

**Biomedical Innovation: Identifying Challenges and Prioritizing Needs  
in Medical Device Research and Development**  
March 5, 2014 • Washington, DC

- 8:30 a.m. Welcome, Introduction, and Meeting Objectives**  
Mark McClellan, Initiative on Innovation and Value in Health Care  
Greg Daniel, Engelberg Center for Health Care Reform
- 8:40 a.m. Opening Discussion: Medical Device Innovation Grand Challenges**  
Mark McClellan - *Moderator*  
Alan Guttmacher, National Institutes of Health  
Jeff Shuren, U.S. Food and Drug Administration  
Omar Ishrak, Medtronic, Inc.  
Michael Mussallem, Edwards Lifesciences  
Josh Makower, ExploraMed , LLC
- 9:30 a.m. Session I: Research and Pre-Clinical Development Challenges in the Current Environment**  
Mark McClellan - *Moderator*  
Bill Murray, Medical Device Innovation Consortium  
Megan Moynahan, Case Western Reserve University  
Michael Minogue, Abiomed  
Paul LaViolette, SV Life Sciences Advisors
- 10:45 a.m. Break**
- 11:00 a.m. Session II: Clinical Development, Product Approval, and Reimbursement**  
Mark McClellan - *Moderator*  
Murray Sheldon, U.S. Food and Drug Administration  
Mark Deem, The Foundry, LLC  
Pamela Tenaerts, Clinical Trials Transformation Initiative  
David Nexon, Advanced Medical Technology Association  
Jo Carol Hiatt, Kaiser Permanente  
Sean Tunis, Center for Medical Technology Policy
- 12:30 p.m. Lunch and Breakout Discussions**
- 1:30 p.m. Session III: Identifying Unmet Needs and Prioritizing Device Research**  
Mark McClellan - *Moderator*  
Imran Babar, Rare Genomics Institute  
Robin Barr, National Institutes of Health  
Bryan Luce, Patient-Centered Outcomes Research Institute  
Diane Dorman, National Organization for Rare Disorders
- 2:45 p.m. Closing Breakout Discussions and Group Recommendations**
- 3:15 p.m. Summary and Next Steps**

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The Brookings Institution • Washington, D.C.  
Wednesday, March 5, 2014

**Biographies**



**Imran Babar, PhD**, is a senior associate on the Private Equity team at OrbiMed Advisors, the world's largest life science focused investment firm. Dr. Babar also serves as the vice-president of scientific affairs for the Rare Genomics Institute, which is a non-profit organization dedicated to advancing research for rare diseases. Prior to joining OrbiMed, Dr. Babar was a biotechnology associate at Cowen & Company. Imran completed his PhD in molecular biology at Yale University in Dr. Frank Slack's laboratory, where he researched microRNAs as both causes and treatments for cancers. Prior to attending Yale, he completed his BA in Biology at Carleton College and conducted research at the Massachusetts Institute of Technology and National Institutes of Health.

**Robin Barr, DPhil**, is director of the Division of Extramural Activities at the National Institute on Aging. A native of Scotland, Dr. Barr obtained his undergraduate and doctoral degrees in psychology from the University of Oxford, England. He completed postdoctoral work at the University of Pennsylvania before joining the faculty of Ball State University in Indiana in the Department of Psychological Sciences. Dr. Barr joined the National Institute on Aging in 1987 as a program administrator in the Behavioral and Social Research Program. During that time he helped to develop the Institute's research initiatives on cognitive functioning, human factors, and older drivers. He helped to establish the NIA Roybal Centers and the Institute's ACTIVE initiative examining cognitive interventions to improve functioning in older adults. From 1994–2006, he was Deputy Head of the Division of Extramural Activities and the NIA Training Officer. In this latter capacity he had particular responsibility for overseeing training initiatives, for anticipating the need for new kinds of training and for working with the National Institutes of Health in shaping overall research training policy. He also played a key role in establishing public-private partnerships to pursue career development and training initiatives. In April 2006, Dr. Barr became Acting Director of the NIA Division of Extramural Activities and was appointed Director of the division in June 2007. Since that time he has worked at the NIH level to help shape policies toward new and early stage investigators. His leadership role at NIA includes managing the National Advisory Council on Aging and advising the NIA Director on all extramural activities of the Institute.



**Gregory Daniel, PhD, MPH, RPh**, is a fellow in Economic Studies and managing director for evidence development and innovation in the Engelberg Center for Health Care Reform at the Brookings Institution. In this position, Dr. Daniel oversees and provides strategic direction regarding the Center's evidence development and biomedical innovation portfolio, including medical product safety surveillance, regulatory science and FDA policy issues, comparative effectiveness research, and other biomedical innovation policies. Dr. Daniel was previously vice president, Government and Academic Research at HealthCore (subsidiary of WellPoint, Inc.) where he led a division responsible for providing research services in the areas of pharmacoepidemiology; drug, vaccine, and biologic safety evaluations; comparative effectiveness research; and health economics and outcomes research. His research has utilized electronic health insurance claims data integrated with clinical data including laboratory results, electronic hospital data, paper-based and electronic medical record data, and registries. Dr. Daniel is a registered pharmacist and holds a PhD in pharmaceutical economics, policy, and outcomes research with a minor in epidemiology from the University of Arizona, a MPH specializing in biostatistics, a MS in pharmaceutical administration, and a BS in pharmacy, all from The Ohio State University.



**Mark E. Deem** is managing partner at The Foundry, LLC. Mr. Deem joined The Foundry at its inception in 1998. In addition to spearheading the research and invention process on new clinical opportunities, Mr. Deem leads the early stage effort in The Foundry's new companies until the company's chief executive officer and senior staff is hired. Prior to joining The Foundry, Mr. Deem served in a founding role as consulting director of research and development for Ventrica, Inc. Previously, Mr. Deem was a senior member of the research and development team at Medtronic Micro Interventional Systems (MIS). Mr. Deem joined MIS as one of the initial members of the company's engineering team and remained there through the acquisition by Medtronic. Mr. Deem has also held engineering positions with Devices for Vascular Engineering, Cordis Corporation and the USCI Division of C.R. Bard.

He has spent over twenty years in the design, testing and manufacture of medical devices. He is a co-inventor on over 150 issued and pending US patents. Mr. Deem earned his BS degree in biomedical engineering from Boston University, and serves as a Director for FIRE1, Holaira, Twelve, and as Chairman of Miramar Labs.

**Diane Edquist Dorman** is the vice president for public policy for the National Organization for Rare Disorders (NORD) and leads NORD efforts in its relationship with the federal government and Congress. She is the primary DC representative for more than 25 million Americans who have one of the 6000 to 7,000 known rare diseases. Her overriding mission is to improve the plight of patients with rare diseases and increase incentives for the development of orphan drugs, devices, and diagnostics. Since joining NORD in October 2000, Ms. Dorman's advocacy has been instrumental in the passage of two new public laws and she has been influential in the adoption of numerous programs, regulations and guidances that touch the lives of patients with rare diseases. On behalf of NORD and coalitions in which NORD participates, Ms. Dorman leads education and outreach programs to gain policymaker support for increased research into rare diseases and greater development of orphan products. She sits on the Board of Directors of the Alliance for a Strong FDA, and serves as NORD's representative to the National Council on Patient Information and Education (NCPPIE) Board of Directors, and sits on the Advisory Committee of the Keck Graduate Institute Center for Rare Disease Therapies based in Claremont, CA. Ms. Dorman has recently been appointed to the Council of the Convention of the US Pharmacopeia. She is responsible for ensuring that patients continue to have access to life-saving orphan therapies through Medicare, Medicaid and private insurance. She also serves as NORD's primary liaison to the Food and Drug Administration, the National Institutes of Health, Social Security Administration, and the Center for Medicare and Medicare Services, as well as the biopharmaceutical and medical device industries. Ms. Dorman has been appointed as a consumer representative to the Medicare Evidence Development Coverage Advisory Committee. Ms. Dorman develops and maintains relationships with other healthcare voluntary agencies and patient groups. She provides technical assistance and legislative analysis to NORD's member agencies on government-related matters, as well as the training of staff and volunteers of member organizations. Her leadership efforts have led to introduction and passage of the *Rare Diseases Act* (P.L. 107-281), and the *Rare Diseases Orphan Product Development Act* (P.L. 107-281). She was also influential in the introduction of House Concurrent Resolution 147, commemorating the 20th Anniversary of the *Orphan Drug Act*.

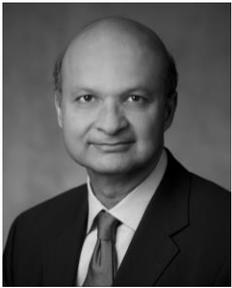


**Alan E. Guttmacher, MD**, is the director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, the focal point at the National Institutes of Health for research in pediatric health and development, maternal health, reproductive health, intellectual and developmental disabilities, and rehabilitation medicine, among other areas. A pediatrician and medical geneticist, Dr. Guttmacher came to NIH in 1999 to work at the National Human Genome Research Institute, where he served in a number of roles, including Deputy Director and Acting Director, thus overseeing that institute's efforts to advance genome research, integrate that research into health care, and explore the ethical, legal, and social implications of human genomics. Among Dr. Guttmacher's areas of expertise is the development of new approaches for translating genomics into better ways of

diagnosing, treating, and preventing disease. A major research interest has been the disease hereditary hemorrhagic telangiectasia. A graduate of Harvard College and Harvard Medical School, Dr. Guttmacher completed an internship and residency in Pediatrics and a fellowship in Medical Genetics at Harvard and Children's Hospital of Boston. He is a member of the Institute of Medicine.



**Jo Carol Hiatt, MD, MBA, FACS**, is chair of the National Product Council for Kaiser Permanente and also chairs KP's Inter-Regional New Technologies Committee. She is a partner in Southern California Permanente Medical Group (SCPMG) and is currently Assistant Medical Director, SCPMG Business Management. Dr. Hiatt chairs Southern California's Technology Deployment Strategy Team as well as the Oversight Committee for Integrated Medical Imaging. Dr. Hiatt joined Kaiser Permanente as a general surgeon at Panorama City, later serving as Chief of Surgery at that location and member of the SCPMG Board of Directors. Dr. Hiatt received her undergraduate degree from Stanford University and her medical degree from Duke University. She trained in general surgery at UCLA. In addition to her clinical degree, Dr. Hiatt received an M.B.A from UCLA's Anderson School of Management. She was designated an American College of Surgeons Health Policy Scholar in 2013.



**Omar Ishrak, PhD**, has served as chairman and chief executive officer of Medtronic since June 2011. Medtronic is the world's leading medical technology company, with more than \$16 billion in annual revenue, and operations reaching more than 120 countries worldwide. Medtronic provides therapies that are used to treat a wide range of conditions, including cardiac and vascular diseases, diabetes, neurological and spinal conditions, and more. The Medtronic Mission is to alleviate pain, restore health, and extend life for millions of people around the world. Dr. Ishrak joined Medtronic from the General Electric Company (GE), where he spent 16 years, most recently as president and chief executive officer of GE Healthcare Systems, a \$12 billion division of GE Healthcare, with a broad portfolio of diagnostic, imaging, patient monitoring and life support systems. He also served as an officer and as a senior vice president at GE. Earlier in his career, Dr. Ishrak amassed 13 years of technology development and business management experience, holding leadership positions at Diasonics/Vingmed, and various product development and engineering positions at Philips Ultrasound. He grew up in Bangladesh, earned a bachelor of science degree and PhD. in electrical engineering from the University of London, King's College. Dr. Ishrak is a member of the board of trustees of the Asia Society and is also on the Health Leadership Council of the Save the Children Foundation.



**Paul LaViolette, MBA**, is managing partner and chief operating officer at SV Life Sciences, to which he brings over 33 years of global medical technology management experience. Mr. LaViolette was most recently chief operating officer at Boston Scientific Corporation (BSC), an \$8 billion medical device leader. During his 15 years at BSC, he served as chief operating officer, group president, president of cardiology and president international as the company grew revenues over 20 times. Paul integrated two dozen acquisitions and led extensive product development, operations and worldwide commercial organizations. He previously held marketing and general management positions at CR Bard, and various marketing roles at Kendall (Covidien). Mr. LaViolette received his BA in psychology from Fairfield University and his MBA from Boston College.



**Bryan R. Luce, PhD, MBA, MS**, is chief science officer at the Patient-Centered Outcomes Research Institute (PCORI). He is responsible for leading the development and implementation of PCORI's patient-centered comparative clinical effectiveness research (CER) agenda. Luce previously founded the outcomes research firm MEDTAP® International, serving as its chairman, president, and chief executive officer and was the senior vice president for science policy at the United BioSource Corporation. Earlier, Dr. Luce was director of Battelle's Centers for Public Health Research and Evaluation; director of the Office of Research and Demonstrations, Centers for Medicare and Medicaid Services; and a senior analyst at Office of Technology Assessment of the United States Congress. Dr.

Luce's research has focused on improving methods and related policies for more efficient healthcare decision making. He has authored more than 100 scientific publications, including three textbooks on health technology assessment, health policy, and health economics. In 2008, Dr. Luce founded the Pragmatic Approaches to Comparative Effectiveness (PACE) Initiative, which studies novel methods to conduct analytical efficiency comparative effectiveness trials. Previously, he founded the Bayesian Initiative in Health Economics and Outcomes Research. He has been an advisor to numerous government and nonprofit agencies, as well as pharmaceutical and device firms worldwide; a member or chair of socioeconomic and public health policy advisory boards for leading biopharmaceutical companies; and a member of the Medicare Evidence Development & Coverage Advisory Committee (MedCAC). Dr. Luce is also a past president of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and in 2008 received the Society's Avedis Donabedian Outcomes Research Lifetime Achievement Award. He has held adjunct faculty positions in the Department of Health Policy at Jefferson Medical College, the Leonard D. Schaeffer Center for Health Policy and Economics at the University of Southern California, and the Department of Pharmacy at the University of Washington. A former special forces officer, Dr. Luce is a lieutenant colonel (retired), US Army Reserves. He holds MS in public health and MBA degrees from the University of Massachusetts at Amherst, and a PhD in health services research from the University of California at Los Angeles.



**Joshua Makower, MD, MBA**, has dedicated his life to the creation of medical technologies which improve the quality of life for patients and is the chief executive officer and founder of ExploraMed Development, LLC, a medical device incubator based on the west coast. He is also a venture partner with New Enterprise Associates where he supports the investing activity in the medical device arena. Dr. Makower serves as a consulting professor of medicine at Stanford University Medical School and co-founded Stanford's Biodesign Innovation Program. A compendium of the materials created to support the teaching efforts in the Stanford Biodesign program has recently been published under the Cambridge University text title of *Biodesign: The Process of Innovating New Medical Technologies*. Dr. Makower has founded several companies through the ExploraMed incubator which have

achieved successful merger and acquisition transactions including Acclarent, Inc., a company focused on developing novel therapies in the ear, nose, and throat (ENT) field, which was acquired by Johnson & Johnson in 2010; TransVascular, Inc., a company focused on the development of a completely catheter-based coronary bypass technology, which was acquired by Medtronic, Inc. in 2003; and EndoMatrix, Inc., a company focused on the development of a novel therapy for incontinence and gastrointestinal reflux, which was acquired by C.R. Bard in 1997. Up until 1995, Dr. Makower was founder and manager of Pfizer's Strategic Innovation Group, a group chartered to create new medical device technologies and businesses for Pfizer's medical device businesses. Dr. Makower also serves on the board of directors for NeoTract, Inc, Moximed, Inc., Intrinsic Therapeutics, Inc., ExploraMed Development, LLC, Ceterix, Inc. and Coravin, LLC. He holds over 100 patents for various medical devices in the fields of orthopedics, ENT, cardiology, general surgery, drug delivery and urology. Dr. Makower holds a MBA from Columbia University, a MD from the New York University School of Medicine, and an SB in Mechanical Engineering from the Massachusetts Institute of Technology.



**Mark McClellan, MD, PhD**, is a senior fellow and director of the Initiative on Value and Innovation in Health Care at the Brookings Institution. Within Brookings, his work focuses on promoting quality and value in patient centered health care. A doctor and economist by training, he also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan chairs the FDA's Reagan-Udall Foundation, is co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and was an associate professor of economics and medicine at Stanford University.



**Michael R. Minogue, MBA**, is the chief executive officer, president and chairman of Abiomed Inc. Since joining in April 2004, Mr. Minogue changed the corporate strategy and mission to creating breakthrough heart support technologies for high-risk patients to enable safer, more complete minimally invasive procedures, heart muscle recovery and cost-effective patient care. To achieve this goal, Abiomed acquired and developed new technology such as the Impella, Symphony, recovery ventricular-assist devices (VADs) and other heart support concepts. The Impella platform is based on the world's smallest heart pumps which can be inserted percutaneously through a small hole in the leg. Prior to joining Abiomed, Mr. Minogue completed a successful 11 year career at General Electric (GE) Healthcare. He departed GE as the vice president of American sales and marketing for the \$1 billion information technology business. At GE, Mr. Minogue held various leadership positions in sales, marketing, service, product engineering and software development. The experience includes the diagnostics of diseases from cancer to heart failure and in various technologies such as MRI, CT, PET, X-ray, cardiology, and information technology and monitoring. Prior to Abiomed and GE, Mr. Minogue served as an infantry officer in the US Army for four years and eight years in the Individual Ready Reserve, which included multiple distinctions including Airborne, Ranger, Combat and Expert Infantryman's Badge, Desert Storm Veteran and Bronze Star. He received his bachelor of science degree in engineering management from the United States Military Academy at West Point and his MBA from the University of Chicago. Mr. Minogue holds three patents, currently serves on the executive board of directors for AdvaMed, was formerly on the board for LifeCell Corporation, and provides personal support for organizations helping military veterans and wounded warriors.



**Megan Moynahan, MSc**, is the executive director of the Institute for Functional Restoration (IFR), a non-profit organization based at Case Western Reserve University in Cleveland, Ohio, that brings technologies out of research and into commercial availability for people with movement disorders. The IFR identifies technologies that are viable solutions for patients and then navigates them through the pathway to availability outside of a research trial, using funding that comes from a combination of grants, philanthropy and reimbursement. Prior to this, Ms. Moynahan enjoyed a 17-year career at the US Food and Drug Administration's (FDA) Center for Devices and Radiological Health, where she served as its associate director for technology and innovation, leading a variety of projects including directing the White House sponsored Entrepreneurs-in-Residence program at FDA, and the Innovation Pathway program designed to streamline the regulatory process for innovative medical devices. Her past regulatory experience includes serving as the chief of the pacemaker and defibrillator branch from 2001-2007, overseeing the multi-disciplinary staff of engineers and clinicians responsible for processing over 800 premarket applications each year, and launching national initiatives for external defibrillators, implantable pacemaker leads, and device safety measures. She holds a bachelor's degree in biomedical engineering from Johns Hopkins University and a master's degree in biomedical engineering from Case Western Reserve University.



**Bill Murray** joined the Medical Device Innovation Consortium (MDIC) in August of 2013 as the first president and chief executive officer. He has over 25 years of senior leadership experience spanning the range of privately financed start-up to billion dollar plus global businesses. Prior to MDIC, Bill held leadership positions as chief executive officer of Envoy Medical, a privately financed commercial stage medical device company and as interim president and chief executive officer of MTS Systems a public \$500 million industrial technology company. Mr. Murray's small company experience spans five years as chief executive officer and executive consultant to privately financed start-up medical device companies. His large company experience includes leadership as the Molecular Biology

Division president of Applied Biosystems, and at Medtronic where he spent nearly 20 years in various senior leadership positions, including president of the pacemaker business. He currently serves on the Board of MDIC and previously served on the Boards of MTS Systems, LifeSync Holdings, and ReShape Medical. Bill has also served on various industry association and community leadership boards. He earned a bachelor of science degree in electrical engineering from the University of Florida.



**Michael A. Mussallem** has been chairman and chief executive officer of Edwards Lifesciences since 2000 when the company spun-off from Baxter International. Prior to his current position, Mr. Mussallem held a variety of positions at Baxter from 1979 until 2000 with increasing responsibility in engineering, product development and general management. Currently, he serves on the boards and executive committees of the Advanced Medical Technology Association (AdvaMed), California Healthcare Institute (CHI) and the Orange County OCTANe Foundation for Innovation. He is an advisory board member for the Leonard D. Schaeffer Center for Health Policy & Economics at the University of Southern California, a member of the Healthcare Leadership Council and a

trustee of the University of California, Irvine Foundation. Mr. Mussallem is the former chairman of the board of directors of both AdvaMed and CHI. He received a bachelor's degree in chemical engineering and also an honorary doctorate degree from the Rose-Hulman Institute of Technology in Terre Haute, Indiana.



**David Nexon** is senior executive vice president of the Advanced Medical Technology Association ("AdvaMed"), where he is responsible for domestic policy. Prior to joining AdvaMed, Mr. Nexon served for more than twenty years as the Democratic Health Policy Staff Director for the Senate's Health, Education, Labor and Pensions Committee and as the Senior Health Policy Advisor to Senator Edward M. Kennedy. In these capacities, he has been involved with most of the major health policy issues of the last two decades. Prior to joining Senator Kennedy's staff, Mr. Nexon was Senior Budget Examiner in the Health Branch of the Office of Management and Budget, where he was responsible for the Health Care Financing Administration (now the Center for Medicare and Medicaid Services). Mr. Nexon held several academic appointments prior to entering government service. He

received his BA from Harvard College and his Ph.D. from the University of Chicago.



**Murray Sheldon, MD**, received his medical degree from the University of Michigan Medical School in 1975. He completed his general surgical residency with Kaiser Permanente Medical Center in Oakland and his cardiovascular fellowships at the University of California, Davis and the Montefiore Hospital and Medical Center in New York. In 1983, he entered private practice as a staff surgeon in several medical centers in Northern California performing cardiac, thoracic and vascular surgery. In 2003, he chose to become engaged in a highly productive career in the medical device industry leading device development projects and providing expert consultative services to numerous device development firms. From 2003-2009, Dr. Sheldon was the medical director for Arbor Surgical Technologies, which developed a unique two-piece, sutureless aortic valve for clinical aortic valve

replacement. Most recently, prior to joining the US Food and Drug Administration (FDA), he was the Medical Director for the minimally invasive surgical program at BioVentrix, Inc. and developed a catheter-based procedure for surgical ventricular reconstruction for heart failure patients. This device has recently obtained a CE mark in Europe. He also was the medical director for Solinas Medical, Inc. and was instrumental in developing a unique device for dialysis access. That device has recently received two 510 (k) clearances. Dr. Sheldon has recently joined the FDA as the associate director for technology and innovation. He oversees the initiative to proactively facilitate medical device innovation to address unmet public health needs and to align what is traditionally done at FDA with what is required to support the US medical device ecosystem. His primary focus is working with staff, the medical device industry, the clinical community and others on ways to facilitate bringing innovative medical devices to the patients in the US first in the world. Dr. Sheldon currently leads the Medical Device Reimbursement Task Force, identifying methods to streamline the path from FDA approval to reimbursement.



**Jeffrey Shuren, MD, JD**, is the director of the Center for Devices and Radiological Health (CDRH) at the US Food and Drug Administration (FDA). He previously served as acting center director. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including acting deputy commissioner for Policy, Planning, and Budget; associate commissioner for Policy and Planning; and special counsel to the principal deputy commissioner. Dr. Shuren is board certified in neurology and served as an assistant professor of neurology at the University of Cincinnati. In 1998, Dr. Shuren joined FDA as a medical officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS).

Dr. Shuren returned to FDA as the assistant commissioner for policy in 2003, and assumed his current position in September 2009. He received both his BS and MD degrees from Northwestern University under its Honors Program in Medical Education and his JD from the University of Michigan Law School.



**Pamela Tenaerts, MD, MBA**, is the executive director of the Clinical Trials Transformation Initiative (CTTI) at Duke University. Dr. Tenaerts works closely with the CTTI executive committee to develop and implement strategies to accomplish CTTI's mission. She provides senior level oversight of the day-to-day operations of CTTI and orchestrates efforts to effectively engage all interested stakeholders to improve the conduct of clinical trials. With more than 20 years' experience in the conduct of clinical trials across a number of sectors, she practiced medicine in both the emergency department and private practice setting for several years before embarking on a career in research. She served as the European coordinator for a 41,000 patient Phase III study of thrombolytic therapy at the University of

Leuven, and later as the North American coordinator for an international Phase II study of anti-thrombin therapy at Duke University Medical Center. She then accepted a position at Sarasota Memorial Hospital, where she directed a multi-specialty centralized clinical trials office for over ten years. Most recently Dr. Tenaerts oversaw European operations for CoAxia, a medical device company focused on cerebral ischemia. She received her MD from Catholic University of Leuven, Belgium, and a MBA from the University of South Florida. She speaks five languages and has obtained Six Sigma Green Belt certification.



**Sean Tunis, MD, MSc**, is the founder and chief executive officer of the Center for Medical Technology Policy (CMTP) in Baltimore, Maryland. CMTP's main objective is to improve the quality, relevance and efficiency of clinical research by providing a neutral forum for collaboration among experts, stakeholders and decision makers. Dr. Tunis was a member of the Institute of Medicine Committee on Initial National Priorities for Comparative Effectiveness Research. He advises a wide range of domestic and international public and private health care organizations on issues of comparative effectiveness, evidence based medicine, clinical research, reimbursement and health technology policy. Through September of 2005, Dr. Tunis was the chief medical officer at the Centers for Medicare and Medicaid Services (CMS), where he had lead responsibility for clinical policy for the Medicare and Medicaid programs. Previously he served as the director of the Health Program at the Congressional Office of Technology Assessment and as a health policy advisor to the US Senate, where he worked on pharmaceutical and device policy issues. Dr. Tunis trained at the University of California in Los Angeles and the University of Maryland in internal medicine and emergency medicine, and holds adjunct faculty positions at the Center for Health Policy at Stanford University, the department of internal medicine at the Johns Hopkins School of Medicine, and the department of surgery at the University of California at San Francisco.

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Experien Group

**Margaret Anderson**

Executive Director, FasterCures

**Naomi Aronson**

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Innovation and Policy, Office of Clinical  
Affairs, Blue Cross Blue Shield Association

**Christopher Austin**

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National Institute on Aging, National Institutes  
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**Rashmi Gopal-Srivastava**

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Center for Advancing Translational Sciences,  
National Institutes of Health

**Richard Greenwald**

Co-Founder and President, Simbex, and Adjunct Associate Professor of Engineering, Dartmouth

**Alan Guttmacher**

Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health

**Charles Haggert**

Senior Advisor for Innovation Research and Policy, Center for Devices and Radiological Health, U.S. Food and Drug Administration

**Noel Harvey**

Vice President, Research and Development, BD Technologies

**Jo Carol Hiatt**

Chair, National Product Council and Assistant Medical Director, Southern California Permanente Medical Group Business Administration, Kaiser Permanente

**Sandra Huang**

Special Assistant to CEO, Center for Medical Technology Policy

**Campbell Hutton**

National Director, Regulatory Affairs - Devices, Juvenile Diabetes Research Foundation

**Omar Ishrak**

Chairman and CEO, Medtronic, Inc.

**Aaron Kaplan**

Director, Dartmouth Device Development Symposia; Director of Clinical Research, Cardiology Section, Dartmouth-Hitchcock Medical Center; and Professor of Medicine (Cardiology), Geisel School of Medicine at Dartmouth

**S. Lawrence Kocot**

Legal Council, Engelberg Center for Health Care Reform and Visiting Fellow, Economic Studies, The Brookings Institution

**Richard Kuntz**

Senior Vice President and Chief Scientific, Clinical and Regulatory Officer, Medtronic, Inc.

**John Langell**

Executive Director, Center for Medical Innovation, University of Utah

**Alexandra Lansky**

Associate Professor, Cardiovascular Medicine, and Director, Interventional Cardiovascular Research, Yale University School of Medicine

**Paul LaViolette**

Managing Partner and Chief Operating Officer, SV Life Science Advisors

**Dirksen Lehman**

Corporate Vice President, Public Affairs, Edwards Lifesciences

**Phillip J. Lerner**

Vice President and National Medical Director, Aetna

**Debra Lewis**

Deputy Director, Office of Orphan Products Development, U.S. Food and Drug Administration

**John Linehan**

Professor of Biomedical Engineering, Northwestern University

**Barry Liden**

Vice President of Government Affairs, Edwards Lifesciences

**Bryan Luce**

Chief Science Officer, Patient-Centered Outcomes Research Institute

**Kip Ludwig**

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Senior Advisor for Endocrine Physiology,  
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**Michael Marge**

Professional Consultant and Scientific  
Advisor, National Center for Medical  
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Human Development, National Institutes of  
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