NBDA WORKSHOP V

“The Ever-Promising but Elusive Surrogate Endpoint: What Will it Take?”

December 1st & 2nd 2014
THE FAIRFAX AT EMBASSY ROW HOTEL
2100 Massachusetts Ave, NW
Washington, DC 20008
http://www.fairfaxhoteldc.com/
NBDA WORKSHOP VI

“The Ever-Promising but Elusive Surrogate Endpoint: What Will it Take?”

December 1 - 2, 2014

WELCOME
Dear Colleague,

On behalf of our NBDA Team, Steering and Scientific Committees, welcome to the sixth in the NBDA’s series of workshops aimed at developing a deep understanding of why the biomarker field is fraught with failure. For those of you who have joined us at prior workshops, you know that our mission is bold (but doable): to enable the development of strategies (including standards and guidelines) to support an end-to-end process for biomarker development. Over the past months, we have examined in depth, the discovery, development and clinical delivery of biomarkers. This has been an extraordinarily complex process that considered all aspects of biomarker discovery, translation and clinical validation. What we learned in this process is being translated into actions that have the capacity to create the desired outcome - i.e., predictable end-to-end standards based processes that will support successful biomarker research and development.

This very brief background brings me to the current workshop. Throughout our diligence process, problems and issues surrounding the use of surrogate endpoints (SEs) in clinical trials has come up time and time again - and for good reason. Biomarkers that can successfully achieve the FDA’s definition of a SE (laboratory measurement or physical sign that can substitute for a clinically meaningful endpoint - i.e., direct measure of how a patient feels, functions, or survives) are, indeed, few in number. The current workshop will consider all aspects of the SE – its history, successes and failures. More important, we will re-look and rethink the SE in view of advances in the vast array of “omics” possibilities and advanced technologies that will theoretically lead to an entirely new era of precision medicine. Our goal is to agree on the barriers to achieving SEs currently and formulate the strategies and actions to support needed levels of evidence; and perhaps of more importance, converge on new approaches to SEs that could integrate advances in the molecular sciences, advanced technologies and entirely new approaches to transform the field in the future.

If you have attended our past workshops, you are familiar with the focus on conversations and both communicating/listening in all of the formats that we employ to build knowledge. We, by design, do not feature a large number of Power Point-centric presentation; but rather focus on large and small group discussions, panels and action groups. If you are participating on a panel, you will have a few moments to offer a brief presentation of 8-10 minutes (3-5 slides), but it is your thoughts and insights on the panel topic that are of high interest to the other panelist and attendees.

We have a reception/dinner following the first day of our work, and the workshop will close at 4:15 p.m. on Tuesday. There will also be some fun – and as always - we look forward to, changing the lives of patients by rethinking (perhaps starting on a road to reinvention) one of the most promising (but difficult in the extreme) concepts in the development of new therapeutic interventions.

Thank-you in advance for your contributions.

NBDA Leadership Team
Anna D. Barker, PhD, Director
George Poste, DVM, PhD, Interim Chief Science Officer
Carolyn Compton, MD, PhD, Chief Medical Officer
Kenneth Buetow, PhD, Director of Bioinformatics and Data Management
Anne Marie Geary, Administrative Director

Our Many Advisors and Collaborators
NBDA WORKSHOP VI

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AGENDA
MEETING ROOM – BALLROOM

MEETING CO-CHAIRS: Anna D. Barker, Ph.D., NBDA and Arizona State University
George Poste, D.V.M., Ph.D., NBDA and Arizona State University
Carolyn Compton, M.D., Ph.D., NBDA and Arizona State University
Federico Goodsaid, Ph.D., Vertex Pharmaceuticals

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

8:00a.m. – 8:50a.m. Breakfast - Salon

9:00a.m. – 9:10a.m. Workshop Background – Why Rethink Surrogate Endpoints? Why Now?
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

9:10a.m. – 9:25a.m. Workshop Process and Outcomes
Robert Mittman, MS, MPP

Brief summary of the process for the next two days: this workshop will initially focus on a dialogue on surrogate endpoints – what has changed and likely to change further? What does evidentiary standards for surrogate endpoints mean in today’s environment? Is it time to rethink the concept through the lens of 21st Century biomedical science? However, as is the case with all of the NBDA workshops, the operative word is “working”; so all that we do to explore the problems and potential solutions will be employed by our Action Groups that will meet tomorrow to deliberate and make recommendations for action.
Surrogate biomarkers (surrogate endpoints) are the “holy grail” of biomarkers. FDA has created a number of innovative approaches to use surrogate endpoints (SE) in trials; but the reality is that there are numerous reasons that SEs to fail prove to predict a specific clinical outcome. This is likely to get worse as we intensify our focus on creating new molecularly-based interventions for complex diseases - such as cancer, Alzheimer’s disease, diabetes, cardiovascular and psychiatric diseases. Given the complexity of these and many other diseases, and the emerging “tsunami” of “omics” data, will it be more (or less) difficult to achieve the original vision for surrogate endpoints in phase III trials? Creating the evidentiary standards today for SEs is a major hurdle. Is it the job of the affected communities to address this challenge? Are there new, innovative high-value SE options for the future?

Overall the expectation that SEs would greatly speed up the clinical trials process for interventions where the real clinical endpoint is survival (or the data needed cannot be collected) has rarely been realized. Are there real barriers to creating the evidence needed for regulatory review of a clinical trial that employs a SE? Work together to identify the real barriers in the field?
11:40 a.m. – 12:00 a.m. Reflections on the Future of SEs from a FED Who Decamped to the Private Sector
Federico Goodsaid, Ph.D.
Vice President for Strategic Regulatory Intelligence, Vertex Pharmaceuticals
SEs are a great idea - with potential to save real time and ultimately reduce the cost of clinical trials. The FDA recognized this concept a number of years ago and has created a number of approval pathways that are enabled by SEs. However, a number of challenges remain for all concerned - most notably in processes to reach consensus on required types and levels of evidence. How do we work together to address these challenges now and in the future?

12:00 p.m. – 1:00 p.m. LUNCH - Salon

1:00 p.m. – 1:30 p.m. The Surrogate Endpoint: Past - Present - Future
Robert J. Temple, M.D.
Deputy Center Director for Clinical Science,
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
The use of surrogate endpoints to enable the evaluation of interventions in clinical trials dates from the mid-1990s. From a regulatory standpoint the SE is viewed as a marker (laboratory measurement or a physical sign) that can substitute for the real clinical endpoint (how a patient feels, functions or survives). A correlate is not a surrogate - which continues to present significant challenges to both those who design and implement clinical trials and for the regulatory agencies. Where are we in the quest for evidentiary standards for SEs and where might the science take us in the future?

1:30 p.m. – 1:45 p.m. Questions/Discussion

1:45 p.m. – 3:00 p.m. Panel Discussion: Where Have All the Surrogate Biomarkers Gone?
Some biomarkers have been successfully developed to the point of approval as a surrogate endpoint. Many others have failed. And still others are a work in progress (some could represent new thinking or new direction for the field). This panel will make brief comments on their "case", discuss the underlying reasons for success or failure, the type and level of evidence needed for approval and/or why it failed. The panel will engage in a conversation with the other panelists and audience on "lessons learned": Two success stories; a work in progress and a cautionary tale.

PCR - A (SE) High-Value Outcome from the ISPY-2 Trial
Laura van‘t Veer, Ph.D.
Professor, Helen Diller Family Comprehensive Cancer Center
Angela and Shu Kai Chan Endowed Chair in Cancer Research; University of California, San Francisco
KIM-1 - A "Qualified Biomarker" for Kidney Injury - Is it a Potential SE

Joseph V. Bonventre, M.D., Ph.D.
Director, Chief, Renal Division;
Harvard Medical School
Samuel A. Levine Professor of Medicine, Brigham and Women’s Hospital

SE Successes for Prostate Cancer

Howard Scher, M.D.
Chief, Genitourinary Oncology Service
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SE Lessons Learned from Cardiovascular Disease and Other Diseases

Anna D. Barker, Ph.D.
Co-Director, Complex Adaptive Systems
President and Director, National Biomarker Development Alliance
Professor, School of Life Sciences, Arizona State University

3:00p.m. – 3:15p.m.  Break

3:15p.m. – 3:45p.m.  Re-Looking and Prioritizing Current Barriers to Achieving Successful SEs - Explore Potential Solution(s)
Small Group Discussion

3:45p.m. – 4:15p.m.  Converging on the Barriers – “Rethinking the Possible” for SEs
Large Group Discussion

4:15p.m. – 4:35p.m.  Systems Approaches to Rethinking SEs - Through the Lens of Angiogenesis

William Li, M.D.
President, Medical Director, and Co-Founder
Angiogenesis Foundation

A change in the state of angiogenesis is one of the "hallmarks" of cancer, and indeed alteration(s) in this very basic physiologic system impacts across a number of disease types. Has biomedical science evolved to a point that it is possible to employ systems thinking as a lens to view future SEs? Blue sky - could such thinking produce SEs that more appropriately and accurately reflect real clinical endpoints?

4:35p.m. – 4:45p.m.  Questions/Discussion

4:45p.m. – 5:00p.m.  Summing Up Today, Plans for Tomorrow

6:00p.m.  Reception – Salon

6:30p.m.  Dinner – Capital Room
THE NATIONAL BIOMARKER DEVELOPMENT ALLIANCE (NBDA)
WORKSHOP VI
DECEMBER 1-2, 2014

“THE EVER-PROMISING BUT ELUSIVE SURROGATE ENDPOINT: WHAT WILL IT TAKE?”*

WORKSHOP AGENDA

December 2, 2014  (Day 2)
Meeting Room – Ballroom

7:30a.m. – 8:20a.m.  Breakfast - Salon

8:30a.m. - 8:45a.m.  Recap from Day 1 - Plan for Today
Robert Mittman, MS, MPP

8:45a.m. – 9:15a.m.  “Let’s Revisit and Perhaps Reinvent the Surrogate Endpoint”
Donald Berry, Ph.D.
Berry Consultants, LLC, Professor, Department of Biostatistics
MD Anderson Cancer Center

With some exceptions, given the rapidly changing landscape of biomarker science and the difficulties associated with the development of biomarkers per se, is the SE likely to remain elusive or is this an era for real change? In that regard, how good are our REAL surrogate endpoints today in complex diseases like cancer? If SEs are the key to achieving precision (personalized) medicine, what might such biomarkers look like in the future and how/when might you prove that you have such a prize? How might this new generation of SEs change clinical trials?

9:15a.m. – 9:30a.m.  Discussion

9:30a.m. – 9:45a.m.  Break

9:45a.m. - 11:00a.m.  Panel Discussion: Predictions are Hard - Especially About the Future: What Changes/Actions/Discoveries could be Transformative in Discovering and Developing Robust SEs (Perspectives from the FDA, Private and Academic Sectors)

The world needs great ideas to better deal with the SE issues and problems. Each of these experts thinks a great deal about the challenges that surround SEs. What ideas (or your favorite/best idea) could have a major impact in identifying, measuring and developing new approaches to achieve accurate SEs.
Are there combinations that could capture sufficient numbers of “casual” pathways? Are there technologies on the horizon that could directly tie biomarkers to real clinical endpoints? Bring your ideas!

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Patrick C. Roche, Ph.D.
Senior Vice President, Research and Development
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11:00a.m. - 12:00p.m.  A Trans-Sector Roundtable Discussion: The Future of SEs: What Changes Would Most Benefit Your Respective Sector/Community?

For example, would we derive greater benefit from a trans-sector effort today to develop/better define the type and level of evidence really needed for SEs (by disease class and context of use for the marker); or would we be better served to turn our attention to rethinking the whole concept in the light of advances in the molecular sciences and advanced technologies? Or both? (All ideas thinking/rethinking welcome)

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Kenneth D. Noonan, Ph.D.
Venture Partner, Advanced Technology Ventures
Senior Advisor, L.E.K. Consulting LLP
European Biopharmaceuticals & Life Sciences Practice
12:00 p.m. – 12:45 p.m. LUNCH - Salon

1:00 p.m. – 2:45 p.m. Work Groups I and II Deliberate, Decide and Declare

We will pursue our earlier discussions through two NBDA Action Groups. The focus for the Action Groups (AGs) will be:

AG – 1 – This group will begin with the assumption that the current regulatory definition for SEs (and guidance documents) will continue without change. Given this assumption, using the NBDA's big six strategic elements to guide biomarker discovery and development (the right clinical question – context of use, a robust experimental design, appropriate numbers of high quality samples, robust technology standards, high quality data and appropriate analytics), and in view of the state of biomarkers science today, define the type and level of evidence needed for regulatory approval (generally within the context of a clinical trial). We will embellish this change at the meeting!

AG – 2 – This group will focus on identifying and exploring new ideas and approaches to the discovery and development of surrogate endpoints. Your group can either assume the current FDA definition and respective FDA guidance for an SE or redefine the surrogate concept. Capture the results of your brainstorming and offer recommendations that the NBDA can act on.

2:45 p.m. – 3:45 p.m. Work Group Reports and Assembly of Recommendations

3:45 p.m. – 4:00 p.m. NBDA Plans for Implementation of Workgroup Recommendations

4:00 p.m. – 4:10 p.m. Closing Comments – Meeting Ends
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TARGETED OUTCOMES
Workshop VI will focus on the surrogate endpoint (SE) concept; its history, successes and failures and what advances in 21st century biomedical research may portend for the future of this very promising “class” of biomarkers. The workshop will proceed from identification of the barriers that have led to numerous failures in late phase clinical trials (overall agnostic in terms of disease) to consideration of potential solutions and even re-thinking and perhaps re-inventing the SE.

Although we begin with careful analysis of problems, the NBDA is about action(s) and bringing transformative positive change to the field of biomarkers – in this case, surrogate markers. We view this initial exploration of the SE landscape the beginning of a process, and in that regard, we anticipate achieving the following outcomes:

- Based on history inclusive of successes/failures and FDA’s regulatory paths that employ SEs, to fully understand the state of SEs today. (Are they achieving the original vision for the concept? If not why?)
- Identify and prioritize the major barriers that are currently negatively affecting the development path and ultimate fate of SEs.
- Fully understand these barriers from the standpoint of the affected sectors.
- Use selected case studies to understand what has worked and what has not, and where possible, determine why.
- Begin the process to identify potential solutions – or at least pathways to solutions.
- Insofar as possible in this first exploration of the SE, focus on recommendations that give due considerations to alternative paths to improving the success of SEs:
  (1) Given that the SE concept doesn’t change – what types and level(s) of evidence will be needed (recognizing that this framework will vary by disease and context of use);
  (2) Assuming that the current SE concept would improve significantly it re-thought and potentially re-invented - with due consideration to the molecular biosciences - what would constitute next steps.
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STEVEN D. AVERBUCH, M.D.
Vice President of Translational Clinical Development and Pharmacodiagnostics, Bristol-Myers Squibb Company

Dr. Averbuch is Vice President, Translational Clinical Development & Pharmacodiagnostics, Bristol-Myers Squibb. In this role, Dr. Averbuch is responsible for overseeing development contributions to translational research activities across the oncology pipeline and the execution of external clinical collaborations for the company's immuno-oncology pipeline. Dr. Averbuch also leads the Pharmacodiagnostics Center of Excellence, whose mission is to drive biomarker strategy, optimize biomarker knowledge and tools across all of R&D and execute on the integrated co-development and co-commercialization of diagnostic tests as companions to Bristol-Myers Squibb medicines.

Dr. Averbuch joined Bristol-Myers Squibb in 2006. Prior to his current role, he co-led the Oncology early strategy team and he was the executive sponsor for Oncology Transition Teams for the execution of Phase 2 Oncology programs. He has made significant Global Clinical Research contributions to business development and he has participated in multiple successful licensing and acquisition deals.

Dr. Averbuch previously held positions at Merck Research Laboratories, AstraZeneca, and Mount Sinai School of Medicine. He received his M.D. and Internal Medicine training from the University of Illinois, Chicago and his Medical Oncology training at the National Cancer Institute in Bethesda, Maryland.

Dr. Averbuch has authored over 60 peer reviewed publications and book chapters and he is a co-author on one patent. He is currently on the Personalized Medicine Coalition Board of Directors, the Steering Committee of the National Biomarker Development Alliance, the Advisory Board for the University of Kansas Institute for Advancing Medical Innovation, and he is a member of the American Society of Clinical Oncology and the American Association for Cancer Research having served on multiple committees for both organizations. Dr. Averbuch is the 2014 recipient of the University of Illinois, College of Medicine Distinguished Alumnus Award.

ANNETTE BAKKER, PH.D.
President and Chief Scientific Officer
Children's Tumor Foundation

Annette Bakker, the Children's Tumor Foundation's President and Chief Scientific Officer, holds a PhD in cell biology from the University of Antwerp. Her past experience includes serving as Oncology Group Leader at Janssen Pharmaceutica, and postdoctoral fellowships at Yale University and La Salpetriere, Paris.

Most recently, Dr. Bakker lived in Siena, Italy and served as the Oncology Head for Siena Biotech, where she created an oncology program from the ground up and managed a large oncology research initiative at the University of Verona.

Dr. Bakker's research has been internationally recognized by more than 30 peer-reviewed papers, patents, and awards, and she has extensive experience liaising and negotiating with biotechnology and pharmaceutical companies.

In her role at the Children's Tumor Foundation, Dr. Bakker will continue to seek innovative breakthroughs in drug development and will effectively implement her personal network of world class centers of excellence to advance neurofibromatosis research and attract top scientists and clinicians to the field of NF.

Dr. Bakker is originally from Belgium, speaks four languages (English, French, Dutch, and Italian), and now lives in Brooklyn, New York with her partner, Armelle Pindon, and their two children, Camille and Brice.
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 the 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 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. Dr. Barker 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.
J. CARL BARRETT, Ph.D.
V.P. of Translational Science in Oncology, AstraZeneca

Dr. Carl Barrett is Vice President of Translational Science in the Oncology Innovative Medicines Unit at AstraZeneca Pharmaceuticals. His responsibility is to develop and execute biomarker strategy and translational sciences efforts to support compound development from research through early and full development in oncology. Previously, he was Global Head of Oncology Biomarkers and Imaging in Novartis Oncology Translational Medicine. Prior to joining Novartis, Dr. Barrett was the founding Director of the NCI Center for Cancer Research. Prior to joining NCI, Dr. Barrett was the Scientific Director at the National Institute of Environmental Health Sciences where his efforts focused on integrating new approaches to toxicology by utilization of molecular approaches of toxicogenomics, molecular toxicology, and the Environmental Genome Project. He received his Ph.D. degree in Biophysical Chemistry from Johns Hopkins University, has published over 600 research articles, and is a member of the Johns Hopkins University Society of Scholars, the Ramazini Foundation, an honorary member of the Japanese Cancer Association. His most significant accomplishment was the cloning of the BRCA1 gene at NIH and participating at AZ in the development of Olaparib for these women.

DONALD A. BERRY, Ph.D.
Founder and Senior Statistical Scientist, Berry Consultants, LLC
Professor, Department of Biostatistics
The University of Texas M.D. Anderson Cancer Center

Dr. Berry is a professor in the Department of Biostatistics of The University of Texas M.D. Anderson Cancer Center. He was founding chair of this department in 1999 and founding head of the Division of Quantitative Sciences, including the Department of Bioinformatics and Computational Biology, in 2006. Dr. Berry received a Ph.D. degree in statistics from Yale University and previously served on the faculties of the University of Minnesota and Duke University. He held endowed faculty positions at Duke University and at M.D. Anderson. Since 1990 Dr. Berry has served as a faculty statistician on the Breast Cancer Committee of the Cancer and Leukemia Group B, a national oncology group. He has designed and supervised the conduct of many large U.S. intergroup trials in breast cancer. A principal focus of Dr. Berry’s research is the use of biomarkers in cancer and other diseases for learning which patients benefit from which therapies, based on genomics and phenotype. He designed and is co-PI of I-SPY 2 (www.ispy2.org), a Bayesian adaptive platform clinical trial in high-risk early breast cancer whose goal is matching experimental therapies with patient subsets defined by tumor molecular characteristics. Since 1997 Dr. Berry has served on the NCI’s PDQ Screening and Prevention Board, for which he received the NIH Award of Merit in 2010. Through Berry Consultants, LLC, he has designed many innovative clinical trials for pharmaceutical and medical device companies and for NIH cooperative groups. Dr. Berry is the author of several books on statistical methodology and over 300 published articles, including first-authored articles in the major medical journals. He has been the principal investigator for numerous research grants from the NIH and the National Science Foundation and is a fellow of the American Statistical Association and the Institute of Mathematical Statistics.
JOHN (JACK) C. BLOOM, VM.D., Ph.D.
President, Bloom Consulting Services, LLC
Consultant, Office of the Center Director, U.S. Food and Drug Administration
Adjunct Professor of Pathology, Purdue University and University of Pennsylvania

Dr. Bloom holds a BS degree in biology from the University of Pittsburgh and doctorates in veterinary medicine and experimental hematology from the University of Pennsylvania. He completed his postdoctoral training at Jefferson Medical College in hematology/oncology and served on the faculty of the University of Pennsylvania School of Veterinary Medicine as chief of clinical laboratory medicine before joining Smith Kline & French Laboratories as associate director of pathology. He later joined Lilly Research Laboratories as head of clinical pathology, in the Toxicology Division, and subsequently moved to the Medical Division, where he established the departments of Clinical Laboratory Medicine, Experimental Medicine, and Clinical Diagnostic Services. As Distinguished Medical Fellow (Executive Director), Diagnostic and Experimental Medicine, Dr. Bloom was responsible for routine laboratory, ECG, imaging and specimen banking support for global clinical development, and novel clinical biomarker discovery, validation, and application in the Division of Translational Medicine and Pharmacogenomics. He is past president of the American Society for Veterinary Clinical Pathology; has authored several manuscripts, chapters, reviews, and texts on toxicology and clinical biomarkers in drug development; and served on committees sponsored by the National Academy of Sciences, Institute of Medicine, Society of Toxicologic Pathology, and PhRMA. Upon his retirement from Lilly in 2009 Dr. Bloom established Bloom Consulting Services, LLC, and has been appointed as a consultant to the Office of the Center Director, FDA, for which he serves on drug advisory committees and on special FDA/NIH project assignments. Dr. Bloom serves on several scientific advisory committees for pharmaceutical, diagnostic, and pharmaceutical services companies and holds adjunct academic appointments at the University of Pennsylvania and Purdue University.

JOSEPH V. BONVENTRE, M.D., Ph.D.
Director, Chief, Renal Division; Samuel A. Levine Professor of Medicine, Brigham and Women's Hospital; President, American Society of Nephrology; Professor, The Harvard Stem Cell Institute, Harvard Medical School

Dr. Bonventre is Chief of the Renal Unit and Director of the Bioengineering Division at Brigham and Women's Hospital and has had a long-standing interest in various aspects of cellular injury and repair mechanisms in the kidney with a special emphasis on the role of inflammation, biomarkers and stem cells. He has established the origin of the epithelial cells that repair the kidney after injury as dedifferentiated surviving proximal tubule cells. He was the first to describe the role of proximal tubule cell cycle arrest in the maladaptive fibrosis that can occur after severe injury leading to chronic kidney disease. He discovered and characterized Kidney Injury Molecule-1 (KIM-1) as the most highly upregulated protein in the proximal tubule after injury to the kidney of various types. Kim-1 expression converts the proximal tubule cell to a phagocyte. Kim-1 is also a very sensitive and specific biomarker of proximal tubular injury in a variety of species including man and has been qualified by the FDA and European Medicines Agency as a sensitive and specific marker for kidney injury in preclinical studies of nephrotoxicity. He has created iPS cells from patients with adult onset polycystic kidney disease and are working on ways to differentiate cells down the kidney lineage.
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.

CHRISTINE M. GATHERS, MS, RAC
Senior Director, Regulatory Affairs-Diagnostics, Eli Lilly and Company

Christine Gathers, Senior Director of Regulatory Affairs-Diagnostics, has worked at Eli Lilly and Company for more than 25 years and has had a multitude of experiences spanning the pharmaceutical value chain while at Lilly. Her work experiences include: Manufacturing, Product Development, Medical, Business Development, Strategic Asset Management, US Brand Planning, Sales, Lilly Research Labs Strategy, Diagnostic and Experimental Medicine, Tailored Therapeutics Group Leader, and Regulatory. Biomarkers have been a focus for her since working in Diagnostic and Experimental Medicine where she was responsible for clinical biomarker operations at Lilly. In Regulatory, Christine provided support for numerous drug efforts in clinical development across multiple therapeutic areas where surrogate markers are a necessity. In her current regulatory role, Christine is responsible for regulatory support across Lilly’s portfolio of companion diagnostics. This support includes collaborating with diagnostic manufacturers to integrate the development and registration of the diagnostic with that of the drug product. She is also engaged in a number of external policy efforts that support Lilly’s commitment to deliver improved outcomes for individual patients through tailored therapeutics. Christine has a BS in Chemical Engineering from Case Western Reserve University, an MSc in Pharmacology with thesis from Butler University, an MSc in Biology from Purdue University as well as a Regulatory Affairs Certification (RAC).
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.

FEDERICO GOODSaida, PH.D.  
Vice President for Strategic Regulatory Intelligence, Vertex Pharmaceuticals

Dr. Goodsaid's work at Vertex is focused on early and effective interaction and collaborations on exploratory and product biomarkers with regulatory agencies. He was previously associate director for operations in genomics and biomarker qualification coordinator at the Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, FDA, where he worked on the regulatory application and development of genomics and biomarkers. His BA degree was in biochemistry and biophysics from the University of California, Berkeley, and his Ph.D. degree in molecular biophysics and biochemistry is from Yale University. Dr. Goodsaid was a postdoctoral fellow at Cornell University and at Washington University in St. Louis. Before he joined the FDA, he was senior staff scientist at Applied Biosystems and lead for the Molecular Toxicology Group at the Schering-Plough Research Institute.
GARY B. GORDON, M.D., PH.D.
Vice President, Global Oncology Development, AbbVie, Inc.

In Dr. Gordon current role, he oversees development of AbbVie’s oncology projects. He joined AbbVie in April 2003 and assumed his current role in July 2004. Prior to joining AbbVie, Dr. Gordon was chief scientific officer and vice president of clinical affairs at Ovation Pharmaceuticals from 2001 to 2003. In this role, he helped obtain funding and introduce five therapies to the market.

He entered the pharmaceutical industry in 1995 when he joined the G.D. Searle division of Monsanto, which eventually became part of Pharmacia. Dr. Gordon’s responsibilities included programs related to COX-2 inhibitors for the prevention and treatment of cancer, the development of angiogenesis inhibitors, and involvement in the hematopoietic and cancer immunization programs. He also helped establish a tissue bank project and a discovery-clinical interface program.

Dr. Gordon is certified in internal medicine and medical oncology through the American Board of Internal Medicine. His professional memberships include the American Association for Cancer Research and the American Society of Clinical Oncology. Dr. Gordon began his career at the Johns Hopkins University (JHU) School of Medicine as a medical student and also worked as an associate professor of medical oncology.

Dr. Gordon received a BS degree in biochemistry from the State University of New York at Stony Brook, and his M.D. and Ph.D. degrees in pharmacology and experimental therapeutics from JHU.

STEVEN I. GUTMAN, M.D., MBA
Strategic Advisor, Myraqa, Inc.

Dr. Gutman is a board-certified pathologist with a BS degree from The Ohio State University, an M.D. degree from Cornell University Medical College, and an MBA degree from the State University of New York at Buffalo. He completed residency training in anatomical pathology at Cornell and clinical pathology at the Mayo Clinic. After 10 years of experience as a clinical pathologist and chief of laboratory service at the Buffalo Veterans Administration Medical Center, he joined the Division of Clinical Laboratory Devices at FDA as a medical officer in 1992. Dr. Gutman was promoted to division director in 1993. In November 2002, he became director of the Office of In Vitro Diagnostic Device Evaluation and Safety, a new office in the FDA’s Center for Devices and Radiological Health. From January 2009 to December 2009 he worked as founding faculty of the University of Central Florida, College of Medicine. In January 2010 Dr. Gutman became an associate director of the BlueCross BlueShield Association Technology Evaluation Center. In January 2013 he became strategic advisor for Myraqa, Inc., a regulatory consulting firm specializing in in vitro diagnostic devices.
PETER KUHN, PH.D.
Dean’s Professor of Convergent Sciences; Director, Southern California Physics Oncology Center; Co-Director, the BRIDGE, University of Southern California

Dr. Kuhn is a scientist and entrepreneur with a career long commitment in personalized medicine and individualized cancer patient care. He is focused on the redesign of cancer care.

Dr. Kuhn is the Dean’s Professor of Convergent Science at USC, a co-founder of the BRIDGE @ USC and director of the Southern California Physics Oncology Center. His research is shedding new light at how cancer spreads through the body. This new science will lead to a personalized care strategy that is biologically informed and clinically actionable.

Leveraging the laboratory’s fluid biopsy technology innovation, the Southern California Physics Oncology Center is advancing daily the forefront of both improving healthcare effectiveness for cancer patients by providing drug guidance and increasing our understanding of cancer as a disease in each individual patient. The technology developed in the academic laboratory has been licensed to Epic Sciences to bring to market high precision diagnostic products.

Dr. Kuhn is a physicist who trained initially at the Julius-Maximilians-Universität Würzburg Germany, before receiving his Masters in Physics at the University of Albany, Albany, NY in 1993 and his Ph.D. in 1995. He then moved to Stanford University where he later joined the faculties of Medicine and Accelerator Physics. From 2002 to 2014 he established a translational science program at the Scripps Research in La Jolla, CA that brought together over forty scientists from basic, engineering and medical sciences to work on understanding the spread of cancer in the human body. He has published over 200 peer scientific articles and patents as a result of his research.

The University of Southern California (USC) recruited Dr. Kuhn in 2014 to advance the next frontier of human scale science that can improve the human condition. At the convergence of biological, engineering and medical sciences will we learn how major diseases from cancer to neurodegenerative to autoimmune diseases evolve in and how we can improve the outcomes for patients.

GABRIELA LAVEZZARI, Ph.D., M.B.A.
Assistant Vice President, Scientific & Regulatory Affairs, Pharmaceutical Research & Manufacturers of America (PhRMA)

Gabriela Lavezzari, Ph.D., M.B.A. joined PhRMA in July 2012 as Assistant Vice President, Scientific Affairs. In this role, Dr. Lavezzari is the primary staff lead for a variety of strategic initiatives aimed at establishing PhRMA as a valuable source of scientific expertise in innovative biopharmaceutical research and development within the Scientific & Regulatory Affairs (S&RA) division of PhRMA. Dr. Lavezzari brings to PhRMA over ten years of combined research experience in the government and industry, with multi-disciplinary expertise in Personalized Medicine and Regulatory Science.

Prior to joining PhRMA, Dr. Lavezzari served as Director Extramural Development at the Medco Research Institute, a subsidiary of Medco Health Solutions, where she led clinical utility and cost-effectiveness research to create value-based reimbursement decisions for a variety of diagnostics products across different therapeutic areas. Prior to Medco, Dr. Lavezzari spent few years at Theranostics Health, a proteomic-based diagnostics company where she led the laboratory operations and the oncology product development. Prior to Theranostics, Dr. Lavezzari worked at Social Scientific Systems where she provided scientific support to and managed multiple Adult Clinical Trial Group (HIV/AIDS), laboratory science, laboratory technical and specialty laboratory committees, subcommittees and working groups.

In addition to his experience in the industry, Dr. Lavezzari spent almost years in research at the National Institutes of Health (NIH), National Institute of Neurological Disorder and Stroke (NINDS) and at Georgetown University, where she completed her post-doctoral training in Neuroscience.

Dr. Lavezzari received her Ph.D. in Biological Sciences from University of Milano (Italy), and has received her MBA from the New York Institute of Technology (NYIT, NY).
Specifically, Dr. Lee is responsible for scientific, programmatic, and operational oversight of CSSI's broad scientific portfolio (~$190.2 million in FY12) carried out by more than 40 staff members within offices that include the Office of Cancer Nanotechnology Research (OCNR), Office of Cancer Clinical Proteomics Research (OCCPR), and the Office of Physical Sciences-Oncology (OPSO). Programs developed and launched to date by Center staff includes the Innovation Molecular Analysis Technologies (IMAT), the NCI Alliance for Nanotechnology in Cancer, The Cancer Genome Atlas (TCGA), Clinical Proteomic Tumor Analysis Consortium (CPTAC), Physical Sciences-Oncology Centers (PS-OC), Provocative Questions (PQ), and Cancer Target Discovery and Development (CTD²) network. These exploratory initiatives focus on the integration of advanced technologies, trans-disciplinary approaches, infrastructures, and standards, to accelerate the creation of publicly available, broadly accessible, multi-dimensional data, knowledge, and tools to empower the entire cancer research continuum for patient benefit.

Prior to joining the NCI, Dr. Lee's research experience involved elucidating mechanisms of age-related diseases by combining cell biology, molecular biology, and engineering approaches to understand various cellular reactions to external stimuli. He has co-authored over a dozen papers, four book chapters, and one book on the role of Rho GTPase-mediated nuclear and cellular mechanical responses to fluid flow and 3D culture and demonstrated their potential impact in diseases such as progeria and cancer. He continues to advance understanding in this area by serving as adjunct assistant professor at Johns Hopkins University, where he earned his bachelor's degree in biomedical engineering and Ph.D. degree in chemical and bimolecular engineering. Dr. Lee also holds an appointment at the Department of Veterans Affairs (VA) Medical Center, Washington D.C. as a research health scientist collaborating with clinicians on patient-centered outcomes research through analysis of existing VA datasets. He is an active member of the American Association for Cancer Research (AACR), Biophysical Society, American Society of Mechanical Engineers (ASME), the American Society for Cell Biology, Tau Beta Pi, and the Innovation Policy Forum of the National Academies Board on Science, Technology, and Economic Policy.
William W. Li, M.D.,
President, Medical Director, and Co-Founder, Angiogenesis Foundation

Dr. William W. Li is President, Medical Director, and co-founder of the Angiogenesis Foundation, a nonprofit organization that is re-conceptualizing global disease fighting. A protégé of angiogenesis pioneer Dr. Judah Folkman, Dr. Li has been leading international efforts to develop effective therapeutic strategies based on angiogenesis for the past three decades. His work leading to the development of more than two dozen antiangiogenic agents used in oncology, ophthalmology, and in surgery and wound care.

Under his leadership, the Angiogenesis Foundation has developed a unique social enterprise model that drives innovation through national and international collaborations with academia, government, advocacy associations, and industry. Based on this model, the Foundation is now working to bring about the next generation of therapies of angiogenesis inhibitors and stimulators to improve patient outcomes. A major part of Dr. Li’s work focuses on identifying gaps and solutions in the clinical application of angiogenesis modulating therapies including functional biomarkers, and integrating cutting edge scientific insights with disease management strategies. His biomarker work has involved collaborations with NIH, NASA, U.S. Air Force, and across a spectrum of diagnostic and imaging industry and academic leaders. Dr. Li’s focus is on developing translational insights to improve disease prevention and management across North America, Europe, Asia, Australia, and Latin America.

Dr. Li received his undergraduate degree with honors in Biochemistry from Harvard College, and his medical degree from the University of Pittsburgh School of Medicine, Pennsylvania. He completed his internship, residency, and clinical fellowship training in General Internal Medicine at the Massachusetts General Hospital, Boston. Dr. Li has held appointments on the clinical faculties of Harvard Medical School, Tufts University School of Veterinary Medicine, and Dartmouth Medical School. His research has been published in Science, Lancet, New England Journal of Medicine, Nature Reviews Clinical Oncology, Investigative Ophthalmology and Visual Sciences, and the International Wound Journal, and other leading peer-reviewed medical and scientific journals. Dr. Li has been a speaker at the TED Conference, is a member of the Clinton Global Initiative, and has designed a new health session at the World Economic Forum. His work has impacted more than 50 million people worldwide.

Jimmy Cheng-Ho Lin, M.D., Ph.D., MHS
Founder & President of Rare Genomics Institute

C. Jimmy Lin, M.D., Ph.D., MHS, is a 2012 TED Fellow and Founder & President of Rare Genomics Institute, the world’s first platform to enable any community to leverage cutting-edge biotechnology to advance understanding of any rare disease. Partnering with top medical institutions, RGI helps custom design personalized research projects for rare diseases. Dr. Lin is also the Director of Clinical Genomics at the Genetics Branch of the National Institute of Health/National Cancer Institute (NIH/NCI). Prior to this, he led the computational analysis of the first ever exome sequencing studies for any human disease at Johns Hopkins and was a research instructor at Washington University in St. Louis. He has numerous publications in Science, Nature, Cell, Nature Genetics, and Nature Biotechnology, and has been featured in Forbes, Bloomberg, Wall Street Journal, Washington Post, BBC, TIME, and the Huffington Post.
ELIZABETH MANSFIELD, Ph.D.
Deputy Office Director for Personalized Medicine, OIR/CDRH/FDA
FDA, Office of In Vitro Diagnostics and Radiological Health

Dr. Mansfield is the Director of the Personalized Medicine Staff in the Office of In Vitro Diagnostic Devices and Radiological Health (OIR) in the Center for Devices, FDA, where she is developing a program to address companion and novel diagnostic devices. Dr. Mansfield formerly served as the Director of Regulatory Affairs at Affymetrix, Inc, 2004-2006. Dr. Mansfield received her Ph.D. from Johns Hopkins University.

LYNN M. MATRISIAN, Ph.D., MBA
Vice President of Scientific & Medical Affairs, Pancreatic Cancer Action Network

Dr. Matrisian is Vice President of Scientific & Medical Affairs at the Pancreatic Cancer Action Network, based in Manhattan Beach, California. She is formerly Professor and the founding Chair of the Department of Cancer Biology at Vanderbilt University School of Medicine and the Vanderbilt Ingram Cancer Center in Nashville, Tennessee. She received a BS in medical technology from Bloomsburg University in Pennsylvania, a Ph.D. in molecular biology from the University of Arizona in Tucson, and an MBA from the Owen Graduate School of Management at Vanderbilt University. She was appointed to the faculty of Vanderbilt University following postdoctoral training in the Laboratory of Eukaryotic Molecular Genetics, Strasbourg, France. She is past President of the American Association of Cancer Research and a Fellow of the AACR Academy, and the recipient of the Paget-Ewing award from the Metastasis Research Society. She served as co-chair of the National Cancer Institute’s Translational Research Working Group from 2005-2007, and Special Assistant to the Director of the NCI on a halftime basis from 2008-2010. Research in her laboratory revolved around the molecular mechanisms underlying tumor progression and metastasis, with emphasis on the biology of matrix-degrading proteinases.
William B Mattes, Ph.D., DABT  
Director of the Division of Systems Biology, part of the FDA’s National Center for Toxicological Research

Dr. Mattes is the Director of the Division of Systems Biology, part of the FDA’s National Center for Toxicological Research in Jefferson, Arkansas. The Division pursues a wide range of research that uses and develops innovative tools for assessing pharmaceutical safety and advancing public health. He has been an independent consultant as well as Director of Toxicology at the Critical Path Institute where he developed and directed the Predictive Safety Testing Consortium (PSTC), a collaboration of 16 of the world’s major pharmaceutical companies, with FDA and EMEA advisors, with the goal of qualifying new biomarkers for drug safety in a regulatory setting. This work resulted in the establishment of a formal process of biomarker qualification for the FDA and EMEA, and FDA/EMA/PM.D.A qualification of new biomarkers of kidney injury. Dr. Mattes also developed the COPD Biomarkers Qualification Consortium, serving as its Senior Director and overseeing interactions with the FDA. Dr. Mattes other positions included senior scientific director of Toxicogenomics at Gene Logic, Associate Director of Toxicogenomics and Group Leader of Genetic Toxicology at Pharmacia Corp, Kalamazoo, MI, Group Leader of Experimental Toxicology and Metabolism at Ciba Pharmaceuticals, Summit, NJ, and Group Leader of Molecular and Cellular Toxicology, Ciba-Geigy Agricultural Chemical Division, Farmington, CT.

Dr. Mattes received his BA from the University of Pennsylvania and Ph.D. in biological chemistry from the University of Michigan, Ann Arbor. He did his postdoctoral training in biochemistry at the Johns Hopkins University, and was a staff fellow at the National Cancer Institute, the National Institutes of Health (NCI/NIH). In 1997 Dr. Mattes became a diplomat of the American Board of Toxicology. He is a full member of the Society of Toxicology (SOT), and has severed on the Continuing Education Committee and in leadership roles in the Molecular Biology Specialty Section. As part of his involvement with the International Life Sciences Institutes (ILSI) Health and Environmental Sciences (HESI) Committee on the application of genomics to risk assessment, Dr. Mattes chaired the subcommittee that established a public toxicogenomics database at the European Bioinformatics Institute. His research interests include bioinformatics and data analysis, cross-species comparisons of molecular responses, as well as group dynamics that lead to successful collaboration between scientists and changes in scientific policy. He also currently fills the guitar chair for the group Jazzicology at the American College of Toxicology annual meeting.
STEVE MCPHAIL
Global Head, Genomic Laboratory Services, Quintiles
President and CEO, Expression Analysis, Inc., A Quintiles Company

Steve has significant senior management, scientific and operational experience in variety life science- focused businesses. He was President and Chief Executive Officer of Expression Analysis, Inc. (EA), a genomic services company, providing genomic technology solutions to a variety of market segments to advance clinical research with the goal of improving the diagnosis, treatment and management of complex disease. He joined the company in 2003, and in 2012, he successfully sold EA to Quintiles Transnational Corporation, where he continues to serve as Global Head of Genomic Laboratory Services. Steve has spent his career serving companies in the diagnostic, biotechnology and medical device markets, including ArgoMed, Xanthon, TriPath Imaging, Dynatech Laboratories and Abbott Laboratories. He has extensive experience in building exceptional management teams, establishing global distribution networks, and developing and executing sales, marketing and operational plans.

Steve serves as Chairman of the Board of Managers for Genome ID Group LLC, a laboratory services company providing cutting edge DNA analysis capabilities to the forensic and criminal justice marketplace. He also serves as Chairman of the Board of Directors of the ImproveCareNow Collaborative, a nonprofit national collaborative of over 50 children's hospitals and pediatric practices employing Quality Improvement principles to create a learning health system that has significantly improved the treatment of children with Inflammatory Bowel Disease (IBD), including Crohn’s disease and ulcerative colitis. He also serves on the Board of Visitors for the North Carolina Children’s Hospital. Steve also serves as Chairman of the Board of The Center for Advanced Forensic DNA Analysis (CAFDA) provides thorough, in depth and efficient genetic analysis of DNA samples from crime scenes for the judicial system, including crime laboratories, prosecutors, law enforcement agencies and other governmental entities such as the, Department of Defense, U.S. Military and Intelligence Agencies.

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.
KENNETH D. NOONAN, Ph.D.  
Venture Partner, Advanced Technology Ventures;  
Managing Director, TKA Associates, LLC; Senior Advisor, L.E.K. Consulting LLP, European Biopharmaceuticals & Life Sciences Practice  

Ken's life-long professional focus has been on all aspects of the global life sciences industries. Currently Ken is the Managing Director of T/K Associates LLC, a specialist consulting firm dedicated to supporting start-ups in the life sciences space with commercial, financial and business planning. He is also a Venture Partner at Advanced Technology Ventures (ATV) a well-established U.S. venture fund. From 2001 – 2013 Ken was the Senior Partner heading the European Life Sciences Practice at L.E.K. Consulting LLP; a global management consultancy. He remains a Senior Adviser to L.E.K. Consulting LLP. Prior to joining L.E.K., Ken was head of the European Pharmaceutical Practice at Booz-Allen and Hamilton. He began his consulting career in 1990 as Head of the European Life Sciences Practice at The Wilkerson Group, a boutique consultancy providing commercial consulting services to the life sciences industry. Ken had line management experience at CooperTechnicon, Inc, BBL Microbiology Systems (a division of BectonDickinson) as well as Bethesda Research Labs.

Ken has had significant experience over the last 15 years as a member of the Board of Directors of public and private, U.S. and European life science companies. He currently sits on the Board of Kailos Genetics Inc; a development-stage pharmacogenomics company as well as the Advisory Board of the BioDesign Institute of Arizona State University. Ken holds a Ph.D. in Biochemistry from Princeton University.

DANIEL J. O’SHANNESY, Ph.D.  
Senior Director Translational Medicine and Diagnostics, Morphotek, Inc.  

Dr. has over 18 years of experience in a combination of scientific, business development and strategic planning roles within the life sciences industry. In recent years Dr. O’Shannessy has held the positions of Chief Operating Officer of Targeted Diagnostics & Therapeutics, Inc. (TDT, West Chester, PA), Senior Director of Strategic Planning, Oncology Diagnostics at Gen-Probe, Inc. of San Diego, California, and Chief Scientific Officer at Fujirebio Diagnostics, Inc. (FDI, Malvern, PA).

While Chief Operating Officer at TDT, Dr. O’Shannessy was responsible for the day-to-day operations of the company including oversight of the company’s CLIA laboratory, approved for high complexity (RT-PCR) testing services for colon cancer. Further, he was closely involved in license negotiations surrounding the company’s proprietary technology and in ensuring adequate IP protection.

As Senior Director of Strategic Planning at Gen-probe, Dr. O’Shannessy was responsible for all aspects of the strategic implementation of prostate cancer diagnostic technologies and for leading Gen-Probe’s efforts to expand its presence in oncology diagnostics.

As CSO of FDI, he was responsible for directing the strategic growth of the company with respect to new diagnostic products and technologies. He built and had direct responsibility for the departments of R&D, Clinical Affairs, Regulatory Affairs and Business Development, and was successful in in-licensing several novel oncology diagnostic markers. Importantly, he was successful in gaining U.S. FDA approval for a novel diagnostic for pancreatic cancer and initiating the approval process for the world’s first diagnostic for mesothelioma.

Dr. O’Shannessy has also held appointments as the Director of Business Development for Alchemia, an Australian biotech company, and spent 9 years at SmithKline Beecham Pharmaceuticals (now GlaxoSmithKline) in Philadelphia, in both drug discovery/development and business development roles.

Dr. O’Shannessy received his BSc, Biochemistry and BSc, Honours Biochemistry degrees from the University of Queensland, Australia, and his Ph.D., Biochemistry from the University of Auckland, New Zealand in 1983. Dr. O’Shannessy was a Visiting Fellow at the National Institute for Neurological, Communicative Disorders and Stroke (NINCDS) of the NIH, under the guidance of Dr. Roscoe Brady. Subsequent to the NIH, Dr. O’Shannessy was a Docent in Biochemistry at the University of Lund, Sweden.
GEORGE POSTE, D.V.M., Ph.D.
Interim Chief Science Officer, National Biomarker Development Alliance; Co-Director, Complex Adaptive Systems; Regents’ Professor and Del E. Webb Chair in Health Innovation, Arizona State University

Dr. Poste serves as the interim chief science officer for the NBDA. In this role, through the NBDA’s think tanks and workshops and literature and other sources, he works closely with the Alliance team to identify and prioritize key barriers in the discovery and development modules of biomarker development. He also creates networks among relevant stakeholders to plan and implement solution strategies for the barriers identified.

Dr. Poste is Regents’ Professor and Del E. Webb Chair of Health Innovation at Arizona State University. He founded and built the Bodesign Institute at ASU and served as its Director from 2003 to 2009. In 2009 he launched the Complex Adaptive Systems (CAS) at ASU which integrates research across disciplines to study the altered regulation of molecular networks in human diseases to provide a contemporary basis for the development of targeted disease interventions, inclusive of remote monitoring of health status using miniaturized body sensors and mobile devices.

Dr. Poste is a Fellow of the U.K. Royal Society, the Royal College of Pathologists, and the U.K. Academy of Medicine, a Distinguished Fellow at the Hoover Institution, Stanford University, a member of the Council on Foreign Relations, and the U.S. Institute of Medicine Board on Global Health. He has served as a member of the Defense Science Board of the U.S. Department of Defense and currently serves on advisory committees for several U.S. government agencies in defense, intelligence, national security, and health care. He has published extensively on pharmaceutical technologies, cancer, and infectious diseases. He was honored in 1999 by Her Majesty, Queen Elizabeth II, as a Commander of the British Empire for his contributions to international health care and security. He serves on the Board of Directors of Monsanto, Exelixis, Caris Life Sciences, and the Scientific Advisory Boards of Burrill and Company and Synthetic Genomics. From 1992 to 1999, he was Chief Science and Technology Officer and President, R&D, of SmithKline Beecham (SB), where he was associated with the registration of 31 drug, vaccine, and diagnostic products. He has received a number of awards including Scientist of the Year by R&D Magazine; the Einstein Award from the Global Business Leadership Council, 2006; and the Scrip Lifetime Achievement Award, 2009.

JOHN QUACKENBUSH, Ph.D.
Professor of Biostatistics and Computational Biology & Professor of Cancer Biology, Dana-Farber Cancer Institute (DFCI) Professor of Computational Biology and Bioinformatics, Harvard School of Public Health

John Quackenbush received his Ph.D. in 1990 in theoretical physics from UCLA working on string theory models. Following two years as a postdoctoral fellow in physics, Dr. Quackenbush applied for and received a Special Emphasis Research Career Award from the National Center for Human Genome Research to work on the Human Genome Project. He spent two years at the Salk Institute and two years at Stanford University working at the interface of genomics and computational biology. In 1997 he joined the faculty of The Institute for Genomic Research (TIGR) where his focus began to shift to understanding what was encoded within the human genome. Since joining the faculties of the Dana-Farber Cancer Institute and the Harvard School of Public Health in 2005, his work has focused on the use of genomic data to reconstruct the networks of genes that drive the development of diseases such as cancer and emphysema.
PATRICK C. ROCHE, Ph.D.
Senior Vice President, Research and Development
HTG Molecular Diagnostics

Patrick Roche, Ph.D, recently joined HTG Molecular Diagnostics where he is Senior Vice President for Research and Development in Tucson, AZ. Previously, he was 11 years at Ventana Medical Systems/Roche Tissue Diagnostics where he served as Vice President of Translational Diagnostics, interfacing with pharmaceutical partners and facilitating the transition of biomarkers into companion diagnostics for targeted cancer therapeutics. Dr. Roche had also led reagent product development at Ventana, launching over thirty *in vitro* diagnostic (IVD) products, including the FDA-approved c-kit and HER2 tests.

Prior to his tenure in Tucson, Dr. Roche spent 20 years at Mayo Clinic in Rochester, MN as Director of the Immunohistochemistry Laboratory and Associate Professor of Pathology and Biochemistry-Molecular Biology. Dr. Roche has co-authored more than 125 peer-reviewed publications.

HENRY RODRIGUEZ, Ph.D., M.B.A
Director of the Office of Cancer Clinical Proteomics Research,
National Cancer Institute, National Institutes of Health

Dr. Henry Rodriguez serves as Director of the Office of Cancer Clinical Proteomics Research at the National Cancer Institute (NCI), and is a Senior Scientific Officer at the National Institutes of Health in Bethesda, Maryland.

Rodriguez oversees global oncology programs in proteomics at the NCI, and serves on various committees to develop agreements across Federal agencies, and build public-private partnerships. In addition, Rodriguez is responsible for providing authoritative leadership on innovative technology initiatives that address NCI’s expanding role in biomedical research (proteogenomics).

He has authored more than 200 publications, that include 118 original research publications (several in Nature Publishing Group), reviews and chapters, including co-editing a best-selling book entitled “Oxidative Stress and Aging: Advances in Basic Science, Diagnostics and Intervention.” Rodriguez serves on the Editorial Boards of *Clinical Proteomics*, *Annals of Laboratory Medicine*, *Scientific Data (Nature Publishing Group)*, and the Editorial Advisory Board of *Journal of Proteome Research*.

Rodriguez has received numerous domestic and international awards and honors, including the Dr. Herbert Wertheim Global Medical Leadership Award, FIU Herbert Wertheim College of Medicine, Leveraging Collaboration Award from the FDA; Director’s Award from the NIH and NCI; Diversity Program Alumni Recognition from the Minority Biomedical Research Support program of NIGMS; Young Scientific Investigator Award from Sigma Xi; Distinguished Alumni Member of the Epsilon of Florida Chapter of Phi Beta Kappa at Florida International University, and the Torch Alumni Award from Florida International University.

Rodriguez began his college career at a community college, Miami Dade College, and went on to earn a B.S. in biology (with minor in chemistry) and a M.S. in biology (toxicology), both from Florida International University. He next attained a Ph.D. in cell and molecular biology at Boston University, and did fellowships at The Scripps Research Institute (La Jolla, CA) and at the City of Hope Cancer Center (Duarte, CA). After consulting with mentors, he enrolled at Johns Hopkins Carey Business School, earning there an M.B.A.
HOWARD I. SCHER, M.D.
Chief, Genitourinary Oncology Service
Memorial Sloan Kettering Cancer Center

Howard I. Scher, M.D. is Chief of the Genitourinary Oncology Service at Memorial Sloan Kettering Cancer Center, Professor of Medicine at the Weill Cornell Medical College, and the D. Wayne Calloway Chair in Urologic Oncology. Dr. Scher has helped elucidate key molecular and genetic features of prostate cancer and translated these insights as leading early and phase 3 registration trials of abiraterone acetate and enzalutamide which are now FDA approved. His research is focused on the validation of circulating tumor cell and other blood based biomarkers to guide the selection of treatment for the individual patient and accelerate drug approvals. Dr. Scher led the international Prostate Cancer Clinical Trials Working Group effort to standardize the design and analysis of phase II trials, and serves as the principal investigator of an NIH-supported Specialized Program of Research Excellence in Prostate Cancer and Department of Defense Transformative Impact Award: Toward the Practice of Precision Medicine – A Biomarker Validation Coordinating Center, and is the leader of the Prostate Cancer Clinical Trials Consortium charged with bringing needed drugs to patients faster.

RICHARD L. SCHILSKY, M.D., FACP, FASCO
Chief Medical Officer, American Society of Clinical Oncology, and Professor Emeritus, University of Chicago

Dr. Schilsky earned his M.D. degree at the University of Chicago, Pritzker School of Medicine in 1975. Following a residency in Internal Medicine at the University of Texas Southwestern Medical Center and Parkland Memorial Hospital, he received training in Medical Oncology and Clinical Pharmacology at the National Cancer Institute (NCI) from 1977 to 1981. He then served as Assistant Professor of Medicine at the University of Missouri-Columbia School of Medicine from 1981-1984 when he returned to the University of Chicago. At the University of Chicago, Dr. Schilsky rose to the rank of Professor of Medicine (tenured) and served as Director of the University of Chicago Cancer Research Center (1991-99), as Associate Dean for Clinical Research (1999-2007) and as Chief of the Section of Hematology-Oncology (2009-2012). From 1995-2010, Dr. Schilsky also served as Chairman of the Cancer and Leukemia Group B, an NCI-sponsored national cancer clinical trials group.

An international expert in gastrointestinal malignancies and cancer pharmacology, Dr. Schilsky has published more than 320 scientific articles, reviews and commentaries. He has served on a number of peer review and advisory committees for the NCI including as a member and chair of the NCI Board of Scientific Advisors and as a member of the Clinical and Translational Research Advisory Committee. Dr. Schilsky also served as a member and chair of the Oncologic Drugs Advisory Committee of the Food and Drug Administration. He presently serves as a member of the Board of Directors of the Reagan-Udall Foundation for the FDA, a member of the Board of Directors of Friends of Cancer Research and as a member of the National Cancer Policy Forum of the Institute of Medicine. Dr. Schilsky has served as a member of the Board of Directors of the American Society of Clinical Oncology (ASCO) and of the Conquer Cancer Foundation of ASCO and as ASCO President 2008-2009.
WENDY K.D. SELIG, M.S.
President and CEO, Melanoma Research Alliance

Ms. Selig is President and CEO of the Melanoma Research Alliance (MRA), a public charity focused on finding and funding the most promising melanoma research worldwide that will accelerate progress toward a cure. Ms. Selig drives and manages MRA’s strategic priorities, research portfolio, and day-to-day operations. Under her leadership, the MRA is accelerating progress toward a cure for melanoma by supporting an international, cross-disciplinary group of biomedical researchers exploring, identifying, and pursuing innovative, transformative research.

Prior to joining the MRA, Ms. Selig spent nearly a decade in leadership positions at the American Cancer Society and its advocacy affiliate, the American Cancer Society Cancer Action Network (ACS CAN). She currently serves on the Board of Directors of the National Coalition of Cancer Research (NCCR), the Government Affairs Committee of the Prostate Cancer Foundation (PCF), and the Patient Leadership Council (PLC) of the Clinical Trials Transformation Initiative (CTTI). She previously served as Chair of the United for Medical research (UMR) coalition and a member of the Directors Consumer Liaison Group (DCLG) at the National Cancer Institute (NCI). From 1989-2000, Ms. Selig served on Capitol Hill as a top aide for U.S. Representative Porter J. Goss (R-FL), the House Rules Committee and the House Permanent Select Committee on Intelligence (HPSCI). Ms. Selig is a Magna Cum Laude graduate of Princeton University and holds a Masters in Science from Northwestern University’s Medill School of Journalism.

LEMING SHI, Ph.D.
Professor and Director, Center for Pharmacogenomics
School of Pharmacy and School of Life Sciences, Fudan University

Dr. Leming Shi is a professor at the School of Pharmacy and the School of Life Sciences of Fudan University in Shanghai, China where he established the Center for Pharmacogenomics. Dr. Shi’s research focuses on pharmacogenomics, bioinformatics, and cheminformatics aiming to realize personalized medicine by developing biomarkers for early cancer diagnosis and targeted therapy. As a Principal Investigator at the US Food and Drug Administration (FDA) from 2003 to 2012, Dr. Shi conceived and led the MicroArray and Sequencing Quality Control (MAQC/SEQC) project (www.nature.com/nbt/focus/maqc/, www.nature.com/focus/maqc2/, and Nature Biotechnology 2014, in press). Dr. Shi was a co-founder of Chipscreen Biosciences Ltd. in Shenzhen, China where he helped develop a chemogenomics-based drug discovery platform leading to several novel small-molecule drug candidates with promising efficacy and safety profiles in anticancer and antidiabetic clinical trials. Dr. Shi is a co-inventor on nine issued patents about novel therapeutic molecules and has published over 170 peer-reviewed papers (ten of them appeared in Nature Biotechnology). Dr. Shi received his Ph.D. in computational chemistry from the Chinese Academy of Sciences in Beijing, and is a guest faculty at the US FDA and an adjunct professor of medicine at the University of Arkansas for Medical Sciences.
Dr. Robert Temple has been Deputy Center Director for Clinical Science at FDA’s Center for Drug Evaluation and Research since 2009, participating in the direction of the Center’s operations. He is also Acting Deputy Director of the Office of Drug Evaluation I (ODE-I). ODE-I is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products. Dr. Temple served as Director, Office of Medical Policy from 1999-2009. The Office of Medical Policy is responsible for regulation of promotion through the Office of Prescription Drug Products (formerly, Division of Drug Marketing, Advertising, and Communication) and for assessing quality of clinical trials. Dr. Temple has a long-standing interest in the design and conduct of clinical trials and has written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control and non-inferiority trials, trials to evaluate dose-response, and trials using "enrichment" designs.

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.

Dr. van't Veer is a world renowned Molecular Biologist, former Head of Diagnostic Oncology at the Netherlands Cancer Institute, and inventor of MammaPrint®. She is the leader of the Breast Oncology Program in the Helen Diller Family Comprehensive Cancer Center and a convener of UCSF’s Precision Medicine Platform. Dr. van ‘t Veer’s research focuses on Personalized Medicine, to advance that patient management is based on knowledge of the genetic make-up of the tumor as well as the genetic make-up of the patient. This allows to optimally assign systemic therapy for those patients that are in need of such treatment and to ensure the selection of the therapy that is most effective. Dr. van’t Veer’s research shows that molecular diagnostics and microarray genomics technology increasingly impacts patient management. Molecular Genomics contributes to the knowledge of who is at risk for breast cancer, how external factors may influence this risk, whether breast tumors are likely to metastasize or not, and which subtype of tumors will likely respond to what therapy.
GEORGE VASMATZIS, Ph.D.
Director, Biomarker Discovery Program, Center Individualized Medicine, Mayo Clinic and Mayo Foundation

Dr. Vasmatzis is the director of the Biomarker Discovery Program, within the Center for Individualized Medicine, and his research program consists of bioinformatics specialists, molecular biologists, epidemiologists, and pathologists. He is a Consultant in the Department of Molecular Medicine and a member of the Mayo Clinic Cancer Center. He is also an Assistant Professor in the Department of Laboratory Medicine at the Mayo Medical School. He has a Ph.D. in Biomedical Engineering and has acquired experience in diverse disciplines, including Bioinformatics, Molecular Biology, and Computational Biology. His laboratory has demonstrated success in discovery and translation of several biomarkers as well as developing evidence-based models that should help clinicians stratify (cancer) patients in order to provide each individual with the appropriate care. With the recent advances in Next Generation Sequencing (NGS) technologies the laboratory have been engaging in massive sequencing to scan the genome of cancer cells for abnormalities that can be used for clinical purposes such as diagnosis and stratification of patients for optimal treatment. Published papers in Journal of Clinical Oncology, Cancer Research and BLOOD further demonstrate their discovery, validation and translation capabilities.

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.


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.

ANDREW W. WOMACK, PH.D
Associate Group Director, Regulatory Policy, Product Development Regulatory, Genentech, A Member of the Roche Group

Dr. Andrew Womack is Associate Group Director for Regulatory Policy in the Washington, DC office of Genentech, A Member of the Roche Group. Genentech's Regulatory Policy group supports Roche’s larger Product Development Regulatory organization, which interprets the needs of worldwide health authorities and provides regulatory intelligence necessary to generate and present information that meets the needs of health authorities, patients, purchasers and prescribers for Roche’s global Pharma Medicines Division, which includes all therapeutic areas and all phases of product development from early development to post-marketing. Prior to joining Genentech, Andy was Director, Science and Regulatory Affairs at the Biotechnology Industry Organization (BIO), the world’s largest biotechnology trade association. In this role, he directed policy activities on issues related to preclinical safety, clinical safety and efficacy, pediatric drug development, biosimilars, and international regulatory affairs and also led BIO’s Clinical Trials Modernization Initiative. Andy came to BIO from the Office of Senator John F. Kerry (MA) where he was a legislative fellow sponsored by the American Association for the Advancement of Science (AAAS). Previously, he studied human cytomegalovirus assembly and tropism as a National Science Foundation Graduate Research Fellow and received his PhD in Molecular Biology from Princeton University.
Dr. Woodcock joined the U.S. Food and Drug Administration (FDA) in 1986, assuming the leadership of the Center for Drug Evaluation and Research (CDER) in May 1994. Prior to joining CDER, she served as Acting Deputy Center Director of the Center for Biologics Evaluation and Research (1990-1992) and Director of the Office of Therapeutics Research and Review (1992-1994), where she oversaw approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis. From 2004 to 2008, Dr. Woodcock provided support to FDA’s Commissioner, serving as Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations, and Chief Operating Officer, overseeing various aspects of scientific and regulatory operations.

During her tenure at FDA, Dr. Woodcock’s achievements have been substantial. Under her leadership, CDER has streamlined review processes for new and generic drugs while improving standards for quality, safety, and effectiveness.

The processes for submitting marketing applications and adverse events reports and for reviewing submissions in FDA have been automated. CDER’s regulatory decision-making processes also have been streamlined, making decisions more open and transparent. CDER’s regulatory procedures and policies are publicly available — scores of technical guidance describing FDA’s thinking on regulatory standards have been issued. Many CDER processes are carried out with an unprecedented degree of participation on the part of consumer and patient representatives. An extensive CDER Web site hosts a myriad of helpful information on drug approvals, safety issues, and other critical information targeting consumers, patients, health care practitioners, regulated industry, and other audiences.

Highlights of select recent accomplishments include negotiating the 2012 Generic Drugs User Fee Act, which will speed access to safe and effective generic drugs to the public and reduce costs to industry and renegotiating the Prescription Drug User Fee Act (PDUFA V) to support timely evaluation and approval of prescription drugs.

In 2011 and 2012, Dr. Woodcock launched multiple efforts to support development of new therapies for rare and neglected diseases, molecularly defined disease subgroups, and new antibacterial therapies. She oversaw the implementation of innovative policies to foster adaptive trial designs (2010) and trial enrichment strategies (2012) and encourage the qualification of new drug development tools (2010) to help speed drug development and evaluation.

Following enactment in March 2010 of the Patient Protection and Affordable Care Act (Affordable Care Act), Dr. Woodcock developed and launched the biosimilars effort to create an abbreviated licensure pathway for biological products; she then negotiated the Biosimilar User Fee Act of 2012 (BsUFA) to support approval using this new pathway.

Dr. Woodcock continues to lead FDA’s Pharmaceutical Quality for the 21st Century initiative to modernize pharmaceutical manufacturing and the Safe Use/Safety First initiatives, which are critical to drug safety throughout the drug lifecycle and ensuring frequent and clear communications to the public about the risks and benefits of drugs.

As Acting Deputy Commissioner for Operations, in 2004, Dr. Woodcock began the Critical Path Initiative, which continues to encourage and foster the development of new and better tools to support medical product research so that drug, device, and biologics development is more predictable and more informative. As Deputy Commissioner and Chief Medical Officer, Dr. Woodcock launched the Sentinel Initiative with the goal of building a new active surveillance system to augment FDA’s existing adverse events monitoring systems.

As Director of CDER, Dr. Woodcock maintains contact with a variety of diverse constituencies, including the clinical and scientific communities, members of Congress and the Administration, patient and consumer advocacy groups, the international drug regulatory community, regulated industry, and representatives of Federal and State agencies. She frequently appears in or is quoted by the national media and has testified repeatedly before Congress.

Dr. Woodcock has earned numerous awards, most recently the Arthritis Foundation’s Floyd B. Odlum Making a Difference Award and the Luminary Award from the Personalized Medicine World Conference. She has been the recipient of the Presidential Rank Meritorious Executive Award and three HHS Secretary’s Distinguished Service Awards among many others. She has authored more than 60 publications. Dr. Woodcock received her M.D. degree from Northwestern University Medical School in 1977, following an undergraduate degree in chemistry from Bucknell University. She has held teaching appointments at Pennsylvania State University and the University of California at San Francisco. Dr. Woodcock lives in Maryland with her husband and is the mother of two daughters.
NBDA WORKSHOP VI

“The Ever-Promising but Elusive Surrogate Endpoint: What Will it Take?”

December 1 - 2, 2014

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