management from Harvard University. He is a Certified Physician Executive (CPE) by the American College of Physician Executives.

Over the past 20 years, he has also served on numerous committees and councils for the College of American Pathologists, including the Government & Professional Affairs, Accreditation, Quality Practices, Technology Assessment, Transformation, Finance, Transfusion Medicine, Performance Measurement, and Patient Safety. During that time, he served as Chair or Vice-Chair of many of those committees and councils. In 2007 and again in 2010, he was elected by the CAP membership to serve on the CAP Board of Governors. In 2013, he was nominated and elected to be an officer of the CAP, and will serve as President-Elect until 2015 and President from 2015-17.

ANNE MARIE GEARY

Administrative Director, National Biomarker Development Alliance

Anne Marie Geary is the Administrative Director for the National Biomarker Development Alliance (NBDA) at Arizona State University's Complex Adaptive Systems Initiative. She heads the planning and implementation of workshops, think tanks, seminars and all NBDA events. She also oversees the NBDA's memberships program, financial and administrative programs and website. Before moving from New York City to Phoenix, Ms. Geary previously served in senior administrative roles at Columbia University including, Administrative Director for the National Center for Disaster Preparedness; Director of Operations and Administration for the Office of the Provost; Director of Recruitment for the Picker Center for Executive Education at The School of International and Public Affairs (SIPA); Program/Event Manager for the FDNY Officer's Management Institute (FOMI) through SIPA's Institute for Not-for-Profit Management and the New York City Fire Department and Assistant Dean for Curriculum and Faculty Affairs. She also served on various faculty committees and the University's Interregional Council. Ms. Geary currently serves as a director on the Jackson Family Foundation board and Chair of the Events Task Force for Lost Our Home Pet Foundation as well as a volunteer animal technician.

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KEVIN GROCH, PH.D.

Consultant

Kevin Groch received his Ph.D. from the Department of Human Oncology at the University of Wisconsin-Madison. He is currently consulting on issues relating to bioinformatics, experimental pathology, and tissue acquisition for the genomics and proteomics spaces. He has held positions with the Pacific Northwest National Laboratory working on the genetics of radon-induced lung cancer, several commercial bioinformatics software firms as a product manager in the functional genomics space, and Leidos Biomedical Research, Inc. While at Leidos, Dr. Groch served as a senior scientist managing the support of a number of NCI projects including caBIG, TCGA, the Clinical Proteomics Tumor Analysis Consortium, and the In Silico Research Centers of Excellence. He also managed the Laboratory's support of the NCI Center for Biomedical Informatics and Information Technology, the Center for Strategic Scientific Initiatives, and the Office of Physical Sciences – Oncololgy. He provided direct bioinformatics support for the Office of Biorepositories and Biospecimen Research piloting the bioinformatics component of the Genotype-Tissue Expression project.

Dr. Groch's current work include providing guidance on refining operational strategies for the collection of human tissue for genomic and proteomic analysis, the long-term maintenance and support of open source bioinformatics solutions, and the creation of publicly-available compendia of tissue procurement documentation.

GENE N. HERBEK, M.D., FCAP

CAP President; Medical Director, Methodist Women's Hospital Laboratory
Medical Director, Transfusion and Coagulation Services, Pathology Center, Methodist Hospital

Gene N. Herbek, M.D., FCAP, is the president of the College of American Pathologists. He has been actively involved in the CAP for more than 25 years and has served on the CAP Board of Governors, most recently as president-elect and secretary-treasurer. He has also chaired the Finance Committee and Council on Membership and Public Affairs, and served as vice chair of the Council of Scientific Affairs among others. Currently, Dr. Herbek serves as medical director of the Methodist Women's Hospital laboratory and medical director of the Transfusion and Coagulation Services for the Pathology Center at Methodist Hospital, both in Omaha, Nebraska.

He is board-certified in anatomic and clinical pathology and is a graduate of the University of Nebraska Medical Center and Residency Training Program.

Among his many professional honors and awards, Dr. Herbek has received the CAP Outstanding Communicator Award and the St. Luke's Regional Medical Center, Sioux City, Iowa, Physician Hero Award. Most recently, Dr. Herbek launched CAP's first See, Test & Treat®, a program that provides free breast and cervical cancer screening to under-served women in the United States. See, Test & Treat is made possible through the volunteer services of CAP member pathologists and their clinical health care colleagues and supported through the generosity of CAP Foundation donors. In 2012, the first Gene and Jean Herbek Humanitarian Award was presented to a CAP member pathologist to celebrate their impact in the lives of women in need though a See, Test & Treat program.

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YUN-FU HU, MS, PH.D.

Chief, Molecular Pathology and Cytology Branch,
FDA/CDRH/OIR/DMGP

Dr. Yun-Fu Hu was born and raised in China. Upon completion of his studies in animal sciences and veterinary medicine at Central China Agricultural University, he went to the Ohio State University (Columbus, OH) to pursue advanced degrees, training, and career opportunities. He studied reproductive endocrinology for his MS degree and cancer biology for his PhD degree.

He spent 5 years at Fox Chase Cancer Center in Philadelphia initially as a postdoctoral fellow, then Research Associate, and eventually a Staff Fellow for the last 2 years there. His research interests centered around molecular mechanisms of carcinogenesis. He then joined Becton Dickson in Baltimore as a Project Scientist leading the development of a molecular diagnostic test for melanoma for 2 years before he was recruited to work at GlaxoSmithKline (GSK) as an Investigator. He was promoted to Group Manager 3 years later. His group was mainly responsible for discovery of biomarkers and development of biomarker tests in support of GSK drug development programs. After more than 6 years at GSK, he joined a biotech company in RTP as the Director of Diagnostics Development to oversee the company's diagnostics programs including discovery of metabonomic biomarkers and development of in vitro diagnostics. He joined FDA 3.5 years ago as a Scientific Reviewer in Hematology branch of the Division of Immunology and hematology Devices at CDRH's Office of In Vitro Diagnostic Device Evaluation and Safety and was promoted to Associate Director last summer in charge of the Immunology branch of that Division. His group is responsible for review and clearance or approval of a variety of immunology and molecular diagnostic devices such as cancer diagnostics and genetic tests as well as tests for autoimmune diseases (e.g., Celiac disease, Crohn's disease), allergies (e.g., pollen allergy), etc. His group has recently approved several companion diagnostics that are intended to select the right patients for the right therapies.

ANDREAS JEROMIN, PH.D.

Founder and CSO, Atlantic Biomarkers, LLC
CSO, Iron Diagnostics, Inc.

Andreas Jeromin, Ph.D., has established research programs in translational neuroscience in both industry and biotech for the last 15 years and co-authored more than 100 publications. He has also been elected a member of the Dana Alliance for Brain Initiatives. Andreas Jeromin has led biomarker qualification programs in diagnostics and therapeutics in acute neurological injury and neurodegeneration in roles with increased responsibilities. This included several drug development program from POC to a NINDS-supported phase III trial (Protect III). He also supports as member of the SABs or steering committee, several biomarker qualification efforts such as ADNI, the Coalition against Major Diseases (CAM.D.) directed by the Critical Path Institute (C-PATH), the Alzheimer's Association CSF QC and biomarker assay standardization initiatives in other CNS disorders, including MS (Accelerated Cure), ALS and PD. He is the founder and CSO of Atlantic Biomarkers, LLC. Andreas Jeromin joined Quanterix, Inc. as scientific and medical advisor and Iron Diagnostics, Inc., as CSO in 2014.

ELAINE K. JETER, M.D.

Pathologist and Medical Director, Palmetto GBA

Elaine K. Jeter is the Palmetto GBA J11 Medical Director. She received a Bachelor of Science degree from the State University of New York at Geneseo in biology/marine science and an MS in biology from the University of South Carolina. Dr. Jeter received her M.D. from Medical University of South Carolina (MUSC), and completed a five-year residency in anatomical and clinical pathology. She has AP/CP boards from the American College of Pathology, and specialty boards in blood-banking/transfusion medicine. Dr. Jeter was on the faculty at MUSC in pathology and in the private practice of pathology for many years prior to joining Palmetto GBA.

SCOTT JEWELL, PH.D.

Professor and Director, Program for Biospecimen Science;
Director, Technologies & Cores Pathology and Biorepository Core;
Van Andel Research Institute (VARI)
Professor, Van Andel Institute Graduate School

Dr. Jewell is Director for the Program of Core Technologies including the Pathology and Biorepository Core at the Van Andel Research Institute (VARI) and a Professor in the Van Andel Institute Graduate School. Dr. Jewell received his B.S., M.S. and Ph.D. degrees from The Ohio State University in Columbus, Ohio, in Immunology and Experimental Pathology. Dr. Jewell has worked in the field of anatomic pathology, biospecimen science and biobanking for more than 30 years. He has served as President of the International Society for Biological and Environmental Repositories (ISBER), directed several projects in biobanking including the NCI Cooperative Human Tissue Network at Ohio State University, the Cancer and Leukemia Group B (now Alliance) Pathology Coordinating Office, Executive Director of OSU's Human Tissue Resource Network and the OSU Comprehensive Cancer Center's Biorepository and Biospecimen Resource. Dr. Jewell has served on several national committees and external advisory boards, including several ISBER committees, the Clinical Cooperative Group Banking Committee, the Biospecimen Subcommittee for NCI, AACR, and FDA's Critical Path Initiative and currently he serves as a member of the Biorepository Accreditation Program of the College of American Pathologists (CAP). At VARI, Dr. Jewell operates the Comprehensive Biospecimen Resource (CBR) for the NCI's Cancer Human Biobank (caHUB; http://biospecimens.cancer.gov/programs/cahub/default.asp) and serves as the biorepository for the Multiple Myeloma Research Foundation's CoMMpass Study (http://www.themmrf.org/research-partners/the-commpass-study/). Dr. Jewell's research focuses on biospecimen science to improve the standards and practices for the collection, processing, storage and distribution of biospecimens.

CHRISTOPHER R. KINSINGER, PH.D.

Program Manager, Clinical Proteomic Tumor Analysis Consortium
National Cancer Institute, NIH

Dr. Kinsinger focuses on biospecimen and informatics-related aspects of NCI's Clinical Proteomic Tumor Analysis Consortium (CPTAC). Currently, he is leading a biospecimen collection effort to accrue 300 colon, breast, and ovarian cases according to a protocol optimized for proteomic and genomic analysis. Chris also oversees the CPTAC Data Coordinating Center and coordinates bioinformatics efforts across the program. He completed postdoctoral training at NIST, where he researched fragmentation pathways of peptide ions in mass spectrometry. He holds a Ph.D. degree in chemistry (2004) from the University of Minnesota.

GREG KORZENIEWSKI, PH.D.

Chief Scientist for the SCI Group

Dr. Korzeniewski is currently the Chief Scientist for the SCI Group where he is responsible for scientific and technical innovation and coordination across SCI organizations with focus on the SCI health related vertical. Previous to that he was the Director of Operations for the Applied Biomedical Science and Informatics Program (ABSIP) in support of the Frederick National Laboratory for Cancer Research (FNLCR). This program supported strategic NCI and NIH initiatives with a variety of scientific, informatics, clinical, program management, and acquisition expertise. Major programs for which ABSIP was the lead support organization within the FNLCR include: The Cancer Genome Atlas (TCGA), the National Cancer Informatics Program (NCIP) (and before that the cancer BioInformatics Grid (caBIG)), the NIH common fund Genotype-Tissue Expression (GTEx) Program, and the Cancer Human Biobank (caHUB) program. Dr. Korzeniewski has a Ph.D. in Theoretical Physical Chemistry from the University of California, Santa Barbara, and did his post-doctoral work at the Massachusetts Institute of Technology.

ROBERT MITTMAN, M.S., MPP

Founder, Facilitation | Foresight | Strategy; Director, Biomedical Strategy & Knowledge Development, Complex Adaptive Systems, Professor of Practice, Ira A. Fulton Schools of Engineering,Arizona State University

As founder of Facilitation, Foresight, Strategy, Mr. Mittman works with groups of organizations to discover and implement shared approaches to complex and intractable problems. He engages audiences in a lively exchange of perspectives to turn simple meetings into forums that allow diverse individuals to work productively together.

Mr. Mittman specializes as a scientific strategist. He helps large groups of scientists from diverse disciplines articulate shared areas of interest, frame significant and innovative research questions, and identify opportunities for new partnerships and collaborations to advance the development of new fields of science.

Mr. Mittman facilitates strategic thinking with non-profit health organizations, government agencies, and the for-profit health care industry, including the National Cancer Institute; the Centers for Disease Control and Prevention, the American Association for Cancer Research; the University of California, San Francisco's School of Medicine; Health Level 7; the Leukemia and Lymphoma Society; the Angiogenesis Foundation; the California HealthCare Foundation; Johnson and Johnson; Ascension Health; and Kaiser-Permanente. Recent work has included integrating the disciplines of biophysics, physical chemistry, and mathematics into biological research; developing a vision of how information technology can improve quality and safety in a range of health care settings from research to the clinic to the home; and crafting a vision for personalized health care.

For nearly two decades, Mr. Mittman provided strategic advice to health care organizations as director at Institute for the Future. He holds graduate degrees in computer science and public policy analysis, and a Bachelor of Science degree in electrical engineering, all from the University of California at Berkeley.

JAN NOWAK, M.D., PH.D.

Director, Molecular Diagnostics Laboratory;
Attending Physician, NorthShore University Health System
Clinical Assistant Professor of Pathology, University of Chicago.

Jan Nowak, MD, PhD, is Director of the Molecular Diagnostics Laboratory at NorthShore University Health System in Evanston, Illinois, where he serves as an Attending Physician. He is also Clinical Assistant Professor of Pathology at the University of Chicago. He has over 26 years of experience and practices in Pathology, Molecular Genetic Pathology, and Anatomic Pathology & Clinical Pathology. Dr. Nowak is a former President of the Association for Molecular Pathology (AMP). In 2013, he was awarded the Association for Molecular Pathology Leadership Award, the highest honor that AMP gives exclusively to one of its members - one who has demonstrated exceptional leadership in the accomplishment of the mission and vision of AMP. Dr. Nowak led AMP through lively deliberations when the BRCA gene patent suit was filed. His advocacy was instrumental in positioning AMP-member laboratories as front-line experts during the 2009 H1N1 outbreak. Dr. Nowak obtained his PhD and MD degrees from the University of Rochester School of Medicine and Dentistry and completed his residency in Anatomic and Clinical Pathology at the University of Rochester Medical Center.

ROBERT PENNY, M.D., PH.D.

CEO, International Genomics Consortium

Dr. Penny is the CEO of the International Genomics Consortium and also serves as a board member and Chief Medical Officer. He has leadership roles in the Cancer Genome Atlas project (TCGA) as the Principal Investigator for the Biospecimen Core Resource (BCR) and for TCGA's Tissue Source Site network. He has created a world-class biorepository at IGC through their expression project for Oncology (expO), which is characterized both clinically with treatment and outcome data as well as molecularly. He has historical competencies in tissue and data standards to complement the high quality biospecimens that he has accrued.

Dr. Penny is one of the Founders, CEO and a board member of Paradigm, a new cutting-edge advanced diagnostics company that is bringing next generation sequencing and other technologies to personalized medicine. The company is located in Phoenix and Ann Arbor.

While at the IGC, he founded the Molecular Profiling Institute and served as its Chief Executive Officer and Chairman of the Board. The Molecular Profiling Institute is the first company to commercially introduce gene expression analysis into oncology in the U.S. He developed the Molecular Profiling Institute's portfolio of molecular testing and pharmaceutical services which includes his successful commercially available holistic genomic analysis of cancer with its award-winning surgical oncology report (Target Now). He led the successful merger of the Molecular Profiling Institute into Caris Life Sciences.

Dr. Penny is a recognized expert in the translation of diagnostics into patient care as well as in biorepositories. He has established two national esoteric reference medical laboratories, a national tissue bank and analysis center, and a national genomics program. He has helped bring cellular and molecular diagnostic, prognostic and therapeutic testing to patient care throughout the nation with leukemia, lymphoma and solid tumors. He has headed up genomic strategies for one of the nation's largest medical diagnostic corporations and chaired committees for TCGA leadership. Dr. Penny received the College of American Pathologists' 2012 Distinguished Patient Care Award. The College of American Pathologists honored Dr. Penny for his extensive scientific translational research to accelerate the adoption of molecular pathways and associated therapies into the field of pathology and oncology to improve the lives of cancer patients. In 2011, the AZ BioIndustry Association honored Dr. Penny with the Jon W. McGarity Leadership Award for his vision in advancing cancer personalized medicine and success in leading the industry.

Dr. Penny received his B.S., M.S., Ph.D. (Genetics) and M.D. from the University of Arizona and then went on to receive his pathology training at Harvard's Brigham & Women's Hospital in Boston, Massachusetts, where he served as Chief Resident and completed fellowships in hematopathology and surgical pathology. Dr. Penny currently is an associate professor at the University of Michigan. Dr. Penny's contributions include a textbook in oncology, publication of articles and leadership roles in laboratory management.

LYNNE RAINEN, PH.D.

Scientific Director, PreAnalytiX GmbH, Becton Dickenson

Lynne Rainen, Ph.D., Scientific Director, PreAnalytiX GmbH, is responsible for scientific affairs for PreAnalytiX PAXgene® products. Her areas of technical expertise include immunochemistry, molecular diagnostics, and separation technology, and she has served as Chairholder of the CLSI Committee on Handling, Transport, and Storage of Specimens for Molecular Methods.

Prior to joining BD in 1996, she served in technical leadership positions for Baxter Travenol, Millipore Corporation, and Johnson and Johnson. She has been the Scientific Director of PreAnalytiX GmbH, since 1999.

Lynne received a B.S. in Chemistry from the University of Missouri, a Ph.D. in Biophysics from the University of Houston, and was an NIH post-doctoral fellow at Tufts University School of Medicine

JAMES A. ROBB, M.D.

Leidos Biomedical Research Consulting Pathologist, the National Cancer Institute's US-Latin America Cancer Research Network (US-LACRN); Lead for Pathology Committee, Qualifying Pathologist for NCI's The Cancer Genome Atlas (TCGA)

Dr. James Robb is currently Leidos Biomedical Research Consulting Pathologist for the NCI's US-Latin America Cancer Research Network (US-LACRN) – Lead for Pathology Committee, Qualifying Pathologist for NCI's The Cancer Genome Atlas (TCGA) program and for site visits of TCGA biospecimen collection sites, member of the College of American Pathologists Diagnostic Intelligence Health IT committee, Biomatrica, Inc. - Scientific Advisory Board member, and consulting pathologist for Strategic Visions In Healthcare, Inc.

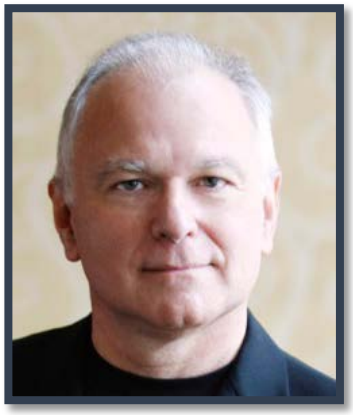
Past: B.A. in theoretical physics (CU), graduate school in astrogeophysics (CU), medical school (CU, 1956), intern and resident in pathology at Yale University Medical Center, Senior Surgeon at NIH in US Public Health Service with Honorable Discharge, Tenured Professor of Pathology at University of California San Diego (UCSD), Staff Pathologist and Director of Cytopathology and Molecular Pathology at Scripps Clinic La Jolla, Associate Director of Pathology and Director of Anatomic and Molecular Pathology – Cedars Medical Center Miami, and Medical Director of the HCA East Florida Division's integrated 14 laboratory system (IRL).

Past National Responsibilities: College of American Pathologists Board of Governors (CAP, 2005-9/2011), Member of US HHS HITSP/ANSI Biosurveillance Standards Committee for the Electronic Health Record (EHR), member HHS SACGHS Genetic Testing Oversight Taskforce, National Cancer Institute's (NCI) Lead Pathologist for their Community Cancer Center Program (NCCCP), and Consulting Pathologist in their Office of Biospecimen and Biorepository Research (OBBR).

KURT A. SCHALPER, M.D., PH.D.

Associate Research Scientist in Pathology: Department of Pathology, Yale School of Medicine

"In situ measurement of tissue biomarkers for companion diagnostics in cancer". Dr. Schalper is trained as cell biologist and surgical pathologist. His research is focused on measuring tissue biomarkers including proteins and nucleic acids; and test their potential for use as companion diagnostics in cancer. Dr. Schalper is currently working on the *in situ* measurement of diverse protein targets and mRNA transcripts in human breast and lung carcinoma samples using automated quantitative fluorescence and novel RNA hybridization techniques. These methods provide increased sensitivity, specificity and reproducibility. More quantitative approaches could open new opportunities for biomarker discovery and patient selection for anti-cancer treatments, an essential component of personalized cancer medicine.



JARED N. SCHWARTZ, M.D., PH.D.

Associate Research Scientist in Pathology: Department of Pathology, Yale School of Medicine

Dr. Jared N. Schwartz is a Pathologist, board certified in Anatomic and Clinical Pathology with subspecialty boards in Medical Microbiology and Cytopathology. He currently is President Jared N. Schwartz MD, PhD LLC. From Dec 2009 to January 2014 he served as the first Chief Medical Officer of Aperio and then after an acquisition as the first CMO of Leica Biosystems retiring in January 2014. He was also a Consulting Professor of Pathology at Stanford University School of Medicine teaching residents medical leadership and management and participated in the new genomics course. 2010-2013.

He was a member of Presbyterian Pathology Group, LLC and served from 1981 to 2009 as Director of Pathology and Laboratory Medicine at Presbyterian Healthcare, Novant Health. Charlotte, NC. He is a graduate of Duke University M.D. (1973) and Ph.D. (1975) and completed his residency and fellowship training serving as Chief Resident in 1977. He has held numerous community leadership positions including Chief of the Medical Staff at Presbyterian Healthcare, President of the Mecklenburg County Medical Society, President of the Metrolina Lung Association, and President of Leadership Charlotte.

He was President of the College of American Pathologists from 2007-2009. Chairman of the North Carolina Medical Society's STD and AIDS Committee, Represented NC State Med Society on NC Governors Task Force on AIDS, Served on Board of Governors for 13 years of the College of American Pathologists. He was appointed to the Clinical Laboratory Improvement Advisory Committee by HHS in 2002 and was a member through 2009. He was a co-chair of the ASCO/CAP Guidelines on Her2 published in Jan 2007 in the Journal of Clinical Oncology and Archives of Pathology and Lab Medicine as well as the Guidelines for ER/PR published by same Guideline Committee.

Dr. Schwartz has given over a thousand lectures and media interviews on a variety of medical topics and has served on consensus groups for the Centers for Disease Control on setting national laboratory testing standards. He has represented the College of American Pathologists, testifying before Congress and at the White House on laboratory quality issues. He was appointed as Chairman of the College of American Pathologists Committee on National Laboratory Preparedness. He testified before Congress in May 2003 on SARS, and was interviewed on CNN's Dr's Housecall, during the Monkeypox outbreak. He has been on Good Morning America and CNN providing information on influenza and has given over 250 international media interviews.

Dr. Schwartz has received numerous awards including the NC Governor's award as an outstanding North Carolina volunteer, a Schley Lyons Circle of Excellence award from Leadership Charlotte, the National Association for Community Leadership Distinguished Leadership Award, and the Young Leader's Award and Outstanding Communicators Award for the College of American Pathologists. One of his most treasured awards is the Presbyterian Healthcare Nursing Award, which he received in 2000 for his "spirit, excellence and commitment to patient care". He is listed in Top Doctors in America and Marquis Who's Who in Medicine and Healthcare. In 2010 he was honored as "Pathologist of the Year" the highest honor recognized by the College of American Pathologists.

He currently serves on the Board of Directors of the Personalized Medicine Coalition (PMC) and the American Pathology Foundation. He is Chair of the Nominating Committee of the PMC and on the Program Planning Committee of the Annual Harvard Symposium on Personalized Medicine.

SHAWN SWEENEY, PH.D.

Associate Director, Translational Research, American Association for Cancer Research

Dr. Sweeney is a scientist, educator, and cyclist. As Associate Director of Translational Research at the American Association for Cancer Research (AACR), he manages the Clinical and Translational Cancer Research Committee (CTCRC) among other roles, including functioning as an internal scientific consultant, a liaison for scientific working groups, and is the project lead and a content developer for the AACR Cancer Progress Report series. The AACR CTCRC will be managing the activities of the redesigned AACR-FDA-NCI Cancer Biomarkers Collaborative, as well as other biomarker-related activities and initiatives. Prior to joining the AACR, Dr. Sweeney was a Research Associate in the Institute for Medicine and Engineering at the University of Pennsylvania. His over fifteen-year career in research focused on the role of the microenvironment in cardiovascular development and disease, as well as in tumor metastasis. Dr. Sweeney is also an adjunct Associate Professor of Medicine at the International University of the Health Science's School of Medicine. He firmly believes in the power of bicycles to transform individuals, neighborhoods, cities, countries, and ultimately the world.

W. FRASER SYMMANS, M.D.

Professor of Pathology, Director of Research Operations
University of Texas MD Anderson ~~Cancer~~ Center

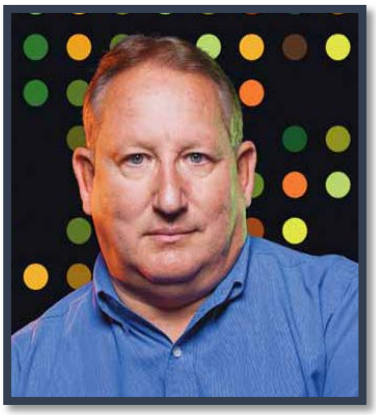
Dr. Fraser Symmans is Professor and Director of Research Operations in the Department of Pathology at MD Anderson Cancer Center, where he practices Breast Surgical Pathology and Cytopathology and also directs the Breast Cancer Pharmacogenomics Laboratory. He received his medical degree from the University of Auckland, New Zealand, completed his residency at Columbia University, New York, and fellowship at MD Anderson Cancer Center, Houston. Dr. Symmans joined the faculty of New York University Medical Center in 1993 and moved to MD Anderson Cancer Center in 2000. Dr. Symmans' research is focused on breast cancer, with specific emphasis on neoadjuvant (pre-operative) treatment trials for evaluation of chemosensitivity and development of diagnostic tests to select the most effective treatments for individuals with breast cancer. This research program has led to the development of predictive molecular tests that are currently being evaluated in a prospective clinical trial. His other ongoing research is addressing the effects of biopsy sample quality on genomic test results in order to establish appropriate best practices for clinical diagnostic use. Additional responsibilities include: Co-Chair for the Translational Breast Cancer Research Consortium, Director of Translational Research Program for the Alliance clinical trials group, and member of the Breast Cancer Steering Committee for the National Clinical Trials Group.

CARRIE TREADWELL, M.A.

Senior Director of Research, National Brain Tumor Society

Ms. Treadwell is Senior Director of Research for the National Brain Tumor Society (NBTS) and Managing Director of Defeat GBM Research Collaborative, a subsidiary of NBTS. She joined the organization in 1998. In these roles, Ms. Treadwell interacts with leading researchers and institutions to guide the development and success of key research initiatives, including overseeing the NBTS's grant process. Under her management the grant portfolio grew from $2 million to over $36 million and the research program expanded into the international market.

She serves as a patient advocate for the NCI's Brain Tumor SPORE Program and sits on the Jimmy Fund Visiting Committee. Ms. Treadwell is also a member of the Board of Directors of the Arizona-based nonprofits Students Supporting Brain Tumor Research and Gray Matters Foundation. Prior to working at NBTS she was the Director of External Research at the Massachusetts Society for Prevention of Cruelty to Children. Ms. Treadwell earned a BA degree from the College of the Holy Cross and an MA degree from Tufts.



JOE VOCKLEY, PH.D.

Chief Scientific Officer & Chief Operations Officer, Inova Translational Medicine Institute

Joe Vockley received a BS in microbiology from The Pennsylvania State University, a Ph.D. in Molecular Genetics from The University of Delaware and completed a 3 year clinical genetics residency and post-doctoral fellowship at The University of California at Los Angeles (UCLA)/Cedars Sinai Medical Center.

He has 30+ years of experience in genetic, genomic and bioinformatics research in academia, the biotechnology sector, pharmaceutical companies and the US Government.

While at GlaxoSmithKline, Dr. Vockley led a team of discovery scientists for diagnostic and therapeutic cancer gene targets from the Human Genome Sciences EST database and was key to starting a new genetic testing facility. Dr. Vockley was Vice President of Genomics at Gene Logic Inc. where he was responsible for building a biobank, a large-scale cancer gene expression database used for target discovery and a cancer diagnostic laboratory. While at Science Applications International Corporation (SAIC) he directed a bioinformatics tool development group and a laboratory group dedicated to the discovery and validation of molecular diagnostic targets.

At the National Cancer Institute, Dr. Vockley was the director of The Cancer Genome Atlas project.

He is currently the Chief Scientific Officer and Chief Operations Officer of the Inova Translational Medicine Institute.

Dr. Vockley is inventor on numerous patents for genetic discoveries, molecular genetic laboratory methods and bioinformatics tools and has published in the fields of metabolic disease and cancer.

ANTHONY WEEKS, MFA, MSW

Real-Time Illustration, Facilitation, and Documentary Video

Mr. Weeks is a documentary filmmaker, illustrator, and writer based in San Francisco, CA. He has more than fourteen years of experience working with senior-level product and strategy development teams to think visually and turn data into stories. As both an information designer and illustrator, Mr. Weeks collaborates with project teams to create visually-rich graphic chronicles and murals of their strategic conversations, often in real time, as a catalyst for facilitating dialogue, clarifying vision, and animating the process of ideation.

A select client list includes: American Heart Association, Baylor Medical Center, Best Buy, Deloitte, Exxon Mobil, Hewlett Packard, Intel, Kaiser Permanente, Kraft Foods, McKinsey and Co., Nestlé, Nokia, Pepsico, Philip Morris, Target, and the US Navy.

Mr. Weeks has illustrated a number of books, including the 2012 release by social media guru Howard Rheingold entitled Net Smart, published by MIT Press. In 2013, Mr. Weeks will be working with the Malaysian Prime Minister's office to author and illustrate a collection of books and materials about the need for creativity and innovation in education. Mr. weeks' documentary films have been screened at venues including the Angelus Film Festival (Los Angeles), Big Sky Documentary Film Festival, Dokufest (Kosovo), Honolulu International Film Festival, Hot Docs (Toronto), Sebastopol Documentary Film Festival, San Francisco Asian American International Film Festival, San Francisco Independent Film Festival, and the Thin Line Film Festival. Mr. Weeks was a 2009 award recipient from the Princess Grace Foundation (New York/Monaco), was selected as a Jury's Choice-First Prize winner in the 2010 Black Maria Film + VideoFestival, and won Honorable Mention for Outstanding Documentary in the 2010 Angelus film competition in Los Angeles. His film Imaginary Circumstances (2010) was an official selection of the New Filmmakers LA series, was named a 2010 winner of the CINE Golden Eagle Awards, and was screened at embassies and consulates abroad in 2011 as part of the US State Department's American Documentary Showcase. The film also won an Emmy in 2011 from the Academy of Television Arts and Sciences and won a student Academy Award in 2011 from the Academy of Motion Picture Arts and Sciences. Mr. Weeks is currently a partner in Dogpatch Films, a documentary media production company in San Francisco.

Mr. Weeks holds an MFA degree in documentary film and video from Stanford University, an MSW from Augsburg College (MN), and a BA from Grinnell College. Mr. Weeks was a 1997-98 Coro Fellow in Public Affairs in San Francisco.