

Personalized Medicine in the 21st Century

Presented by
**RTI International and the
North Carolina Biotechnology Center**



In partnership with
**Duke University
North Carolina State University
The University of North Carolina at Chapel Hill**



Sponsored by



DATE

June 15, 2010

LOCATIONSheraton Imperial Hotel
Research Triangle Park, NC**Agenda**

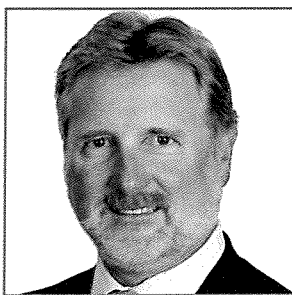
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| 7:30–8:15 a.m. | Registration and continental breakfast |
| 8:15 a.m. | Welcome and Introductions Jennie Hunter-Cevera , PhD, Conference Co-Chair, Executive Vice President, Discovery and Analytical Sciences, RTI International Norris Tolson , President, North Carolina Biotech Center |
| 8:30 a.m. | Keynote Address: <i>Funding and Investment Perspective</i> "Value Creation in Personalized Medicine: Is There Enough Capital? And Are Company Business Models Sustainable?" G. Steven Burrill , CEO, Burrill & Company |
| | Introduction by Michael Luther, President, David H. Murdock Research Institute |
| 9:30 a.m. | Panel Discussion: <i>Public Policy Perspective</i> "Government's Role in Making Personalized Medicine Measurable and Meaningful: Initiatives, Incentives, and Standards" |
| | Introduction by Terri L. Lomax , Vice Chancellor for Research and Graduate Studies, North Carolina State University |
| | Moderator: Don Bailey , PhD, Distinguished Fellow, RTI International |
| | Panelists: Michael Amos , PhD, Biosciences Advisor to the Director, National Institute for Standards and Technology (NIST) Vicki Seyfert-Margolis , PhD, Senior Advisor for Science Innovation and Policy, Office of the Commissioner, U.S. Food and Drug Administration (FDA) Steven McPhail , CEO, Expression Analysis |
| 10:45 a.m. | Coffee Break |
| 11:15 a.m. | Keynote Address: <i>Scientific Perspective</i> "The Future of Genomic and Personalized Medicine: Foundations and Applications" Geoffrey Ginsburg , MD, Institute for Genome Sciences and Policy, Duke University |
| | Introduction by James N. Siedow , Vice Provost for Research, Duke University |
| 12:15 p.m. | Luncheon and Keynote Address: <i>International Perspective</i> "Metabolism-Directed Systems Biology Approaches to Personal and Public Health Problems" Jeremy Nicholson , PhD, Professor, Department of Biomolecular Medicine at Imperial College, London, and Chair of Biological Chemistry, Division of Surgery, Oncology and Reproductive Biology |
| | Introduction by Victoria Haynes , PhD, President, RTI International |

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| 1:45 p.m. | <p>Panel Discussion: <i>Functional Perspective</i> “The Multidisciplinary Approach to Personalized Medicine: Fitting Together the Pieces of the ‘P-4’ Puzzle (Predictive, Preventive, Personalized, and Participatory)”</p> <p>Introduction by Catherine Innes, Director, Office of Technology Development, University of North Carolina–Chapel Hill</p> <p>Moderator: Jennie Hunter-Cevera, PhD, Conference Co-Chair, Executive Vice President, Discovery and Analytical Sciences, RTI International</p> <p>Panelists: Nathan Price, PhD, University of Illinois Institute for Genomic Biology Clay Marsh, MD, Executive Director, Center for Personalized Health Care, Ohio State University Karen Weck, MD, Director, Molecular Genetics Laboratory; Associate Director, Institute for Pharmacogenomics and Individualized Therapy, University of North Carolina–Chapel Hill Lee Mobley, PhD, Senior Fellow, Health Economics, RTI International Susan Sumner, PhD, Senior Scientist, RTI International</p> |
| 3:00 p.m. | <p>Panel Discussion: <i>Future Prospects</i> “Potential Stumbling Blocks Along the Road: Comparative Effectiveness, Reimbursements, and Biomarkers as Intellectual Property”</p> <p>Moderator: Steven Casey, Vice President, Statewide Operations, North Carolina Biotechnology Center</p> <p>Panelists: Amy Abernethy, MD, Program Director, Duke Cancer Care Research Program and representative of Personalized Medicine Coalition Steven Hultquist, Founder and Principal, Intellectual Property and Technology Law Paul Brown, PhD, Research Associate Professor, Lineberger Comprehensive Cancer Center, University of North Carolina–Chapel Hill</p> |
| 4:00 p.m. | <p>Closing Remarks Jennie Hunter-Cevera, PhD, Executive Vice President, Discovery and Analytical Sciences, RTI International</p> |
| 4:15–5:15 p.m. | Reception |

G. Steven Burrill

CEO, Burrill & Company

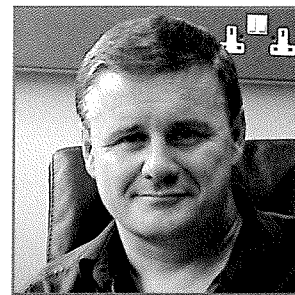
G. Steven Burrill has been involved in the growth and prosperity of the biotechnology industry for more than 40 years. An early pioneer, Burrill is one of the original architects of the industry and one of its most avid and sustained developers. He currently serves as Chairman of the Board of Pharmasset and is a member of the Boards of Directors of Catalyst Biosciences, DepoMed, Intranasal, Phytomedics, Proteogenix, Proventys, Targacept, and XDX. Before founding Burrill & Company in 1994, he spent 28 years with Ernst & Young, directing and coordinating the firm's services to clients in the biotechnology/life sciences/high-technology/manufacturing industries worldwide. In 2002, Burrill was recognized as a biotech investment visionary by the prestigious Scientific American magazine (*The Scientific American* 50). Burrill is a founder and currently serves as the Chairman of the Board of the National Science & Technology Medals Foundation. Additionally, he serves as Chairman of the Board on Campaign for Medical Research as well as Chairman of the San Francisco Mayor's Biotech Advisory Committee.



Jeremy Nicholson, PhD

*Head of the Department of Surgery and Cancer
Imperial College London*

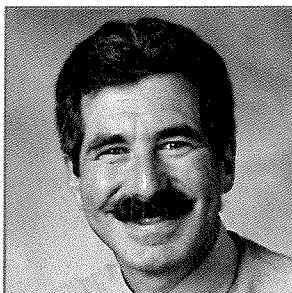
Professor Jeremy Nicholson obtained his BSc from Liverpool University (1977) and his PhD from London University (1980) in biochemistry, working on the application of analytical electron microscopy and the applications of electron microscopy and energy-dispersive X-ray microanalysis in molecular toxicology. He was appointed Professor of Biological Chemistry in 1992 (Birkbeck College, London University). In 1998 he transferred to Imperial College London as Head of Biological Chemistry, and in 2009 he was appointed Head of Surgery and Cancer. He is the author of over 500 peer-reviewed scientific papers and many other articles/patents on the development and application of novel spectroscopic and chemometric approaches to the investigation of disturbed metabolic and physicochemical processes. His work has been recognized by awards such as the Royal Society of Chemistry (RSC) Silver (1992) and Gold (1997) medals for Analytical Chemistry; the UK Chromatographic Society Jubilee Silver Medal (1994); the Pfizer Prize for Chemical and Medicinal Technology (2002); the Pfizer Global Research Prize for Chemistry (2006); the RSC medal for Chemical Biology (2003); the RSC Theophilus Redwood Lectureship and Interdisciplinary Prizes (2007, 2008); and the Semelweis Budapest Prize for Biomedicine (2010). Professor Nicholson was elected as a Fellow of the Academy of Medical Sciences in 2010.



Geoffrey Ginsburg, MD, PhD

*Institute for Genome Sciences and Policy,
Duke University*

Dr. Geoffrey Ginsburg is the founding Director of the Center for Genomic Medicine in the Duke Institute for Genome Sciences & Policy. He is also professor of medicine and of pathology at Duke University Medical Center. Ginsburg received his MD and PhD in biophysics from Boston University. He completed residency and postdoctoral training in clinical cardiovascular medicine at Beth Israel Hospital in Boston and in molecular biology at Children's Hospital as a Bugher Foundation Fellow of the American Heart Association. In 1990 he joined the faculty of Harvard Medical School, where he was director of preventive cardiology and led a laboratory in applied genetics of cardiovascular disease. In 1997 he joined Millennium Pharmaceuticals, Inc., as senior program director for cardiovascular diseases. In 2000, he was appointed vice president of Molecular and Personalized Medicine at Millennium, where he was responsible for developing pharmacogenomic strategies for therapeutics, as well as biomarkers for disease and their implementation in the drug development process. He assumed his current position in the Duke Institute for Genome Sciences & Policy in September 2004, and in 2006, he was also appointed as Co-Director, Duke Translational Medicine Institute.



Jennie Hunter-Cevera, PhD

Executive Vice President, Discovery and Analytical Sciences, Government Affairs, and Corporate Development, RTI International

Dr. Jennie Hunter-Cevera joined RTI International in July 2009. She has more than 22 years of experience in the biotechnology and pharmaceutical industry. Before joining RTI, she was president of the University of Maryland Biotechnology Institute and head of the Center for Environmental Biotechnology at the Lawrence Berkeley National Laboratory. Hunter-Cevera holds five patents, has 15 pending patents, and currently serves on the editorial board for *International Microbiology* and the advisory board for the *International Journal of Environmental Research and Public Health*.

Norris Tolson

President, North Carolina Biotech Center

E. Norris Tolson became president and CEO of the North Carolina Biotechnology Center in July 2007. He has served on the Biotechnology Center's Board of Directors since 1997 and as a member of the Executive Committee since 2001. Tolson previously served the state as Secretary of Commerce, Secretary of Transportation, and Secretary of Revenue. He also served in the North Carolina House of Representatives from 1994 to 1997, representing parts of Nash, Edgecombe, Pitt, and Wilson counties.

Michael Luther, PhD, MBA

President, David H. Murdock Research Institute

Dr. Michael Luther is the President of the David H. Murdock Research Institute. Before joining the David H. Murdock Research Institute earlier this year, he held the position of Vice President of Basic Research and Site Head at Merck Frosst Centre for Therapeutic Research in Montreal, QC. He headed efforts in drug discovery and development in Inflammation and Metabolic Diseases. Before Merck, Luther was with GlaxoSmithKline, including his last role as Vice President in Discovery Research.

Terri Lomax, PhD

Vice Chancellor for Research and Graduate Studies, North Carolina State University

Dr. Terri Lomax is Vice Chancellor for Research and Graduate Studies and Professor of Plant Biology at NC State University. Lomax, who served as Interim Vice Chancellor 2008 through 2009, arrived at NC State in the fall of 2006 as Dean of the Graduate School and Associate Vice Chancellor for Research. Before arriving at NC State, she was on assignment from Oregon State University to NASA Headquarters in Washington, DC.

Don Bailey, PhD

Distinguished Fellow, RTI International

Dr. Don Bailey joined RTI as a Distinguished Fellow in early childhood development in November 2005. He is internationally known as an expert on young children with disabilities, with a particular emphasis on their families and the role of early intervention. Before coming to RTI, Bailey was W. R. Kenan Jr. Distinguished Professor at the University of North Carolina at Chapel Hill, and from 1992 to 2006, he was director of the Frank Porter Graham Child Development Institute.

Michael Amos, PhD

BioSciences Advisor to the Director, National Institute for Standards and Technology (NIST)

Dr. Michael Amos has held various industry research, marketing, and business development positions in the fields of biopharmaceuticals, nutraceuticals, drug delivery, transgenics, immunodiagnostics, molecular biology, and molecular pathology. He is also a founder of two biotechnology companies. He joined NIST in 2002 as a program manager and biologist in the Chemistry and Life Sciences Office of the Advanced Technology Program, an extramural funding arm of NIST. There he participated in and led evaluation of biotechnology proposals for funding and managed projects on stem cells, nanotechnology, immunotherapeutics, cancer vaccines, neurobiology, protein therapeutics, drug discovery, gene therapy, metabolic engineering, and medical devices.

Vicki Seyfert-Margolis, PhD

Senior Advisor for Science Innovation and Policy, Office of the Commissioner, U.S. Food and Drug Administration (FDA)

Dr. Vicki Seyfert-Margolis joined the NIH as Director of the Office of Innovative Scientific Research Technologies, where she worked to integrate emerging technologies into existing immunology and infectious disease programs. In 2000, Seyfert-Margolis joined the Immune Tolerance Network (ITN), a clinical research consortium sponsored by NIAID and JDRE. As Chief Scientific Officer, she oversaw the creation and coordination of the ITN's extensive and ambitious tolerance assay infrastructure.

Steven McPhail

CEO, Expression Analysis

Steven McPhail has spent his career serving companies in the diagnostic, biotechnology, and medical device markets. He previously acted as Executive Vice President and Chief Operating Officer of ArgoMed, Inc. Earlier, McPhail held senior-level sales, marketing, and business development positions for Xanthon, TriPath Imaging, Dynex Technologies, and Abbott Laboratories. He has extensive experience in executing mergers and acquisitions, developing strategic marketing plans, and establishing global distribution networks. He serves on the board of the NC Children's Hospital and the Pediatric Inflammatory Bowel Disease Network.

James N. Siedow, PhD

Vice Provost for Research, Duke University

Dr. James Siedow performed postdoctoral research at the University of Michigan and Rice University before joining the Duke faculty as an Assistant Professor of Botany in 1976. He became a full Professor of Botany in 1987 and a Professor of Biology in 2000. He became Vice Provost for Research in January 2001. Professionally, Siedow has held numerous positions in the American Society of Plant Biologists, and he also spent a year as a Program Director of the Cellular Biochemistry Program at the National Science Foundation in 1998-99.

Victoria Haynes, PhD

President, RTI International

Dr. Victoria Franchetti Haynes became RTI International's third president in 1999. Her career spans 31 years of technology leadership, management, and new business development. She began her career at Monsanto Company in 1977 and held a number of senior management positions, including Director of Technology in the company's Plastics Division until 1992. Prior to joining RTI, she worked for seven years at Goodrich Corporation as Vice President of Research and Development and later as Chief Technical Officer and Vice President of the company's Advanced Technology Group.

Catherine Innes

Director, Office of Technology Development, University of North Carolina—Chapel Hill
Catherine Innes came to the Office of Technology Development at UNC-Chapel Hill to take on the role of Director with 14 years of experience in all facets of university technology transfer. She was with the Office of Technology Licensing at the University of California, Berkeley for three years as a Software Licensing Associate and then served an additional three years with the University of California system as Campus Liaison Officer, offering her expertise in copyright management, licensing, and policy development for nine campuses and three national labs.

Nathan Price, PhD

University of Illinois Institute for Genomic Biology
Dr. Nathan Price is an assistant professor in the Institute for Genomic Biology and the Department of Chemical and Biomolecular Engineering at the University of Illinois, where he runs a lab of 18 post-doctoral and graduate students. He earned his doctorate in bioengineering from UCSD in 2005, working with Bernhard Palsson, after which he did his postdoctoral training with Lee Hood at the Institute for Systems Biology. Price is also a Deputy Editor-in-Chief of PLoS Computational Biology and an associate editor of BMC Systems Biology and Biotechnology Journal.

Clay Marsh, MD

Executive Director, Center for Personalized Health Care, Ohio State University
Dr. Clay Marsh is currently Senior Associate Vice President, Health Sciences Research; Vice Dean of Research for the College of Medicine; Executive Director, Center for Personalized Health; Director, Center for Critical Care and Respiratory Medicine; Professor of Internal Medicine. He is an NIH-funded investigator, and his laboratory focuses on translational research in the area of acrophage biology and understanding molecular mechanisms underlying human health and wellness. Marsh leads the efforts in Personalized Health Care at the Ohio State University.

Karen Weck, MD

Director, Molecular Genetics Laboratory; Associate Director, Institute for Pharmacogenomics and Individualized Therapy, University of North Carolina—Chapel Hill
Dr. Karen Weck is Associate Professor of Pathology and Laboratory Medicine and Genetics, Director of the Molecular Genetics Clinical Laboratory, and Associate Director of the UNC Institute for Pharmacogenomics and Individualized Therapy (IPIIT) at the University of North Carolina in Chapel Hill. She is the Associate Editor of Pharmacogenomics and Personalized Medicine for the journal *Genetics in Medicine*. Her CLIA-certified laboratory performs clinical molecular diagnostic testing for inherited diseases, cancer, infectious diseases, and pharmacogenomics. Weck's primary research interests are in translating developments in genomic knowledge and technology to advance diagnostic medicine.

Lee Mobley, PhD

Senior Fellow, Health Economics, RTI International
Dr. Lee Rivers Mobley was appointed a Senior Fellow at RTI in December 2008. She specializes in spatial epidemiology and analysis of health care markets and behaviors, using spatial modeling and spatial econometrics, and developing spatial decision support systems. She joined RTI in July 2001, and her work has included market analysis for several Medicare reform initiatives, spatial analysis explaining cardiac risk factors in low-income women, and analysis of access to preventive care services, with a focus on quality and cancer screening.

Susan Sumner, PhD

Senior Scientist, RTI International
Dr. Susan Sumner has more than 15 years of experience in mechanistic-based research, specializing in the areas of metabolism and metabolomics. Sumner has served as a principal investigator and GLP study director, conducting studies to evaluate pharmacokinetics, ADME (absorption, distribution, metabolism, and excretion), and toxicity of compounds. Upon joining RTI in 2004 as a Senior Metabolism Scientist, she immediately integrated an RTI-wide metabolomics effort and developed a scientific plan to study mechanisms of idiosyncratic drug-induced liver injury.

Steven Casey, MBA

Vice President, Statewide Operations, North Carolina Biotechnology Center
Steven Casey is responsible for developing, directing, and coordinating all biotechnology growth and development activities surrounding the Biotechnology Center's five regional offices. As the former Biotechnology Center Business Development Director, Casey helped to create the Technology Evaluation and Acceleration Model loan program and the Business Acceleration and Technology Outlicensing Network (BATON), which supports, streamlines, and provides business-related inception activities for new companies emanating from North Carolina research organizations. Casey is the founder and former Chief Operating Officer of Expression Analysis.

Amy Abernethy, MD

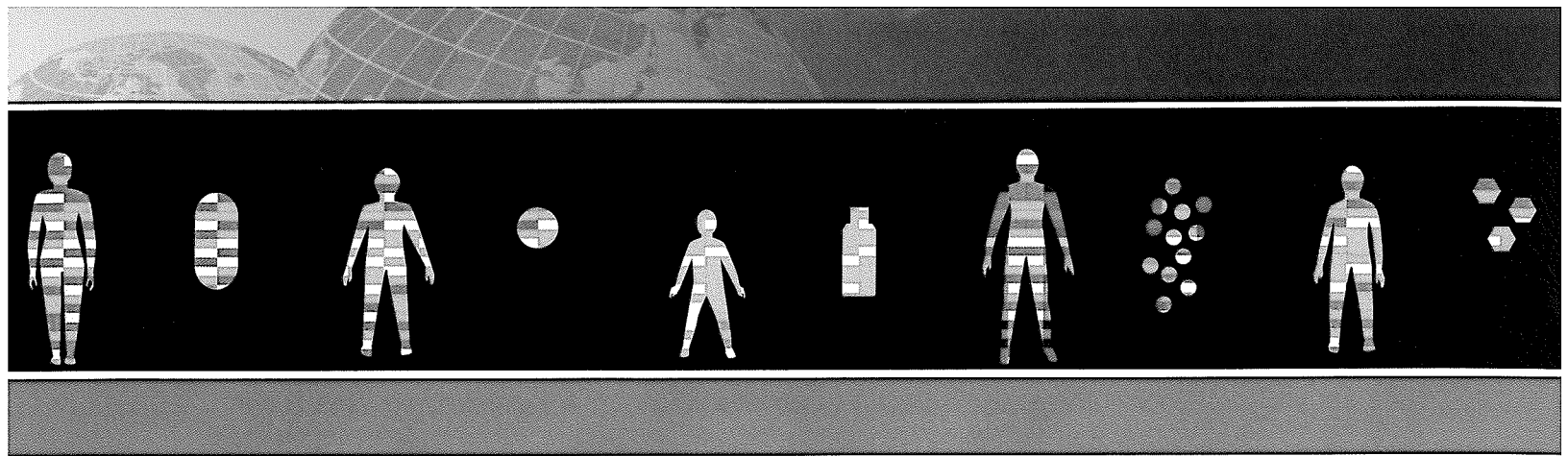
Program Director, Duke Cancer Care Research Program and representative of Personalized Medicine Coalition
Dr. Amy Abernethy is Associate Professor of Medicine in the Division of Medical oncology at Duke University School of Medicine, Assistant Professor of Nursing at Duke University School of Nursing, and adjunct Associate Lecturer at Flinders University, South Australia. An NIH-funded investigator, she codirects both the Duke Quality Cancer Care Initiative and the Duke Integrative Oncology Program. Abernethy's research program—the Duke Cancer Care Research Program (DCCRP)—handles all aspects of high-quality clinical trials that generate evidence-based solutions for common problems in supportive oncology.

Steven Hultquist

Founder & Principal, Intellectual Property & Technology Law
Steven Hultquist, the founder of IPTL, is licensed in New York, North Carolina, California, and Connecticut, and registered to practice before the U.S. Patent and Trademark Office. He holds a master of science degree in chemical engineering from Washington University (St. Louis), and a law degree from Fordham University. Hultquist was an Adjunct Professor of Chemical Engineering at North Carolina State University from 1995 to 1997 and has been the intellectual property author for the North Carolina General Practice Deskbook since 1996. He also holds a number of patents.

Paul Brown, PhD

Research Associate Professor, Lineberger Comprehensive Cancer Center, University of North Carolina—Chapel Hill
Dr. Paul Brown is a health economist with the Lineberger Comprehensive Cancer Center and the Department of Health Policy and Management at UNC-Chapel Hill. He has research interests in comparative and cost-effectiveness analysis and cost-effectiveness evaluations of existing health services. He also has an interest in outcomes research and measuring health status, particularly in regards genetic testing and personalized medicine. Before joining UNC in March 2010, he was Director of a research center at the University of Auckland focusing on comparative effectiveness research.



RTI International and the North Carolina Biotechnology Center wish to thank our partners and sponsors for their gracious support of this conference.



NC STATE UNIVERSITY



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL



RTI International is one of the world's leading research institutes, dedicated to improving the human condition by turning knowledge into practice. Our staff of more than 2,800 provides research and technical expertise to governments and businesses in more than 40 countries in the areas of health and pharmaceuticals, education and training, surveys and statistics, advanced technology, international development, economic and social policy, energy and the environment, and laboratory and chemistry services. For more information, visit www.rti.org.



The North Carolina Biotechnology Center is the world's first state-funded entity dedicated to developing the biotechnology industry. For 25 years the Center has worked statewide building a firm foundation of research, business, education and policy, creating an industry whose ripple effect generates \$45.8 billion in economic activity and 250,000 jobs in North Carolina. More information at www.ncbiotech.org.